Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K102199 - 1462 pages
COMPANY:	SOPHONO, INC (SOPHONO)
PRODUCT:	Hearing aid, bone conduction (LXB)
SUMMARY:	Product: OTOMAG BONE CONDUCTION HEARING SYSTEM MODEL ALPHA 1 (S) AND ALPHA 1 (M
DATE REQUESTED:	Jul 27, 2015
DATE PRINTED:	Jul 27, 2015

Note: Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K102199

MAY 2 3 2011

510(k) Summary: Otomag Bone Conduction Hearing System

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

Submitter: Sophono, Inc.

Establishment Registration Number: 3008514292

Contact Information:

Sophono, Inc.
3022 Sterling Circle
Boulder, Colorado 80301
Ph: 303-546-1663
Fax: 720-222-2432
Contact: Jim Kasic
Email: Jim.Kasic@sohpono.com

Date Prepared: May 20, 2011

Name of Device: Otomag Bone Conduction Hearing System

Common Name: Bone Conduction Hearing System

Classification Name: Hearing Aid

Device Classification:

- Classification: II
- Classification Panel: Ear, Nose and Throat
- Regulation Number: 874.3300
- Product Code: LXB

Predicate Device:

Otomag Bone Conduction Hearing System, Unmodified Version – K100193

Xomed Audiant Bone Conductor - K855059 / K861971

Device Description:

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. A variety of magnetic

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spacers, each with a different magnetic strength, are provided with the Alpha 1(M) configuration to allow adjustment of the magnetic field strength that holds the sound processor against the head.

The magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Technological Characteristics:

The technological characteristics of the version of the Otomag Bone Conduction Hearing System are equivalent to those of the predicate device. Items that are identical between the modified version and the predicate are:

- Overall Device Performance
- Fundamental Technology (bone conduction)
- Software

Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment of the sound processor assembly to the patient's skin.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Non-clinical and clinical performance testing and evaluation were used to support the safety and effectiveness of the modified device.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

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Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patients using the Alpha 1(M) configuration of the device, which utilizes a magnetic implant, should not undergo magnetic resonance imaging (MRI) without having the implant removed prior to scanning.

Performance Standards:

The design of the Otomag Bone Conduction Hearing System conforms to the following voluntary standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
- AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI/ANSI ST8:2008, Hospital steam sterilizers
- AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products – Requirements for products labeled "STERILE"
- AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization
- AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications

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- IEC 60601-1-2:2007: Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Immunity (ESD, Radiated RF Electromagnetic Field Amplitude Modulated, Power Frequency Magnetic Field)

Non-Clinical Performance Testing:

The Otomag Bone Conduction Hearing System has been subjected to extensive safety and performance testing. Testing of the Otomag Bone Conduction Hearing System included verification and validation of the following;

- Simulated Use: Device Retention
- Simulated Use: Vibration Transmission Comparison Alpha 1(M) vs. Alpha 1(S)
- Software Validation
- Sound Processor Performance: Frequency Response
- Immunity (IEC 60601-1-2)
- Implant Performance after 3x Sterilization
- Autoclave Cycle Performance (Sterilization)
- Accelerated Aging: Magnet Retention
- Dislodgement Force: Normal and Tangential
- Accelerated Aging: Screw Retention

The testing information presented in this submission demonstrates the device's performance is substantially equivalent to the predicate devices.

Clinical Performance Testing:

Clinical data on eighty-six (86) Alpha 1(M) devices implanted into 57 patients ranging in age from 5 years to 67 years was submitted in support of the safety and effectiveness of the Alpha 1(M) configuration of the device. The mean follow up time for the study was 1.6 years from the time of implant, with a range of 0.5 years to 3.8 years. The study showed the following important results:

- No surgical or post-surgical infections or adverse events associated with implant were reported as a part of the trial.
- No tissue necrosis or other significant tissue problems were reported in any of the 57 subjects at any time in the trial.
- A small percentage of subjects (8%) showed some initial redness under the magnetic spacer after installing the Alpha 1 (M) sound processor assembly. These issues were resolved by changing the strength of the magnetic spacers. Data showed none of these patients had recurring problems with pressure points or reddening.
- None of the subjects complained of issues, either mild or severe, of external processor dislodgement.
- Unaided and aided hearing performance is shown in the following table

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Measure	Unaided Air Conduction Thresholds	Unaided Bone Conduction Thresholds	Unaided Speech Understanding	Aided Speech Understanding	Free Field Gain	Aided Free Field Thresholds
Mean and Stdev	54+/- 12dB	16+/-10dB	4+/- 10%	86+/- 17%	38+/- 8db	16dB (calculated from unaided thresholds and free field gain)

Conclusion:

Based on the clinical and non-clinical performance testing, the modified version of the Otomag Bone Conduction Hearing System is safe and effective and considered to be substantially equivalent to the predicate Otomag device cleared in K100193 and the Audiant cleared K855059 and K861971.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 2 3 2011

Sophono Inc.
c/o Clay Anselmo
Reglera LLC
555 Zang Street
Lakewood, CO 80228

Re: K102199
Trade/Device Name: Sophono Otomag Bone Conduction Hearing System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: May 10, 2011
Received: May 13, 2011

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number: K102199

Device Name: Otomag Bone Conduction Hearing System

Indications for Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
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- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Page 1 of 1

510(k) Number K102199

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 22, 2011

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET
SUITE 100
LAKEWOOD, COLORADO 80228
ATTN: CLAY ANSELMO

510k Number: K102199

Product: OTOMAG BONE CONDUCTION HEARING

Extended Until: 07/19/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

for Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3939
CONNECTION TEL	913038326700
SUBADDRESS	
CONNECTION ID	
ST. TIME	03/22 14:58
USAGE T	00'20
PGS. SENT	1
RESULT	OK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) – Request for 30 Day Extension

March 21, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for 180 Day Extension

510(k) Applicant / Manufactured by:
Sophono, Inc.
903 Brooklawn Drive
Boulder, CO 80303
Ph: 303-546-1663
Fax: 720-222-2432

510(k) Contact / Submission Correspondent:
Clay Anselmo
President and CEO
Reglera LLC
Email: anselmoc@reglera.com
Phone/fax: 303-223-4303
Mobile: 303-907-2955

Dear Office of Device Evaluation,

We received a request for additional information dated January 20, 2011 and an addendum to this request on February 22, 2011, in response to our 510(k) premarket notification (K102199). We have been in ongoing dialog with the review team interactively to address the open issues related to clinical data and, at the suggestion of our reviewer, respectfully request a 180 day extension to allow Sophono and the Agency time to continue to interact on the matter and complete our response in a comprehensive manner.

We appreciate your time and consideration of this request.

Sincerely,

Clay Anselmo
Reglera LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Regulation Name: Hearing Aid
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Product Code: LXB
Dated: May 10, 2011
Received: May 13, 2011

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Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K102199

Device Name: Otomag Bone Conduction Hearing System

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510(k) Number K102199

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Sophono

Patient User Manual

Alpha I (S) & Alpha I (M)
Bone Conduction Hearing Systems

29

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 About this Manual

This Patient Manual provides a description of the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. Please read this manual thoroughly before using the system.

This Patient Instruction Manual included with each Alpha I (S) & Alpha I (M) Bone Conduction Hearing System should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

2 Introduction

Dear Customer:

Congratulations on the purchase of your new Otomag Bone Conduction Hearing System!

The Otomag Bone Conduction Hearing System includes a family of Sound Processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag Bone Conduction Hearing System is supplied in either of two configurations. The first configuration is the Alpha 1 (S), in which the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), in which the Otomag Sound Processor is attached magnetically to a Magnetic Implant placed behind your ear. The Headband, Softband, or Magnetic Implant holds the Sound Processor against the head, and vibration is transduced through direct contact with your skin and the bone below.

The Otomag System is designed for use for patients with conductive hearing loss, patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and patients who suffer from single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software package allow for programming the Otomag System for individual patient hearing loss.

This Patient Manual will help you quickly gain confidence with your new Otomag Bone Conduction Hearing System. If you have further questions please consult your hearing healthcare provider.

General Information

A hearing device will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of a hearing device does not permit a user to attain full benefit. The use of a hearing device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading.

Note

- The components and packaging of the Otomag Bone Conduction Hearing System contain **no** natural rubber **latex**

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	Note ▪ The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer you for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- Hearing loss occurring suddenly;
- Hearing loss that grows worse rapidly;
- Pain in either ear;
- A sudden recent onset of ringing or a similar sensation in the ears, also known as tinnitus. Tinnitus may be bilateral (occurring in both ears) or unilateral (occurring in one ear);
- Unilateral or markedly asymmetrical (not equal in both ears) hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

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Patients using the Alpha 1(M) configuration of the device, which utilizes a magnetic implant, should not undergo magnetic resonance imaging (MRI) without having the implant removed prior to scanning.

Note: While the contraindications listed above may affect the process of hearing aid fitting, it should be noted that the treatment plan for use of the Otomag Alpha 1 Sound Processor may vary with worsening or improving hearing. Your treatment plan will be determined by your hearing health specialists.

Warnings and Cautions Overview

The following section contains a description of all patient related Warnings and Cautions associated with the Otomag Bone Conduction Hearing System. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to patient instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warning	▪ Thoroughly read Patient Manual before using the Otomag Bone Conduction Hearing System. ▪ Rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in personal injury and damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not undergo scanning with Magnetic Resonance Imaging (MRI) if you are using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. For patients with the Alpha 1(M) magnetic implant, the implant must be removed prior to scanning. ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire. ▪ Do not attempt to recharge batteries. ▪ If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device. ▪ Both the Alpha 1(S) and Alpha 1(M) configurations of the device contain magnets which could impact the performance of pacemaker or implantable cardioverter defibrillator (ICD) devices. The magnets of the softband/headband of the Alpha 1(S) and the magnetic spacer of the Alpha 1(M) should therefore be kept away from a pacemaker or ICD.

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Caution	▪ Read this Patient User Manual and keep it available so you can refer to it when needed. ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4 °F (-20 °C) or above 122 °F (+50 °C) at any time. ▪ To avoid damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. ▪ Remove the Sound Processor, Headband and Softband before x-rays of the head and neck ▪ Remove the Sound Processor, Headband, and Softband during radiation therapy ▪ Portable and mobile RF (radio frequency) communications equipment can affect the performance of the Sound Processor. ▪ Interference may occur in the area of equipment which is labeled with the following symbol: ▪ Dispose of batteries and electronic items in accordance with your local regulations. ▪ When navigating through security in airports remove the Sound Processor, Headband and Softband and have them screened through the x-ray screening process. The Sound Processor, Headband and Softband contain metal that may activate the airport security metal detectors. ▪ Do not use the Alpha 1 Sound Processor, Headband or Softband while participating in contact sports. Hard physical contact with the device or a blow to the head in the area of the Alpha 1 Sound Processor, Headband or Softband may result in damage to the device or device failure. ▪ Clean the Alpha 1 Processor, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

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Caution	▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device. ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor. ▪ Do not expose the Sound Processor to strong sunlight. ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case. ▪ The Alpha 1(M) version of this Bone Conduction Hearing system utilizes a metal, magnetic implant. Patients must take care when in the proximity of devices that could influence the implant. Devices such as security systems, metal detectors, radio frequency identification (RFID) systems, and electronic article surveillance (EAS) system may affect or be affected by the implant. You should avoid prolonged exposure to these systems and should not stand near, lean on or linger in the vicinity of such devices. ▪ Patients with a pacemaker or ICD should consult their care provider for safe use of the Otomag system with their cardiac medical device.

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3 Operating Instructions

Insertion of the battery

A **Size 675** battery is required for your Alpha I Sound Processor.

See Figure 1 for details. Open the battery compartment (1) with a fingernail and insert the battery (2) so that the plus (+) sign on the battery and the plus (+) sign on the battery compartment are on the same side. Close the battery compartment with a finger. The Sound Processor is now switched on.

⚠	**Caution** ▪ Dispose of batteries and electronic items in accordance with your local regulations.

Switch off your Sound Processor whenever you're not using it by pivoting the battery compartment fully out. This will help preserve battery life. The Alpha 1 has a low battery indicator that generates a tone when it is time to replace the battery. Your hearing healthcare provider can adjust the volume and tone of the low battery indicator for you.

Figure 1. Alpha I Sound Processor

⚠	**Warning** ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals ▪ Do not attempt to recharge batteries. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire

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Start-up and Operation

Switch on the Alpha 1 Sound Processor by pivoting the battery compartment fully in.

Positioning the Sound Processor

Alpha 1 (S)

To place the Alpha 1 (S) Sound Processor, simply guide it into the vicinity of the magnetic pad in the Softband or Headband. The magnetic forces will bring it to its correct position. See Figure 2.

Figure 2. Positioning the Alpha I (S) Sound Processor on the Softband

⚠	**Warning** ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 3. If you have thicker hair, it may be necessary to part your hair over the implant site or shorten the hair at the implant location to ensure an adequate holding force between magnets.

Figure 3. Positioning the Alpha I (M) Sound Processor on the Magnetic Implant

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Warning

- If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device.

Caution

- The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient.

Volume Control

The volume can be adjusted with the small wheel that is situated on the outside of the Alpha 1 Sound Processor. Using the tip of the index finger, apply slight pressure on the rotary button and simultaneously turn forward to increase volume. Turn the rotary button in the opposite direction to reduce volume.

You can switch off the Sound Processor by opening the battery access door. As soon as you take off the device, switch it off. See Figure 4 for details.

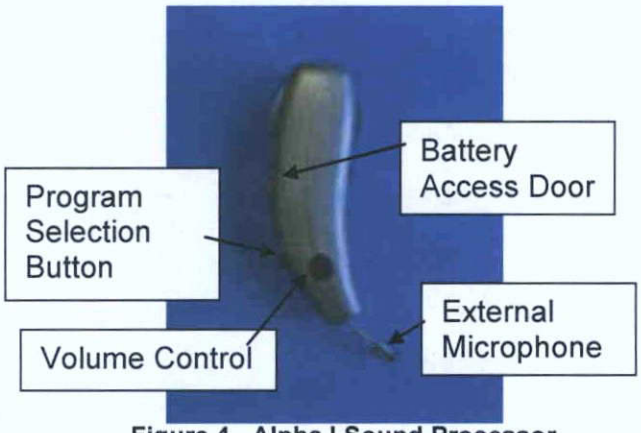

Figure 4. Alpha I Sound Processor

Program Selection Button

The Alpha 1 Sound Processors offer four program settings for different hearing situations. By pressing the small button on the Sound Processor, the programs can be activated. For each activated program you will hear a corresponding signal tone for recognition.

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- Program 1: Instrument beeps once
- Program 2: Instrument beeps twice
- Program 3: Instrument beeps three times
- Program 4: Instrument beeps four times

Your hearing healthcare provider will inform you when each of the programs should be used

Removing the Sound Processor

To remove the Alpha 1 Sound Processor, pull **ONLY** on the steel disk. See Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

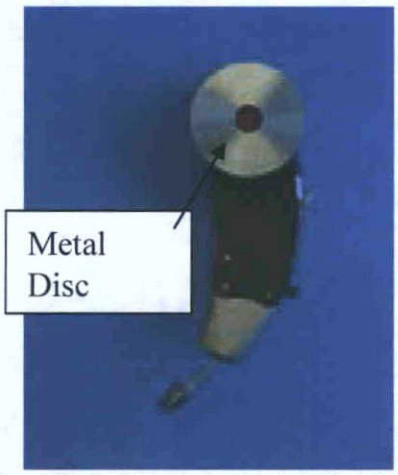

Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

	Note ▪ If you remove the Sound Processor without switching it off, it generates a vibrating tone which leads to high battery consumption. Therefore, always properly switch off the Sound Processor when you are not wearing it.

	Caution ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device.

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If Your Sound Processor Does Not Function

Check the following if the Sound Processor is not functioning properly:

- The device is properly switched on and the battery compartment is fully closed
- The battery is not dead
- The battery surface is clean.

If the device still is not functioning properly, see your hearing healthcare provider.

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4 Product Maintenance

Cleaning and Care

Sound Processor

- Have your Sound Processor checked at regular intervals as specified by your hearing professional.
- To clean your Sound Processor, wipe it with a soft cloth or a Clorox® type disinfecting wipe
- The battery compartment may be cleaned by wiping it out with a DRY cotton swab or a cotton swab that has been moistened by a Clorox® type disinfecting wipe.

	Note ▪ Remove the Sound Processor, Softband, and Headband during the application of hairspray or styling gels. If hairspray or gel comes in contact with the Sound Processor it may become sticky and difficult to clean

- If the Sound Processor becomes soaked with water:
  - Immediately open the battery door and remove the battery
  - Put the Sound Processor in a container with drying capsules such as Dri-aid kit or similar overnight. Drying kits are available from most hearing care professionals.

	Caution ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case

- The Sound Processor is provided in a plastic case which may be used to store the processor. This case may be cleaned with a Clorox® type disinfecting wipe. Make sure the case is completely dry before storing the Sound Processor in it.

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⚠	**Caution** ▪ The Sound Processor is designed to operate within the temperature ranges of 41°F (+5°C) to 104°F (+40°C). The processor should not be subject to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor ▪ Do not expose the Sound Processor to strong sunlight ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case

Softband and Headband

- The Headband can be cleaned with a Clorox® type disinfecting wipe.
- The Softband may be submerged and hand washed with a mild clothes washing detergent (with or without a small amount of color safe bleach) and air dried or may be cleaned with a Clorox® type disinfecting wipe.

Magnetic Spacer

- The Magnetic Spacer can be cleaned with a Clorox® type disinfecting wipe.

⚠	**Caution** ▪ Clean the Alpha 1 Processor, Magnetic Spacer, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

Retention Clip / Lanyard

- The Retention Clip / Lanyard can be cleaned with a Clorox® type disinfecting wipe.

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Damage and Replacement

The expected live span for the Sound Processor, Magnetic Spacer, Softband, and Headband is approximately 4 years depending on use, wear, and tear. The Sound Processor will need to be repaired or replaced when it no longer produces adequate vibrations or the sounds become highly distorted. The Softband should be replaced when it becomes damaged or the elastic begins to be stretched out and it can no longer be tightened adequately for sound transmission. The Headband should be replaced when it becomes damaged or no longer has enough spring force to press the magnetic pad against the head for adequate sound transmission. Replacement Headbands and Softbands may be purchased through your hearing healthcare provider from Sophono, Inc.

5 Accessories

If your Alpha 1 Sound Processor has a jack for an FM boot, you may plug the boot of a Phonak MLxi FM receiver into the bottom of the Sound Processor.

If you are concerned about the Alpha 1 Sound Processor falling off your head, a clip and tether are available so that the Sound Processor can be tethered to a garment you're wearing.

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6 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

The magnetic implant associated with the Alpha 1(M) configuration of the device is not compatible with Magnetic Resonance Imaging (MRI). If MRI is required, the implant must be removed prior to scanning.

Warning

- Do not undergo scanning with Magnetic Resonance Imaging (MRI) if you are using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. For patients with the Alpha 1(M) magnetic implant, the implant must be removed prior to scanning.
- Both the Alpha 1(S) and Alpha 1(M) configurations of the device contain magnets which could impact the performance of pacemaker or implantable cardioverter defibrillator (ICD) devices. The magnets of the softband/headband of the Alpha 1(S) and the magnetic spacer of the Alpha 1(M) should therefore be kept away from a pacemaker or ICD.

Caution

- Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices.
- To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.
- The Alpha 1(M) version of this Bone Conduction Hearing system utilizes a metal, magnetic implant. Patients must take care when in the proximity of devices that could influence the implant. Devices such as security systems, metal detectors, radio frequency identification (RFID) systems, and electronic article surveillance (EAS) system may affect or be affected by the implant. You should avoid prolonged exposure to these systems and should not stand near, lean on or linger in the vicinity of such devices.

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⚠	**Caution** ▪ Patients with a pacemaker or ICD should consult their care provider for safe use of the Otomag system with their cardiac medical device.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a Titanium case.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid (bony protrusion on the skull located directly behind the ear): Fotoplast Lacquer 3 (light-curing one-component lacquer)

The components and packaging for the Otomag Bone Conduction Hearing System contain no natural rubber latex.

The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction Sound Processor
- Fully programmable digital hearing system
- Programs (programmable by audiologist)
- 4 channels
- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery)

Alpha 1 Sound Processor Performance Data

(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)

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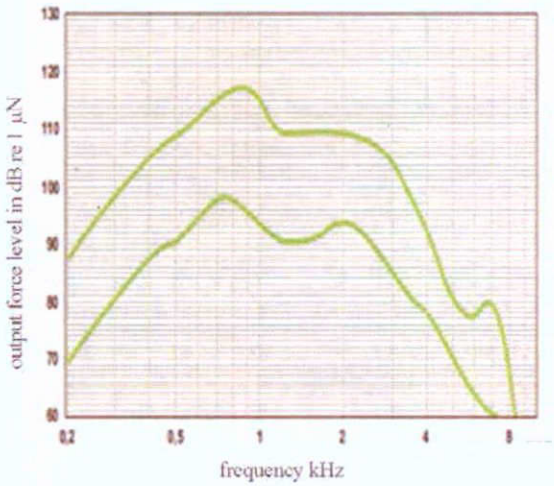
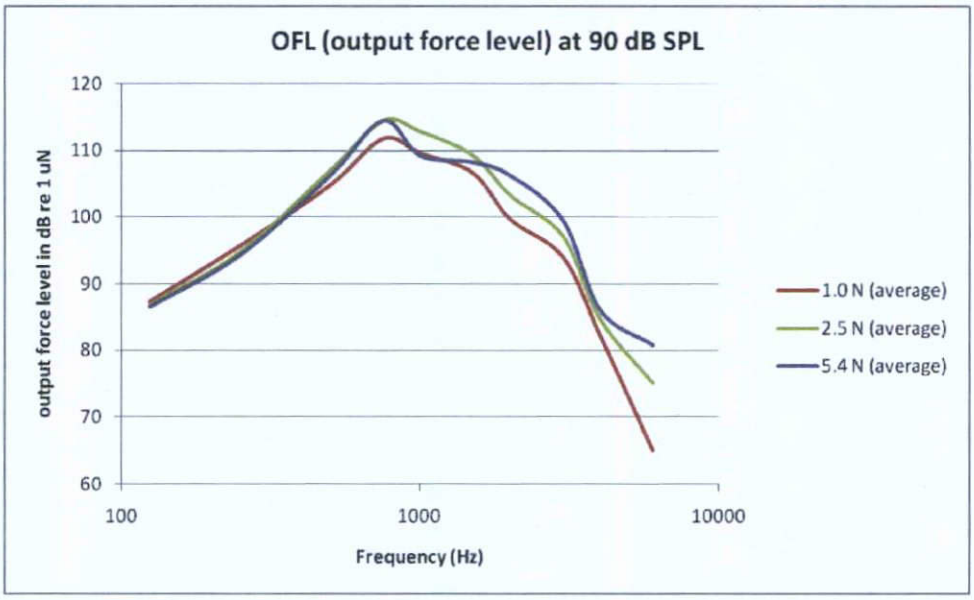


OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

(Measured according to DIN IEC 60118-9. Averages include all configurations of softband, headband, and magnetic spacers for a given normal force)



- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 µN
- Peak Output at 90 dB SPL: 115 dB re 1 µN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms

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- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

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7 Patient Support

If you experience any device related issues, develop unexpected or excessive symptoms, or have general concerns or questions, please contact your hearing health specialists.

Manufactured for: Sophono, Inc. 903 Brooklawn Dr., Boulder, Colorado 80303 USA
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Sophono

Physician Manual

Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems

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Company Information

Contact information:

Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 About this Manual

This Physician Manual provides a description of the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. This manual provides the information necessary for the physician to prescribe the Alpha 1 (S) & Alpha 1 (M) Bone Conduction Hearing Systems to the appropriate patient population. Please read this manual thoroughly before prescribing the system.
A Patient Instruction Manual is included with each **Alpha I (S)** & **Alpha I (M)** Bone Conduction Hearing System and should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

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2 Introduction

Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patients using the Alpha 1(M) configuration of the device, which utilizes a magnetic implant, should not undergo magnetic resonance imaging (MRI) without having the implant removed prior to scanning.

Patient Selection Criteria

- Patients to be fitted with the Otomag Alpha 1 (S) Sound Processor and its Headband or Softband may be any age.

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- Patients to be fitted with the Otomag Alpha 1 (M) Sound Processor and its Magnetic Implant should be 5 years old or older.
- Patients and/or patient guardians must be able to understand that the Otomag System will not restore hearing to normal and will not prevent additional hearing impairment resulting from conditions such as disease, old age hearing loss, genetic hearing loss, ototoxic drugs or noise induced hearing loss.

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Warnings and Cautions Overview

The following section contains a description of all physician related Warnings and Cautions associated with the Otomag Bone Conduction Hearing Systems. Additional patient and use related Warnings and Cautions can be found in the Patient User Manual. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to physician instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warnings

Warning	▪ Thoroughly read the Physician Manual and the Patient Manual before prescribing the Otomag System. ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform scanning with Magnetic Resonance Imaging (MRI) on an patient using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterilized prior to implantation according to the provided instructions. Failure to sterilize appropriately can result in serious infection. ▪ The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device. ▪ Do not sterilize the Alpha 1 (M) Magnetic Implant more than a total of three (3) times. Additional sterilization cycles may cause a reduction in magnet performance or cause the magnetic case of the implant to leak. ▪ Purchased screws may be provided non-sterile and if so must be sterilized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection. ▪ Excessive, long term use of magnetic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test. ▪ Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this warning may result in prolonged healing, further irritation, or infection.

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Warning	▪ Both the Alpha 1(S) and Alpha 1(M) configurations of the device contain magnets which could impact the performance of pacemaker or implantable cardioverter defibrillator (ICD) devices. The magnets of the softband/headband of the Alpha 1(S) and the magnetic spacer of the Alpha 1(M) should therefore be kept away from a pacemaker or ICD.

Precautions

Caution	▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual. ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws. ▪ Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches. ▪ The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or pain, numbness, or tingling occurs. ▪ Patients with a pacemaker or ICD should consult their care provider for safe use of the Otomag system with their cardiac medical device.

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Product Description

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag System is configured in either of two configurations. The first configuration is the Alpha 1 (S), where the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), where the Otomag Sound Processor is attached magnetically to an implanted magnet. The Headband, Softband, or Magnetic Implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Possible Adverse Effects

General

It is possible that a reaction to the materials of the Headband, Softband, or Magnetic Implant could occur. Such a circumstance may necessitate that use of the device be discontinued. Please report any adverse effects to Sophono, Inc. The address and phone number for Sophono, Inc. are listed at beginning and end of this Physician Manual. If a reaction to the Headband or Softband occurs, Sophono will supply appropriate instructions so that the device can be sent to the laboratory for analysis.

Risks that may occur during surgery:

The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, dural exposure, CSF leak, perforation of sigmoid sinus, subdural hematoma and noticeable changes in head noise.

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	Warning ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System.

Risks that may occur after surgery:

Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma, inflammatory reaction, skin breakdown or skin necrosis.

It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant.

The magnetic implant associated with the Alpha 1(M) configuration of the device is not compatible with Magnetic Resonance Imaging (MRI). If MRI is required, the implant must be removed prior to scanning.

	Warning ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform scanning with Magnetic Resonance Imaging (MRI) on an patient using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Other Symbols on Equipment and Labeling

Symbol	Description
	Consult Physician Manual
LOT	Batch Code or Lot Number
SN	Serial Number
	Keep Away From Rain / Keep Dry
	Manufacturer
MR	MR Unsafe: Device should not be worn when patient is undergoing an MRI
	Interference may occur in the area of equipment which is labeled with the following symbol.
122°F -4°F	Temperature Limitation: The sound processor is designed to operate within the temperature ranges of 41oF (+5oC) to 104oF (+40oC). The processor should not be subject to temperatures below -4oF (-20oC) or above 122oF (+50oC) at any time.
NON STERILE	Device provided Non-Sterile

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3 Patient Fitting Procedures

Alpha 1 (S) System: Instructions for Placement of the Softband or Headband and Alpha 1 Sound Processor

Notes

- Record the product and lot or serial numbers for the Alpha 1 Sound Processor in the patient file and send the patient to a qualified audiologist for proper programming of the Alpha 1 Sound Processor.

The Otomag Softband is an elastic Softband similar to a sweat band used in sports. The Alpha 1 (S) Sound Processor magnetically adheres to the Softband via a magnetic pad sewn into the band. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by an audiologist.

- To use the Otomag Softband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Softband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Softband around the patient's head, quite loosely at first by slipping the end of the band through the slot next to the magnetic pad and attaching the mating Velcro ® loops and hooks to each other.
- Place the magnetic pad against the mastoid or other boney location.
- Tighten the Softband by adjusting the Velcro® strap until it is close-fitting enough to ensure effective sound transmission, but not tight enough to cause discomfort. The Softband is too loose if it slips off of the head, can be rotated easily around the head or no sound transmission can be heard. The Softband is too tight if the patient complains of pain or discomfort while wearing the Softband. Make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

Warning

- When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

The Otomag Headband is a springy Headband, similar to that used for earphone devices. It comes in one size and is not adjustable. The Alpha 1 (S) Sounds Processor magnetically adheres to the Headband via a magnetic pad fitted to the Headband. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by the audiologist.

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- To use the Otomag Headband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Headband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Headband on the patient's head and place the magnetic pad against the mastoid or other boney location.

The choice of a Headband or Softband is a matter of patient preference.

Alpha 1 (M) System: Compatible Screws

Notes

- The Alpha 1 (M) implant requires 5 screws for implantation that are **NOT** included with the implant.

Screws

The Alpha 1 (M) implant requires 5 screws to be used to affix the implant to the skull. These screws are NOT included as part of the Alpha 1 (M) implant system and must be obtained separately.

The implant bracket holes are sized to accept Stryker/Leibinger 1.7 mm diameter Craniomaxillofacial titanium Self Tapping Screws, (Gold) and 1.7 mm diameter Self Drilling Screws (Silver) in 4 mm lengths and 1.9 mm Emergency Screws (Purple) in 3 mm lengths.

Craniomaxillofacial Titanium Screws	*1.7 mm dia. x 4.0 mm Self Tapping*	*1.7 mm dia. x 4.0 mm Self Drilling*	*1.9 mm dia. x 3.0 mm Emergency*
Stryker/Leibinger Part Numbers / 510(k) Clearance Numbers	*50-17004 / K970912*	*50-17904 / K970912*	*50-19004 / K963739*

While all screw sizes / types specified above have been validated for this application, the Stryker/Leibinger 1.7mm x 4 mm self drilling screws, part number 50-17904 is considered optimal.

Other commercially available craniomaxillofacial titanium screws may be used as long as the screw shaft diameter is less than 2.0 mm and the screw head size is greater than 2.45 mm. Screw must be 4 mm in length (3mm for emergency screws).

The screws must be sterile prior to implantation. If the screws are not purchased sterile, refer to the screw manufacturer's instructions for sterilization.

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⚠	**Warning** ▪ Purchased screws may be provided non-sterile and if so must be sterilized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection.

⚠	**Caution** ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws.

If the initial attempt to place a screw does not work and the screw hole becomes "stripped" emergency "rescue" screws can be threaded into the stripped hole. The largest size screw that can be used is 1.9 mm in diameter.

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Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

⚠	**Warning** ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterilized prior to implantation according to the provided instructions. Failure to sterilize a device appropriately can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Place a single steam sterilization indicator into the pouch with the implant.
- Immediately seal the autoclave pouch.

⚠	**Caution** ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be re-sterilized two additional times by gravity steam sterilization (autoclaving) if it is not used during the implantation procedure. The following sterilization parameters have been validated for sterilization of the implant.

Limitations on Reprocessing: Magnetic implants may be re-sterilized two additional times if not used during the implant procedure. Implants should be stored in the sterilization pouch. However, the implant must be transferred to a new sterilization pouch just prior to resterilization and implant.

Presterilization Decontamination / Cleaning / Disinfection: None Required

Cycle Type: Gravity

Sterilization Time: 15 minutes minimum

Sterilization Cycle Temperature: 132 degrees C / 270 degrees F

Drying Time: 30 minutes minimum

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Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)

Storage in Sterile State: Final sterilization immediately pre-implant only

Upon completion of sterilization verify that both sterilization indicator strips (interior and on exterior of package) indicate the steam cycle was completed correctly. Follow manufacturer instructions for interpretation of these indicators. If both the indicators do not show completion of the sterilization cycle, repeat the cycle.

Warning

- The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device.
- Do not sterilize the Alpha 1 (M) Magnetic Implant more than a total of three (3) times. Additional sterilization cycles may cause a reduction in magnet performance or cause the magnetic case of the implant to leak.

Sterilization Pouch Specifications

To ensure the validated parameters are replicated appropriately, the following is to be used to individually pouch each implant prior to performing the sterilization cycle:

Manufacturer: Cardinal Health, http://www.cardinal.com, 800.964.5227

Catalog Number: 92510

Size: 5.5" x 10" Paper Self Seal Pouch

Materials: Arjowiggins 60g/m^2 Paper / CN PET 12/CPP40 Micron

Total Product Area: 0.035 m^2

Paper Area: 0.035 m^2

Ink: Medical Grade

Caution

- Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches.

Internal Steam Indicator Strip

As described above, each time an implant is steam sterilized, place a single indicator strip labeled for use with the specified gravity steam sterilization cycle into the inside of the specified pouch. Follow manufacturer's

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instructions for interpretation of results.

Pre-Surgical Training Requirements

Before attempting to implant the Otomag Implant, surgeons are required to complete training provided by Sophono, Inc. During the training they will receive guidance regarding the procedure, a thorough understanding of the device and surgical procedure and other important information. Contact Sophono Customer Services at the contact number listed in Section 6 of this manual to arrange training.

Surgical Risks

The implantation of the Otomag Implant requires a surgical procedure involving the removal of tissue and bone. As with any surgical procedure involving a general anesthetic, certain risks exist. Those risks include the risk of infection from poor hygiene or non-sterile technique, irritation of tissues during the implantation procedure, unintended cuts and abrasions, and irritation of tissues due to unintended exposure to implant materials. The implant is made of materials considered to be hypo-allergenic but in the case of unintended damage to the device, a patient could come in contact with substances that could generate an adverse reaction.

Surgical Site Preparation:

The hair should be clipped and the scalp shaved at the incision site immediately before surgery. With the incision site skin free of gross contamination, apply antiseptic (such as iodophors, alcohol-containing products, or chlorhxidine gluconate) in the area of the proposed incision to an area large enough to allow for the extension of the incision or creation of a new incision or drain sites (if necessary).

Pre-Surgical Antibiotic Prophylaxis:

Antibiotic prophylaxis should be considered if the surgeon determines that this surgical procedure may be associated with a considerable risk of infection or if a post operative infection would cause a serious hazard to the patient's recovery or well being.

Surgical Implantation Steps

Step 1 - Making The Incision

The proper position for the implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant will be placed. The incision must be large enough to allow placement of the implant. See Figure 1.

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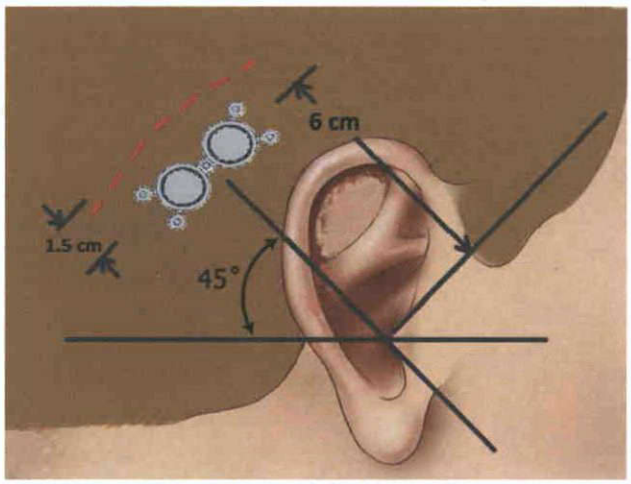

Figure 1 : Incision Location

Step 2 - Create a bone bed (optional)

The implant is approximately 2.6 mm thick and optimal tissue thickness over the implant is 4 mm to 5 mm.

To create a bone bed, mark the position of the implant magnets on the bone and drill the bone bed to a depth of approximately 3 mm. The implant magnets have a diameter of 10 mm.

Figure 2: Bone Beds

Step 3 - Implant Placement

After creation of the bone bed, install the magnetic implant using the specified screws such that the implant is oriented with the "This Side Up" label facing out. In addition, be sure to place the implant so that the small fiduciary mark is located in the most anterior and superior location. Place one screw in each of the bracket holes to securely attach the implant to the skull. The surface of the implant should be nearly flush with the surface of the mastoid.

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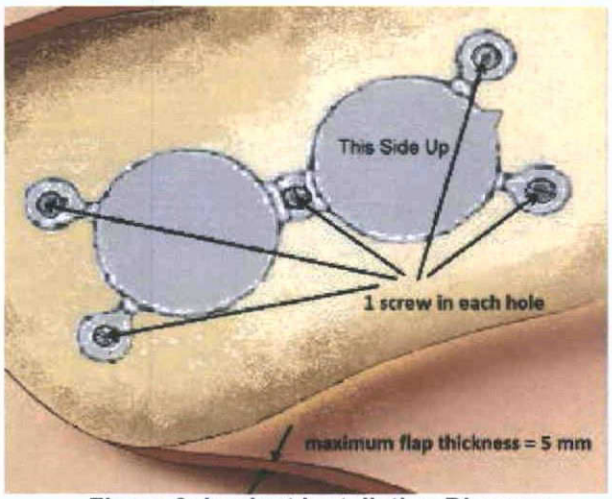

Figure 3: Implant Installation Diagram

Step 4 - Tissue Thinning and Closing the Incision

If the tissue flap is thicker than 6 mm, thin down a 10 mm wide strip of tissue to 5 mm directly over the implant magnets. Suture the incision closed.

Implant Surgical Removal Steps

Step 1 - Making The Incision

The implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant has been placed. The incision must be large enough to allow removal of the implant. See Figure 1 above.

Step 2 - Implant Removal

Remove each of the 5 screws holding the magnetic implant in place. It may be necessary to excise bone or tissue growth occurring over the face of the implant. Once the screws are removed the implant can be lifted carefully from the bone or bone beds. Suture incision closed.

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Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system and patient comfort. The Alpha 1 (M) configuration is supplied with five strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid.

The spacers are labeled with "dots" to indicate magnetic strength. Magnetic strength increases based on the number of dots present on the spacer. One dot is the lowest strength and five dots is the highest strength.

Several magnetic spacer strengths may be applicable to an individual patient. To determine the appropriate magnetic spacer for a patient use the "Go" and "No-Go" gages as follows.

The "Go" and "No-Go" gages used in the selection of the appropriate magnetic spacers may be re-used with multiple patients. However, prior to using with another patient the accessories must be cleaned and disinfected using an EPA-registered hospital disinfectant wipe.

Using the "Go" gage to determine the weakest appropriate magnetic spacer

1. *Starting with the one dot magnetic spacer, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the magnetic spacer poles align with the implant poles and the strongest magnetic attraction is achieved.*
2. *Ask the patient to sit upright with their head in a typical vertical position. Attach the "Go" gage clip to the patient's clothing.*
3. *Hang the "Go" gage disk from the magnetic spacer.*
4. *If the magnetic spacer detaches from the side of the patient's head, then the spacer is too weak and the process should be repeated with increasing magnetic spacer strengths until the magnetic spacer remains attached to the side of the head while attached to the "Go" gage disk.*
5. *The lowest dot number magnetic spacer that passes the "Go" test indicates the weakest magnetic spacer strength that should be recommended to the patient.*

Using the "No -Go" gage to determine the strongest applicable magnetic spacer

1. *Starting with the lowest dot number magnetic spacer that passes the "Go" test, place the magnetic spacer over the implant. Magnetic attraction will*

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pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the poles align with the implant poles and the strongest magnetic attraction is achieved.

2. *Again, ask the patient to sit upright with their head in a typical vertical position. Attach the "No-Go" gage clip to the patients clothing.*
3. *Hang the "No-Go" gage disk from the magnetic spacer.*
4. *The magnetic spacer **should detach** from the head from the weight of the disk. If the magnetic spacer detaches from the head then the magnetic spacer is one of the appropriate spacers for the patient.*
5. *Repeat this process, increasing magnetic spacer strength one dot at a time until the magnetic spacer **does not detach** from head.*
6. *The highest number magnetic spacer that **detaches** from the head using the "No-Go" test indicates the highest magnetic spacer strength that **should be used** by the patient on a regular basis.*
7. *Any magnetic spacer that remains attached during the "No-Go" test is too strong and should not be recommended for patients long term use.*
8. *If all magnetic spacers used in the "No-Go" test detach when the "No-Go" disc is attached, then all of the spacers tested in the "No-Go" test may be appropriate for the particular patient.*

Several spacer magnet strengths may be applicable for an individual patient. The patient should be prescribed the lowest dot magnet strength that is both comfortable, functions correctly and fits with their age and lifestyle.

⚠	**Warning** ▪ Excessive, long term use of magnetic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test.

⚠	**Caution** ▪ The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or if pain, numbness, or tingling occurs.

Placement of the Alpha 1 (M) Audio Processor

Approximately 4 weeks after the incision site has healed and all signs of inflammation are gone, the patient may be fit with the Alpha 1 (M) Audio Processor.

⚠	**Warning** ▪ Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this warning may result in prolonged healing, further irritation, or infection.

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4 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

⚠	**Warning** ▪ Both the Alpha 1(S) and Alpha 1(M) configurations of the device contain magnets which could impact the performance of pacemaker or implantable cardioverter defibrillator (ICD) devices. The magnets of the softband/headband of the Alpha 1(S) and the magnetic spacer of the Alpha 1(M) should therefore be kept away from a pacemaker or ICD.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. ▪ Patients with a pacemaker or ICD should consult their care provider for safe use of the Otomag system with their cardiac medical device.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a biocompatible titanium case. Only the titanium case of the implant is in contact with patient tissue.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid (bony protrusion on the skull located directly behind the ear): Fotoplast Lacquer 3 (light-curing one-component lacquer)

The components and packaging for the Otomag Bone Conduction Hearing System contain no natural rubber latex.

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The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Alpha 1 Sound Processor Technical Characteristics

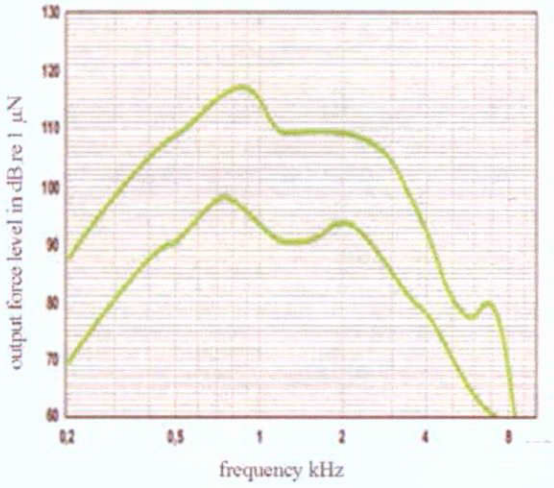
- Magnetically coupled bone conduction sound processor
- Fully programmable digital hearing system
- programs (programmable by audiologist)
- 4 channels
- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Alpha 1 Sound Processor Performance Data

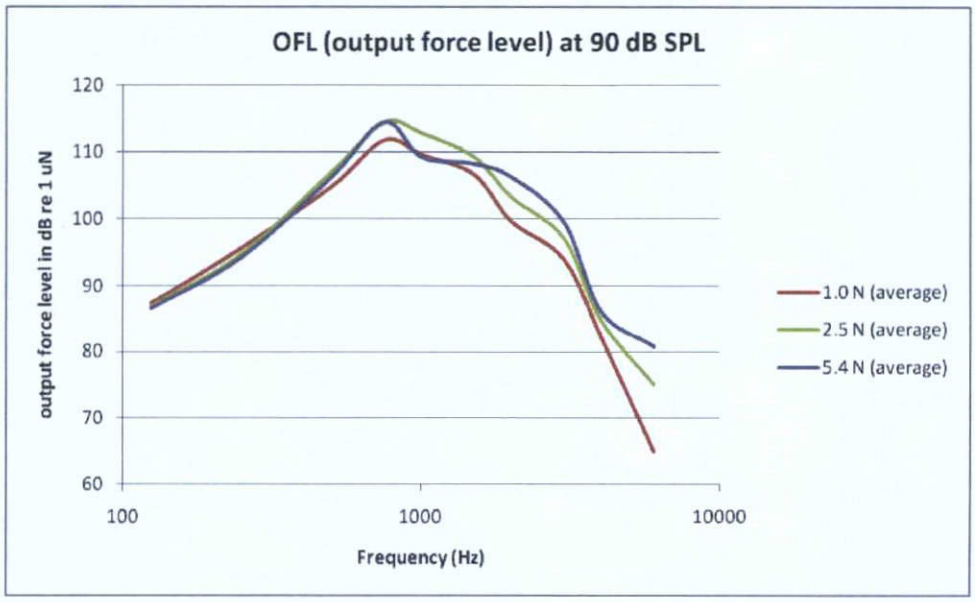
(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

(Measured according to DIN IEC 60118-9. Averages include all configurations of softband, headband, and magnetic spacers for a given normal force)



75

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 μN
- Peak Output at 90 dB SPL: 115 dB re 1 μN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

5 Storage and Handling

Storage

⚠	**Caution** ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -20 C (-4 F) or above +50 C (122 F) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Handling

⚠	**Caution** ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

6 Professional Support

For more information or to report concerns, device malfunctions, adverse events, or patient complaints, please contact:

Sophono, Inc.

903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663
postmaster@sophono.com

Manufactured for: Sophono, Inc. 903 Brooklawn Dr., Boulder, Colorado 80303 USA +1 (303) 564-1663

Printed in U.S.A.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 23, 2011

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET
SUITE 100
LAKEWOOD, COLORADO 80228
ATTN: CLAY ANSELMO

510k Number: K102199

Product: OTOMAG BONE CONDUCTION HEARING

Extended Until: 07/19/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

453

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

510(k) – Request for 30 Day Extension

March 21, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for 180 Day Extension

510(k) Applicant / Manufactured by:
Sophono, Inc.
903 Brooklawn Drive
Boulder, CO 80303
Ph: 303-546-1663
Fax: 720-222-2432

510(k) Contact / Submission Correspondent:
Clay Anselmo
President and CEO
Reglera LLC
Email: anselmoc@reglera.com
Phone/fax: 303-223-4303
Mobile: 303-907-2955

Dear Office of Device Evaluation,

We received a request for additional information dated January 20, 2011 and an addendum to this request on February 22, 2011, in response to our 510(k) premarket notification (K102199). We have been in ongoing dialog with the review team interactively to address the open issues related to clinical data and, at the suggestion of our reviewer, respectfully request a 180 day extension to allow Sophono and the Agency time to continue to interact on the matter and complete our response in a comprehensive manner.

We appreciate your time and consideration of this request.

Sincerely,

Clay Anselmo
Reglera LLC

K42

454

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 16, 2011

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET
SUITE 100
LAKEWOOD, COLORADO 80228
ATTN: CLAY ANSELMO

510k Number: K102199

Product: OTOMAG BONE CONDUCTION HEARING

Extended Until: 03/21/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 24, 2011

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET SUITE 100
LAKEWOOD, COLORADO 80228
UNITED STATES
ATTN: CLAY ANSELMO

510k Number: K102199
Product: OTOMAG BONE CONDUCTION HEARING

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 23, 2010

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET SUITE 100
LAKEWOOD, COLORADO 80228
UNITED STATES
ATTN: CLAY ANSELMO

510k Number: K102199

Product: OTOMAG BONE CONDUCTION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 19, 2010

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET SUITE 100
LAKEWOOD, COLORADO 80228
UNITED STATES
ATTN: CLAY ANSELMO

510k Number: K102199

Product: OTOMAG BONE CONDUCTION HEARING

Extended Until: 12/22/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

510(k) – Request for 60 Day Extension

October 15, 2010

FDA CDRH DMC

OCT 18 2010

Received

K-41

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for 60 Day Extension

510(k) Applicant / Manufactured by:
Sophono, Inc.
903 Brooklawn Drive
Boulder, CO 80303
Ph: 303-546-1663
Fax: 720-222-2432

510(k) Contact / Submission Correspondent:
Clay Anselmo
President and CEO
Reglera LLC
Email: anselmoc@reglera.com
Phone/fax: 303-223-4303
Mobile: 303-907-2955

Dear Office of Device Evaluation,

We received a request for additional information dated September 23, 2010, in response to our 510(k) premarket notification (K102199). We respectfully request a 60 day extension to allow Sophono time to complete its response in a comprehensive manner.

We appreciate your time and consideration of this request.

Sincerely,

Clay Anselmo
Reglera LLC

666

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 24, 2010

510k Number: K102199
Product: OTOMAG BONE CONDUCTION HEARING

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET SUITE 100
LAKEWOOD, COLORADO 80228
UNITED STATES
ATTN: CLAY ANSELMO

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 05, 2010

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET SUITE 100
LAKEWOOD, COLORADO 80228
UNITED STATES
ATTN: CLAY ANSELMO

510k Number: K102199
Received: 8/4/2010
Product: OTOMAG BONE CONDUCTION HEARING

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015 K102199

510(k) – Request for 30 Day Extension

FDA CDRH DMC

FEB 16 2011

Received

K-22

February 15, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for 30 Day Extension

510(k) Applicant / Manufactured by:
Sophono, Inc.
903 Brooklawn Drive
Boulder, CO 80303
Ph: 303-546-1663
Fax: 720-222-2432

510(k) Contact / Submission Correspondent:
Clay Anselmo
President and CEO
Reglera LLC
Email: anselmoc@reglera.com
Phone/fax: 303-223-4303
Mobile: 303-907-2955

Dear Office of Device Evaluation,

We received a request for additional information dated January 20, 2011, in response to our 510(k) premarket notification (K102199). We have been working with the review team interactively to address the open issues and respectfully request a 30 day extension to allow Sophono time to complete its response in a comprehensive manner.

We appreciate your time and consideration of this request.

Sincerely,

Clay Anselmo
Reglera LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

FDA CDRH DMC
AUG 0 4 2010
Received

K102199

Sophono

FDA CDRH DMC
AUG 0 4 2010
Received

510(k) Cover Letter

Date of Submission: August 3, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Submission for Changes to Otomag Bone Conduction Hearing System

Dear Madam/Sir:

Sophono Inc. hereby submits this Traditional 510(k) for modifications made to a previously cleared device. The modification described adds a new configuration into the Otomag Bone Conduction Hearing System family. The new configuration (Alpha 1(M)) uses an implantable magnet as a fixation system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193 – Otomag Bone Conduction Hearing System – May 18, 2010.

The addition of the Alpha 1(M) configuration of the product requires no change in intended use of the device, but does require minor wording changes to the Indications for Use statement. In addition, this new configuration introduces new design specifications and new materials to the product as well as revisions to product labeling. Modifications do not affect the fundamental scientific technology of the device.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Confidentiality:

Please be aware that Sophono Inc. considers our intent to market the Otomag Bone Conduction Hearing System, and the information provided in support of this premarket notification, to be confidential commercial information and afforded such protection under 21 CFR 807.95.

Material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and, therefore, non-discloseable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

Electronic Copy:

Please be aware that this submission contains one (1) paper copy with signatures and (1) electronic copy that is an exact duplicate of the paper copy created in accordance with instructions on FDA's website. The electronic copy has been placed along with a second paper copy of the cover letter in the binder being submitted to FDA.

If any additional information is required, or the Agency has questions regarding the contents of the submission, please contact our submission correspondent, Clay Anselmo. His contact information is included below. We are looking forward to working with the agency and will promptly respond to any requests or questions you may have.

Sincerely,

James F Kasic II
President and CEO
Sophono, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Submitter/Manufacturer Name and Street Address:	Sophono, Inc. 903 Brooklawn Drive Boulder, CO 80303 Ph: 303-546-1663 Fax: 720-222-2432 jkasic@comcast.net
Official Submission Contact:	Clay Anselmo President and CEO Reglera LLC Email: anselmoc@reglera.com Phone/fax: 303-223-4303 Mobile: 303-907-2955
Establishment Registration Number:	Not Yet Assigned
Type of Submission:	Traditional 510(k)
Trade Name:	Otomag Bone Conduction Hearing System
Common Name:	Bone Conduction Hearing Aid
Classification Name:	874.3300 – Hearing Aid
Classification:	Class II
Device Classification Panel:	Ear, Nose and Throat
Device Product Code:	LXB
Basis for Submission:	Device Changes: Indications Statement, Technical Specification Changes, Material Changes, Labeling Changes
Identification of the legally marketed devices (predicate):	Prior version of Otomag Bone Conduction Hearing System cleared in K100193.
Compliance with special controls, mandatory performance standards or radiation device standards:	• Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Cited Voluntary Standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic?		√
Is the device provided sterile?		√
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?	√	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Otomag Bone Conduction Hearing System 510(k)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Appendix A – Standards Data Reports - FDA Form 3654

Appendix B – Biocompatibility

Appendix C – Bench Performance Testing

Appendix D – Sterilization Validation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 01: Medical Device User Fee Cover Sheet (Form 3601)

See attached Form 3601

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015
Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
SOPHONO INC 903 Brooklawn Boulder Co 80303 US	Jim Kasic
	2.1 E-MAIL ADDRESS jkasic@comcast.net
	2.2 TELEPHONE NUMBER (include Area code) 303-5641663
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8585	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD106241

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted]

09-Jul-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Section 02: CDRH Premarket Review Submission Cover Sheet (Form 3514)

See attached Form 3514

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
8/03/2010	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Sophono, Inc.	Establishment Registration Number *(if known)*:
Division Name *(if applicable)*:	Phone Number *(including area code)*: 303-546-1663
Street Address: 903 Brooklawn Drive	FAX Number *(including area code)*: 720-222-2432

City	State / Province	ZIP/Postal Code	Country
Boulder	Colorado	80303	USA

Contact Name: James F Kasic II	
Contact Title: President and CEO	Contact E-mail Address: jkasic@comcast.net

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

(b)(4) [redacted]

FORM FDA 3514 (3/08)

PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Response to FDA correspondence:

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Traditional 510(k) submission for modification to an existing cleared device. The proposed modification does not affect the intended use of the device or alter the fundamental scientific technology of the device. Minor wording changes to indications for use statement are being requested.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LXB	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K100193	1	Otomag Bone Conduction Hearing System	1	Sophono, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Bone Conduction Hearing Aid

	Trade or Proprietary or Model Name for This Device		Model Number
1	Otomag Bone Conduction Hearing System	1	Alpha 1(S) and Alpha 1(M)
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K100193	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LXB	21 CFR 874.3300	[ ] Class I [x] Class II
Classification Panel		[ ] Class III [ ] Unclassified
Ear Nose & Throat		

Indications *(from labeling)*

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)

[redacted]

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	14971	ISO	Medical Devices: Application of risk management to medical devices	Second Edition	03/01/2007
2	#G95-1	FDA	Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	N/A	05/01/1995
3	17665-1	ISO	Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices	First Edition	08/15/2006
4	17664-1	ISO	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	First Edition	03/01/2004
5	15223-1	ISO	Medical Devices: Symbols to be used with medical device labels, labelling and information to be supplied	First Edition	04/15/2007
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 03: Requirements of ClinicalTrials.gov (Form 3674)

See attached Form 3674

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   Sophono Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   903 Brooklawn Drive
   Boulder, CO 80303

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 303-546-1663
   (Fax) 720-222-2432

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
   FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
   (Attach extra pages as necessary)

   Proprietary Name: Otomag Bone Conduction Hearing System

   Classification Name: Bone Conduction Hearing Aid; 21 CFR 874.3300

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(if number previously assigned)*
   K100193

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*
   ☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
   ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
   ☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*
    NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) Jim Kasic
    (Title) CEO

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    903 Brooklawn Drive
    Boulder, CO 80303

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 303-546-1663
    (Fax) 720-222-2432

15. DATE OF CERTIFICATION

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Page 11 of 192

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14.** - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Form FDA 3674 (11/08) (BACK)

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

510(k) Cover Letter

Date of Submission: August 3, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Submission for Changes to Otomag Bone Conduction Hearing System

Dear Madam/Sir:

Sophono Inc. hereby submits this Traditional 510(k) for modifications made to a previously cleared device. The modification described adds a new configuration into the Otomag Bone Conduction Hearing System family. The new configuration (Alpha 1(M)) uses an implantable magnet as a fixation system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193 – Otomag Bone Conduction Hearing System – May 18, 2010.

The addition of the Alpha 1(M) configuration of the product requires no change in intended use of the device, but does require minor wording changes to the Indications for Use statement. In addition, this new configuration introduces new design specifications and new materials to the product as well as revisions to product labeling. Modifications do not affect the fundamental scientific technology of the device.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Confidentiality:

Please be aware that Sophono Inc. considers our intent to market the Otomag Bone Conduction Hearing System, and the information provided in support of this premarket notification, to be confidential commercial information and afforded such protection under 21 CFR 807.95.

Material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and, therefore, non-discloseable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

Electronic Copy:

Please be aware that this submission contains one (1) paper copy with signatures and (1) electronic copy that is an exact duplicate of the paper copy created in accordance with instructions on FDA's website. The electronic copy has been placed along with a second paper copy of the cover letter in the binder being submitted to FDA.

If any additional information is required, or the Agency has questions regarding the contents of the submission, please contact our submission correspondent, Clay Anselmo. His contact information is included below. We are looking forward to working with the agency and will promptly respond to any requests or questions you may have.

Sincerely,

James F Kasic II
President and CEO
Sophono, Inc.

Submitter/Manufacturer Name and Street Address:	Sophono, Inc. 903 Brooklawn Drive Boulder, CO 80303 Ph: 303-546-1663 Fax: 720-222-2432 jkasic@comcast.net
Official Submission Contact:	(b)(4) [redacted]
Establishment Registration Number:	
Type of Submission:	Traditional 510(k)
Trade Name:	Otomag Bone Conduction Hearing System
Common Name:	Bone Conduction Hearing Aid
Classification Name:	874.3300 – Hearing Aid
Classification:	Class II
Device Classification Panel:	Ear, Nose and Throat
Device Product Code:	LXB
Basis for Submission:	Device Changes: Indications Statement, Technical Specification Changes, Material Changes, Labeling Changes
Identification of the legally marketed devices (predicate):	Prior version of Otomag Bone Conduction Hearing System cleared in K100193.
Compliance with special controls, mandatory performance standards or radiation device standards:	• Not Applicable

Cited Voluntary Standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic?		√
Is the device provided sterile?		√
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?	√	

Section 05:

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet	✓		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet	✓		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D	✓		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E	✓		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G	✓		
Class III Summary and Certification	Class III Summary and Certification Form			✓
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators Financial Disclosure by Clinical Investigators	✓		
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations FDA Standards program Declaration of conformity Required Elements for Declaration of Conformity to Recognized Standard	✓		
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		

Title	Related Information	Present	Inadequate	N/A
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)	✓		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H	✓		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	✓		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993,	✓		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	✓		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; EMC - Requirements and Tests (Second Edition, 2001)	✓		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			✓
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators			✓
FORM FDA 3654 *Standards Data Report for 510(k)s -*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**	✓		
Kit Certification	Device Advice			✓

Last Updated: 9/3/08 – Brandi Stuart

Section 06: Indications for Use

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Indications for Use

510(k) Number: _____

Device Name: Otomag Bone Conduction Hearing System

Indications for Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 07: 510(k) Summary

510(k) Summary: Otomag Bone Conduction Hearing System

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

Submitter: Sophono, Inc.

Establishment Registration Number: Not Yet Assigned

Contact Information:

Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
Ph: 303-546-1663
Fax: 720-222-2432
Contact: Jim Kasic
Email: jkasic@comcast.net

Date Prepared: July 27, 2010

Name of Device: Otomag Bone Conduction Hearing System

Common Name: Bone Conduction Hearing System

Classification Name: Hearing Aid

Device Classification:

- Classification: II
- Classification Panel: Ear, Nose and Throat
- Regulation Number: 874.3300
- Product Code: LXB

Predicate Device:

Otomag Bone Conduction Hearing System, Unmodified Version – K100193

Device Description:

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Osseointegrated Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an osseointegrated implanted magnet assembly. This configuration of the system is based on osseointegration of the implant through which living tissue integrates with the titanium implant causing the implant to be integrated into the bone. The magnetic field holds the sound processor

agains the head and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Technological Characteristics:

The technological characteristics of the Osseointegrated version of the Otomag Bone Conduction Hearing System are equivalent to those of the predicate device (non-Osseointegrated version). Items that are identical between the Osseointegrated version and the predicate are:

- Overall Device Performance
- Fundamental Technology (bone conduction)
- Software

Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Through non-clinical performance testing and evaluation, the identified technological differences do not raise new questions of safety and effectiveness.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Performance Standards:

The design of the Otomag Bone Conduction Hearing System conforms to the following voluntary standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Non-Clinical Performance Testing:

The Otomag Bone Conduction Hearing System has been subjected to extensive safety, performance testing, and verification / validation. Testing of the Otomag Bone Conduction Hearing System included various device performance tests and software validation tests designed to ensure that the device meet all of its functional specifications and is fit for its intended use. Tests have also been performed to ensure the device complies with industry and safety standards. The testing information presented in this submission demonstrates the device's performance is substantially equivalent to the predicate device.

Conclusion:

Based on the non-clinical performance testing, the Osseointegrated version of the Otomag Bone Conduction Hearing System is as safe and effective and considered to be substantially equivalent to the previously 510(k) cleared non-Osseointegrated version of the device (K100193).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 08: Declarations of Conformity and Summary Reports

1. Conformity with Standards

1.1. The Otomag Bone Conduction Hearing System and its development process conforms with all applicable requirements of the following National and International Standards.

1.1.1. ISO 14971:2007: Medical devices – application of risk management to medical devices;

1.1.2. FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

1.1.3. ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices

1.1.4. ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

1.1.5. ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

1.2. FDA Form #3654 has been completed for each of the standards referenced above. These forms are included in Appendix A to the overall submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Section 09: Truthful and Accuracy Statement

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President and CEO of Sophono Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

James Kasic II
President and CEO

7/26/2010
Date

*Premarket Notification [510(k)] Number _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10: Class III Summary and Certification

The Otomag Bone Conduction Hearing System is a Class II device. This section is not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 11: Financial Certification or Disclosure Statement

No information from clinical studies is submitted in this application. Therefore no financial certification or disclosure statement is required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 12: Executive Summary

1. INTRODUCTION

1.1. The following section contains the Executive Summary for the Otomag Bone Conduction Hearing System, including the Osseointegrated Alpha 1(M) version. This 510(k) is being submitted to add the Osseointegrated Alpha 1 (M) configuration to the existing product family.

2. DEVICE DESCRIPTION

2.1. The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Osseointegrated Alpha 1 (M).

2.1.1. In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

2.1.2. In the Otomag Osseointegrated Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted Osseointegrated magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. The pressure applied by the magnetic attraction between the implant and the sound processor is equivalent to that in the Alpha 1 (S) configuration.

2.2. The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

3. INDICATIONS FOR USE

3.1. The Indications for Use for the Osseointegrated device are identical to the predicate cleared in K100193.

3.2. The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

3.2.1. Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

3.2.2. Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

3.2.3. Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

4. CONTRAINDICATIONS

4.1. Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

4.1.1. A hearing loss of sudden onset;

4.1.2. A rapidly progressing hearing loss;

4.1.3. Pain in either ear;

4.1.4. Tinnitus of sudden recent onset, or unilateral tinnitus;

4.1.5. Unilateral or markedly asymmetrical hearing loss of unknown origin;

4.1.6. Vertigo (e.g. dizziness)

5. SUBSTANTIAL EQUIVALENCE

5.1. The changes to the device that are the subject of this 510(k) relate to the addition of another device configuration to the product family. The additional configuration, called Osseointegrated Alpha 1(M) includes a Magnetic Implant that is placed in bone beds behind and above the patient's ear to provide for attachment of the sound processor without the use of the headband or softband. This change impacts detailed engineering specifications, labeling and patient contact materials, but does not alter the overall performance of the device. Due to the specificity of the Indications for Use statement for the prior version of the device, minor wording changes are also required.

5.2. The following table summarizes and compares data on the Otomag Bone Conduction Hearing System cleared in K100193 (predicate device) to the Osseointegrated Alpha 1 (M) device that is the subject of this 510(k) submission.

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Osseointegrated Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	Identical
Class	Class II	Class II	Identical
Product Code	LXB	LXB	Identical
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	Identical

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Osseointegrated Bone Conduction Hearing System	Comparison
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical
Power Supply	Zinc-air battery	Zinc-air battery	Identical
Sound Processing	Digital	Digital	Identical
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical
Frequency Processing Range	125 – 8kHz	125 – 8kHz	Identical
Max Gain (60dB SPL)	38 dB	38 dB	Identical
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	29 dB	Identical
Material of sound processor coupling	Stainless Steel Disc	Stainless Steel Disc	Identical
Accessories/Options	Direct audio input via FM jack	Direct audio input via FM jack	Identical
Patient Contact Materials for Biocompatibility Purposes	Fotoplast-Lac	Fotoplast-Lac Titanium Grades 4 and 5 (Magnetic Implant)	See discussion below
Sterilization	No sterile components	Steam sterilization of surgical implant	See discussion below
Manufacturer	Otomag GmBH	Otomag GmBH	Identical
Peak Output at 90 dB SPL	115 dB	115 dB	Identical

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Specification / Characteristic	**Original Otomag Bone Conduction Hearing System K100193 (predicate device)**	**Otomag Osseointegrated Bone Conduction Hearing System**	**Comparison**
Frequency range per ANSI S3.22-2009	280-5000 Hz	280-5000 Hz	Identical
Total harmonic distortion per ANSI S3.22-2009	<3%	<3%	Identical
Equivalent input noise:	17 dB SPL	17 dB SPL	Identical
Battery current drain	0.95 mA	0.95 mA	Identical
Processor:	16 Band, 4 Channel WDRC	16 Band, 4 Channel WDRC	Identical
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical
Compression Attack Time (minimum)	0.25 ms	0.25 ms	Identical
Compression Release Time (maximum)	8192 ms	8192 ms	Identical
Patient Volume Control Wheel	38 dB range	38 dB range	Identical
Power Supply	1.3 V, #675 Zinc Air Battery	1.3 V, #675 Zinc Air Battery	Identical
Force Application Methods	Headband or Softband	Headband or Softband (Alpha 1(S) Version) Osseointegrated Magnetic Implant (Alpha 1(M) Version)	Substantially Equivalent – See discussion below

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6. DISCUSSION OF DIFFERENCES

6.1. The differences in specifications identified in the comparison table above between the predicate Otomag Bone Conduction Hearing device and the Otomag Osseointegrated device as reflected in the above SE table are the following. A detailed discussion of each device change is contained in Section 13 – Device Description / Description of Changes.

6.1.1. Indications for Use:

6.1.1.1. The changes in the Indications For Use statement simply add the additional Osseointegrated Magnetic Implant version of the product to the overall statement including an age limitation for use of the Osseointegrated Magnetic Implant configuration (Osseointegrated Alpha 1(M)) to patients 5 years of age or older. These changes do not impart a new intended use for the product and do not raise new questions of safety and effectiveness.

6.1.2. Patient Contact Materials:

6.1.2.1. The Magnetic Implant (includes attachment screws) constitute new patient contacting materials. The implant is made of Titanium Grades 4 and 5. This material is a biocompatible metal alloy not containing toxic substances. The addition of new patient contact materials that are biocompatible does not raise new questions of safety and effectiveness.

6.1.3. Sterilization:

6.1.3.1. The Magnetic Implant is provided clean but not sterile and intended to be sterilized via gravity or prevacuum steam sterlization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The addition of an appropriately specified and validated sterilization cycle does not raise new questions of safety and effectiveness.

6.1.4. Force Application Method:

6.1.4.1. The new Osseointegrated Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 4 different strength magnetic spacers provided with the product. Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device.

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6.1.4.2. The approach of using a magnetic implant to attach the sound processor has been previously employed by another family of bone conduction hearing devices. The Xomed Audiant Bone Conductor cleared in K855059 and K861971 employs this same technology for the attachment of the sound processor.

7. APPLICATION OF DESIGN CONTROLS

7.1. In accordance with 21 CFR 820.30 all the changes described in this submission were subject to the Design Control Program and Associated Procedures of both Sophono and Otomag. The major elements of the Design Control System applied to these changes included:

7.1.1. Design and Development Planning
7.1.2. Development of Design Outputs
7.1.3. Risk Analysis / Risk Management
7.1.4. Verification and Validation
7.1.5. Design Review
7.1.6. Design Transfer

8. SUMMARY OF PERFORMANCE TESTING

8.1. As a result of the application of risk analysis and the differences identified in the substantial equivalency comparison table, the following verification and validation activities were completed to ensure that the differences between the non-osseointegrated predicate device and the Osseointegrated version of the Otomag Bone Conduction Hearing System do not raise new questions of safety and effectiveness.

8.2. Risk Areas identified as a result of risk analysis included:

8.2.1. Material Biocompatibility
8.2.2. Implant Anchoring
8.2.3. Force Application to patient skin / mastoid
8.2.4. Sealing of Magnetic Implant

8.3. The following section outlines the categories of Verification and Validation testing that were conducted and rationale for those areas where additional testing was unnecessary as a result of the scope of changes.

8.4. **Performance Testing:**

8.4.1. **Implant Anchoring:** Implant Anchoring using titanium bone screws (Liebinger 4mm facial plating screws) were validated for this use in validation protocol (b)(4) [redacted] to this overall submission.

8.4.2. **Force Application:** Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device. This validation is documented in validation protocol (b)(4) [redacted] to this overall submission.

8.4.3. **Sealing of Magnetic Implant:** The two halves of the titanium casing are welded together, cleaned and 100% leak tested. Each of these processes has been appropriately validated by the manufacturer (Eberle, EFS GmBH).

8.4.4. **Sound Processor:** The sound processor itself was not modified and therefore additional performance testing of this part of the device was not necessary

8.4.5. **Vibration Transmission:** The method, mechanics, and materials used to transmit vibration from the sound processor to the patient are unchanged in the Osseointegrated Alpha 1(M) configuration. The metal disc and magnetic spacers used in the Osseointegrated Alpha 1(M) configuration are identical in material and vibration application method to the Fotoplast encased magnets used in Alpha 1(S) configuration of the device (headband and softband versions). As a result, no additional performance testing related to these characteristics was required for the Osseointegrated Alpha 1(M) configuration.

8.5. **Sterilization Validation including Sterile Packaging:**

8.5.1. The sterilization process specified in the Physician's Manual was validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The validation was performed by Nelson Laboratories and the protocol and final report documenting this validation is contained in Appendix D to this overall submission. In addition, the Physician's Manual contains the information required by ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

8.6. **Biocompatibility Testing:**

8.6.1. In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible.

8.7. **Software:**

8.7.1. No changes were made to either the embedded software in the sound processor or the fitting software associated with the device; therefore no software testing is associated with this modification to the device.

8.8. **Electrical Safety Testing:**

8.8.1. The changes made to the modified version of the device have no effect/impact on electrical safety, and therefore no additional electrical safety testing was required.

8.9. **EMC Testing:**

8.9.1. The changes made to the modified version of the device have no effect/impact on EMC performance, and therefore no additional EMC testing was required.

8.10. **Animal / Clinical Testing**

8.10.1. Animal and Clinical studies were not deemed necessary to validate the changes in the Osseointegrated Alpha 1(M) version of the device.

9. CONCLUSION

9.1. The results of analyses, evaluation, and testing of the Otomag Bone Conduction Hearing System demonstrate that the Osseointegrated device is substantially equivalent to the prior cleared version of the device both in Intended Use and technological characteristics. The changes to the device do not raise new questions of safety and effectiveness and have been appropriately validated through the application of Otomag's and Sophono's design control programs.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 13: Device Description / Description of Changes

1. General Introduction

1.1. The following section contains both a detailed description of the device in its various configurations as well as a detailed description of the planned changes to the device which are the subject of this 510(k).

1.1.1. The changes described in section 9 below introduce a new configuration into the Otomag Bone Conduction Hearing System family. The new osseointegrated configuration (Alpha 1(M)) uses an implantable magnet encased in titanium as a retention system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193.

1.1.2. The addition of the Alpha 1(M) configuration of the product requires no change in intended use of the device, but does require minor wording changes to the Indications for Use statement. In addition, this new configuration introduces new material, performance and design specifications to the product as well as revisions to product labeling. No changes to software or to the sound processor are being made as a part of introducing this additional configuration.

1.2. The content of the Device Description sections below (sections 2-8) are intended to fulfill the device description requirements from 21 CFR 807.87. Section 9 is intended to describe in detail each planned device change.

2. Device Introduction

2.1. The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and the osseointegrated Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

2.1.1. In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

2.1.2. In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. Vibration is not primarily transmitted through the magnetic implant.

2.2. The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

3. Indications For Use:

3.1. The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

3.1.1. Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

3.1.2. Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

3.1.3. Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

4. Classifying Regulation and Product Code

4.1. Regulation Number: 21 CFR 874.3300

4.2. Product Code: LXB

5. Detailed Device Description

5.1. Device and Company Nomenclature

5.1.1. The Otomag Alpha 1 Sound Processor may also be called the Alpha 1 Sound Processor, the Sound Processor, or Alpha 1. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.2. The Otomag Alpha 1(S) Configuration may also be called the Alpha 1(S) or 1(S) configuration. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.3. The Otomag Osseointegrated Alpha 1(M) Configuration may also be called the Alpha 1(M) or 1(M) configuration. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.4. Sophono, Inc. (b)(4) [redacted]
(b)(4) [redacted]

5.2. Description of the Alpha 1(S) Configuration

5.2.1. In the Alpha 1(S) configuration, the Sound Processor can be used with a

headband or softband. Both the headband and softband are equipped with magnets encapsulated by Fotoplast (plastic) materials.

5.2.2. For this configuration, a metal disc is screwed into the Alpha 1 Sound Processor (Figure 3). The magnets within on the headband or softband magnetize to the Alpha 1 Sound Processor metal disc (Figure 1, Boxes B, D, E).

5.2.3. The softband holds the Alpha 1 to the side of the head by adjusting its elastic band and securing the fit with a Velcro closure (Figure 1, Boxes A-D). The headband holds the Alpha 1 to the side of the head by means of a springy metal bow (Figure 1, Boxes E & F). The figure shows the headband and softband with and without the Alpha 1 Sound Processor attached via the magnets.

Figure 1: Alpha 1(S) Configuration / Headband, Softband, and Sound Processor

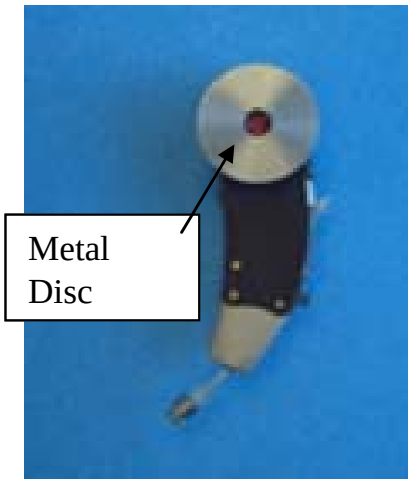

Figure 2: Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment to Headband / Softband

5.3. Description of the Osseointegrated Alpha 1 (M) Configuration (Addition to Product Family)

5.3.1. In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Osseointegrated Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 3 below shows the details of the configuration.

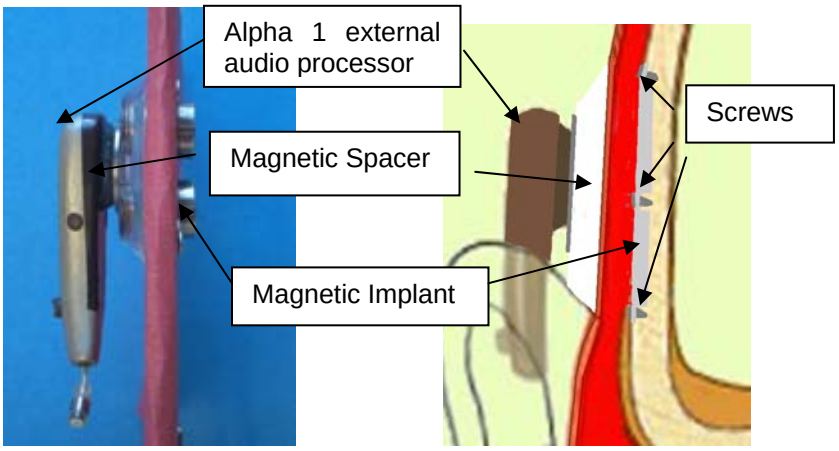

Figure 3: Alpha 1 (M) Magnetic Implant System

5.3.2. For this configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

5.3.3. To ensure that appropriate pressure is applied between the sound processor and the patient's skin / bone, various strengths of magnetic spacers are available (b)(4) [redacted] (b)(4) [redacted]

5.3.4. The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical impant site. See the Physician's Manual in Section 15 of the overall submission for detailed implantation instructions.

5.4. Description of the Otomag Alpha 1 Sound Processor

5.4.1. A key component of the Otomag System is the Alpha 1 Sound Processor, which is similar to a behind the ear air conduction hearing with a traditional bone conduction vibrator. The Alpha 1 Sound Processor utilizes proprietary software. The Alpha 1 Sound Processor is available for left or right sides with or without an external microphone, and with or without an FM jack.

5.4.2. The Alpha 1 Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone (Figure 4) within a plastic housing. The microphone opening is situated in the bottom of the housing and the vibrator in the upper part of the

housing. The volume control with integrated switch and the battery compartment are accessible to the patient on the housing. The programming socket is situated beneath a cover. The programming socket is used for initial programming of the hearing device, as well as when adjustments are needed. No part of the sound processor has prolonged user contact.

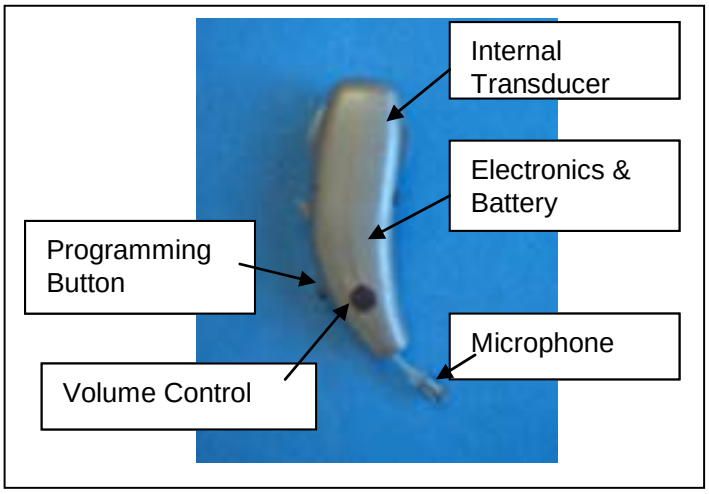

Figure 4: Alpha 1 Sound Processor

5.4.3. Sound Processor Circuit Description

5.4.3.1. The Alpha 1 Sound Processor utilizes a conventional hearing aid circuit based (b)(4) [redacted]

5.4.3.2. As an alternative to sound reception with the microphone, an electromagnetic signal can also be received by means of an FM link on those Alpha 1 Sound Processors that have an FM jack. The jack is compatible with the Phonak MLxi FM receiver boot.

5.4.3.3. (b)(4) [redacted]

5.4.4. Gravity 2 Software Description

5.4.4.1. The Otomag Gravity 2 Fitting Software is based on the (b)(4) [redacted]

5.4.4.2. (b)(4) [redacted]

5.4.4.3. The design of the Otomag Alpha 1 Sound Processor requires that it is a four-channel bone conduction sound processor whose signal processing is implemented by a digital signal processor (DSP). It is required that adjustment of the acoustic parameters occurs through digital control via a PC and the Otomag Gravity 2 software. The following programmable parameters are available in all four channels:

(b)(4) [redacted]

(b)(4) [redacted]

5.5. Osseointegrated Magnetic Implant

5.5.1. The implant consists of two Samarium Cobalt (b)(4) [redacted]) magnets hermetically sealed in a titanium housing as shown in Figure 5. The implant is manufactured for (b)(4) [redacted] Validation documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in Appendix C to the overall submission. Biocompatibility information, including material specifications for the implant can be found in Appendix B to the overall submission. Each implant is welded, cleaned, and 100% leak tested by the manufacturer using formally validated processes.

5.5.2. The magnetic implant is placed in 3 mm deep bone beds as shown in Figure 6 and Figure 7. The implant is secured using 4 mm titanium facial plating screws.

Figure 5: Magnetic Implant

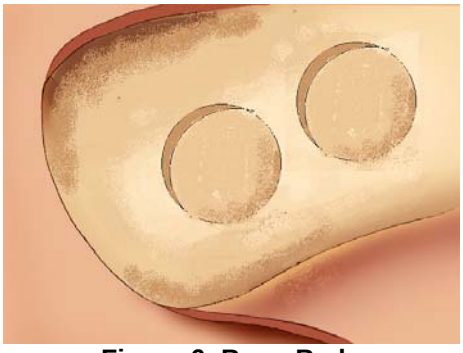

Figure 6: Bone Beds

5.5.3. The magnetic implant is supplied to the physician clean but non-sterile, in sealed packaging to prevent contamination. The device is intended to be steam sterilized at the healthcare facility prior to implantation. Instructions and requirements for performing steam sterlization are included in the Physician's Manual contained in Section 15 to the overall submission.

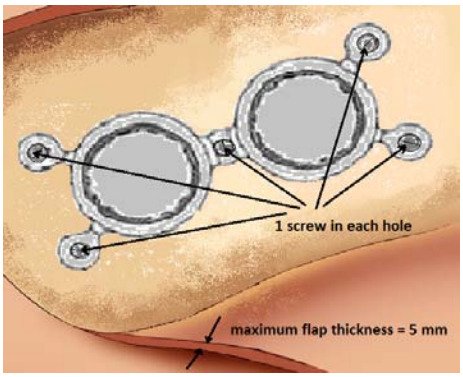

Figure 7: Implant Secured into Bone Beds

5.6. Magnetic Spacer

5.6.1. The spacer consists of a nickel plated neodymium iron boron magnet (b)(4) [redacted] (b)(4) [redacted] as shown in Figure 8 and Figure 9. Both plastic materials are those commonly used for the production of custom ear molds. Complete material specifications can be found in Appendix B to the overall submission. Four magnetic strengths of the spacer are available to accommodate for variations in skin thicknesses and holding requirements to obtain approximately 2.5 N to 5.4 N of holding force.

Figure 8: Magnetic Spacer

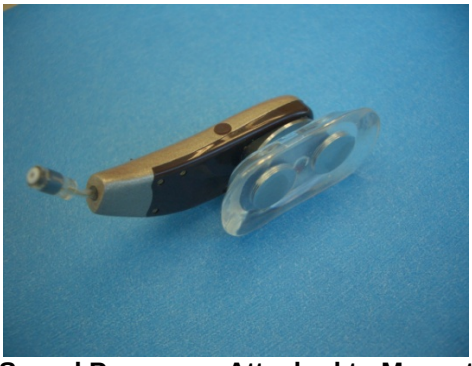

Figure 9: Sound Processor Attached to Magnetic Spacer

6. Patient-Contacting Components and Materials

6.1. The components of the Otomag System that are patient contacting are the Fotoplast components on the headband / softband, the Fotoplast Magnetic Spacer, and the

titanium magnetic implant. All materials used in the Alpha 1 device are materials commonly used in medical devices in the same applications (external tissue contact, implant). Biocompatibility information for these materials is contained in Section 17 and Appendix B of the overall submission. Each Magnetic Implant is cleaned to remove any manufacturing process contaminants.

6.2. Fotoplast-Lac and Fotoplast S IO

6.2.1. The Fotoplast S IO is the material that directly encapsulates the magnets in the softband and headband. The Fotoplast-Lacquer 3 is a light-curing one-component lacquer used to coat the Fotoplast S IO encapsulated magnets. This Fotoplast-Lacquer 3 material is in direct skin contact with healthy skin behind the ear, at the site of bone conduction. Both materials have been found biocompatible for their intended use. These materials are commonly used to fabricate hearing aid earmolds and thus have years of use in the ear canal without biocompatibility problems.

6.3. Titanium

6.3.1. In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible and is used in many medical implant applications.

6.3.2. The bone screws used to anchor the magnetic implant are also titanium. These screws are manufactured by Stryker Leibinger and are a legally marketed device which was cleared under K970912 for use as self threading bone screw.

7. Kit Configurations

7.1. The Otomag System will be available in two kit configurations (e.g., Alpha 1 (S) with appropriate means of attachment, Alpha 1 (M) with appropriate magnetic spacers) or the components may be ordered separately. Each kit or component will be labeled appropriately and will include the Patient User Manual and / or the Physician Instructions for Use as appropriate.

7.2. Each Alpha 1 Sound Processor will be available in right or left sided versions, with either an internal or external microphone, and with or without an FM jack. Alpha 1 Sound Processor configurations are show in Table 3.

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Table 3		
Sound Processor Configurations		
Right sided	Internal Microphone	With FM Jack
	External Microphone	
Left sided	Internal Microphone	
	External Microphone	
Right sided	Internal Microphone	Without FM Jack
	External Microphone	
Left sided	Internal Microphone	
	External Microphone	

7.3. An example of a component that is likely to be sold separately is an Alpha 1 (S) Sound Processor. Because it will not be known if the patient prefers a softband or headband, the Alpha 1 (S) will likely be shipped separately from the softband or headband.

7.4. Sophono, Inc. will also distribute to qualified hearing healthcare providers the Otomag Gravity 2 Fitting Software.

8. Specifications and Characteristics

8.1. Device Technical Specifications

8.1.1. Alpha 1 Sound Processor Specifications

8.1.1.1. Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB

8.1.1.2. Maximum Gain at 60 dB SPL: 38 dB

8.1.1.3. Peak Output at 90 dB SPL: 115 dB

8.1.1.4. Frequency range per ANSI S3.22-2009: 280-5000 Hz

8.1.1.5. Frequency processing range: 125-8000 Hz

8.1.1.6. Total harmonic distortion per ANSI S3.22-2009: <3%

8.1.1.7. Equivalent input noise: 17 dB

8.1.1.8. Battery current drain: 0.95 mA

8.1.1.9. Processor: 16 Band, 4 Channel WDRC

8.1.1.10. Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz

8.1.1.11. Compression Attack Time: 0.25 ms

8.1.1.12. Compression Release Time: 8192 ms

8.1.1.13. Patient Volume Control Wheel: 38 dB range

8.1.1.14. Power Supply: 1.3 V, #675 Zinc Air Battery

8.1.2. Magnetic Spacer Specifications

8.1.2.1. Magnetic Field Force (b)(4) [redacted]

(b)(4) [redacted]

8.1.2.2. Spacer Sizes: 2mm, 4mm, 6mm, 8mm

8.1.2.3. Patient Contact Material: Fotoplast LAC

8.1.3. Magnetic Implant Specifications

(b)(4) [redacted]

9. Description of Changes

9.1. The following section contains a summarized description of the changes to the device that include Indications for Use, additional hardware, and labeling. It should be noted that the changes described below do not constitute a change in intended use of the device, or the fundamental scientific principles of the device.

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C1	**Indications for Use**	Minor wording change in the Indications for Use statement to add the term "..or magnetic implant" to the end of the first paragraph. The new paragraph now reads: "The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband, Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:…" In addition, the following paragraph was removed because it was redundant with the first paragraph: "The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband."	None: Changes in Indications for Use statement are minor and do not result in a new Intended Use for the device. Specific impacts of design changes associated with this Indications for Use change are analyzed in each additional line item in this table.	None

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C2	**Force Application Method**	Addition of the magnetic spacer in 4 strengths, to be used in conjunction with the magnetic implant, to mimic the pressure applied by the softband or headband. Spacers are chosen by the fitting physician, based on tissue thickness, to ensure an application force of between approximately 2.5 and 5.4 N. Material of the magnetic spacer is identical to the skin contact materials present in the headband and the softband (Fotoplast Lacquer 3). Part of the function of the magnetic spacer is identical to the prior version of the device which utilized a magnetic field to hold the sound processor to the headband or softband. In addition to holding the Sound Processor, the magnetic spacer additionally holds the Sound Processor assembly (Sound Processor and magnetic spacer) to the patient's skin through the creation of an attractive magnetic field.	None: • Patient Contact materials for this component are identical to the prior version of the device • The switch from pressure application via the headband or softband to an attractive magnetic field does not impact risk assessment as long as forces are equivalent	Otomag Softband, Headband, and Magnetic Implant Static Force Verification / Validation Protocol, DG-35: Validation showed magnetic attachment mechanism via magnetic implant is equivalent to headband / softband versions of the device.

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C3	**Force Application Method / Patient Contact Materials**	Addition of the magnetic implant, to be used in conjunction with the magnetic spacer, to mimic the pressure applied by the softband or headband. Patient contact material of the magnetic implant is Titanium. Magnets are hermetically sealed within the titanium case. The magnet is of similar design and the same construction methods as is used in currently available cochlear implants. Screws used to anchor the implant in the bone beds are included with the device and are 4 mm titanium bone screws manufactured by Stryker Leibinger and cleared under K970912.	The addition of the implanted magnet raises the following new risks not present in the prior version of the device • Biocompatibility related the implant As discussed immediately above, the switch from pressure application via the headband or softband to an attractive magnetic field does not impact risk assessment as long as forces are equivalent	• See Appendix B for Biocompatibility information for the magnetic implant • Otomag Softband, Headband, and Magnetic Implant Static Force Verification / Validation Protocol, DG-35: Validation showed magnetic attachment mechanism via magnetic implant is equivalent to headband / softband versions of the device. • Otomag Magnetic Implant Screw Retention Force Validation Protocol, DG-36: Showed the retention force of the 5 retention screws far exceeds the forces applied to the implant during operation.

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C4	**Labeling**	Primary Device Labeling has been modified to include clear identification of which configuration of the device is included (Alpha 1(S) or Osseointegrated Alpha 1(M)) Physician's Manual has been revised to include implant and explant instructions, magnetic spacer fitting instructions, and additional Warnings / Cautions related to the magnetic implant. Users Manual has been revised to include additional user instructions for placement of the Sound Processor with the magnetic implant, and additional Warnings / Cautions related to the magnetic implant. A label has been developed for the magnetic implant packaging to correctly identify this portion of the device.	None: Additional instructions are intended to ensure safe, effective use of the device. New Warnings and Cautions are included as a result of detailed risk analysis. The labeling changes themselves only serve to lower overall risk associated with the device	None

Section 14: Substantial Equivalence Discussion

1. INTRODUCTION

1.1. Section 14 of this Traditional 510(k) identifies the predicate device and provides a detailed comparison between the modified device that forms the subject of this Traditional 510(k) and the predicate device in order to demonstrate the substantial equivalence of the two devices.

2. PREDICATE DEVICE

2.1. The predicate device for the osseointegrated version of the Otomag Bone Conduction Hearing System is the non-osseointegrated version of this device. The device changes presented in this 510(k) do not substantially alter the device with regards to the following:

- 2.1.1. Intended Use
- 2.1.2. Fundamental Technological Characteristics
  - 2.1.2.1. Device Performance
  - 2.1.2.2. Operating Principles
- 2.1.3. Target User and Patient Populations
- 2.1.4. Use Environment

2.2. The changes to the device that are the subject of this 510(k) relate to the addition of another device configuration to the product family. The additional configuration, called Alpha 1(M), includes an osseointegrated Magnetic Implant that is placed in bone beds behind and above the patient's ear to provide for attachment of the sound processor without the use of the headband or softband. This change impacts detailed engineering specifications and patient contact materials, but does not alter the overall performance of the device. Due to the specificity of the Indications for Use statement for the prior version of the device, minor wording changes are also required.

3. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

3.1. The following table summarizes and compares data on the Otomag Bone Conduction Hearing System cleared in K100193 (predicate device) to the osseointegrated device that is the subject of this 510(k) submission.

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	Identical
Class	Class II	Class II	Identical
Product Code	LXB	LXB	Identical
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	Identical
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical
Power Supply	Zinc-air battery	Zinc-air battery	Identical
Sound Processing	Digital	Digital	Identical
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical
Frequency Processing Range	125 – 8kHz	125 – 8kHz	Identical
Max Gain (60dB SPL)	38 dB	38 dB	Identical
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	29 dB	Identical
Material of sound processor coupling	Stainless Steel Disc	Stainless Steel Disc	Identical
Accessories/Options	Direct audio input via FM jack	Direct audio input via FM jack	Identical
Patient Contact Materials for Biocompatibility Purposes	Fotoplast-Lac	Fotoplast-Lac Titanium Grade 4 and 5 (Magnetic Implant)	See discussion below

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Sterilization	No sterile components	Steam sterilization of surgical implant	See discussion below
Manufacturer	Otomag GmBH	Otomag GmBH	Identical
Peak Output at 90 dB SPL	115 dB	115 dB	Identical
Frequency range per ANSI S3.22-2009	280-5000 Hz	280-5000 Hz	Identical
Total harmonic distortion per ANSI S3.22-2009	<3%	<3%	Identical
Equivalent input noise:	17 dB SPL	17 dB SPL	Identical
Battery current drain	0.95 mA	0.95 mA	Identical
Processor:	16 Band, 4 Channel WDRC	16 Band, 4 Channel WDRC	Identical
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical
Compression Attack Time (minimum)	0.25 ms	0.25 ms	Identical
Compression Release Time (maximum)	8192 ms	8192 ms	Identical
Patient Volume Control Wheel	38 dB range	38 dB range	Identical
Power Supply	1.3 V, #675 Zinc Air Battery	1.3 V, #675 Zinc Air Battery	Identical
Force Application Methods	Headband or Softband	Headband or Softband (Alpha 1(S) Version) Osseointegrated Magnetic Implant (Alpha 1(M) Version)	Substantially Equivalent – See discussion below

4. DISCUSSION OF DIFFERENCES

4.1. The differences in specifications identified in the comparison table above between the predicate Otomag Bone Conduction Hearing device and the modified Otomag device as reflected in the above SE table are the following. A detailed discussion of each device change is contained in Section 13 – Device Description / Description of Changes.

4.1.1. **Indications for Use:**

4.1.1.1. The changes in the Indications For Use statement simply add the additional Magnetic Implant version of the product to the overall statement including an age limitation for use of the Osseointegrated Magnetic Implant configuration (Alpha 1(M)) to patients 5 years of age or older. These changes do not impart a new intended use for the product and do not raise new questions of safety and effectiveness.

4.1.2. **Patient Contact Materials:**

4.1.2.1. The Magnetic Implant contains new patient contacting materials. The implant is made of (b)(4) [redacted] In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible. The addition of new patient contact materials that are biocompatible does not raise new questions of safety and effectiveness.

4.1.3. **Sterilization:**

4.1.3.1. The Magnetic Implant is provided clean but not sterile and intended to be sterilized via gravity or prevacuum steam sterilization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The addition of an appropriately specified and validated sterilization cycle does not raise new questions of safety and effectiveness.

4.1.4. **Force Application Method:**

4.1.4.1. The new osseointegrated Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 4 different strength magnetic spacers provided with the product. Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device.

4.1.4.2. The approach of using a magnetic implant to attach the sound processor has been previously employed by another family of bone conduction hearing devices. The Xomed Audiant Bone Conductor cleared in K855059 and K861971 employs this same technology for the attachment of the sound processor.

5. CONCLUSION

5.1. The Intended Use of the osseointegrated version of the Otomag Bone Conduction Hearing System remains the same as the predicate device (non-osseointegrated version). Performance data demonstrate that the modified device meet or exceed the applicable requirements.

5.2. The osseointegrated version of the Otomag Bone Conduction Hearing System is substantially equivalent to the predicate Otomag device cleared in K100193 and that the differences between the two devices:

5.2.1. Do not raise any new issues of safety and effectiveness

5.2.2. Do not amount to a change in the "fundamental scientific technology" of the device

5.2.3. Do not present any adverse health effect or safety risks to patients when used as intended.

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Section 15: Labeling

1. Introduction

1.1. In conjunction with the addition of the osseointegrated Alpha 1(M) configuration of the Otomag Bone Conduction Hearing System, labeling updates were made. As a part of these updates the original manuals have been reorganized and reformatted to better and more clearly present the original information. No substantive changes to the original labeling pertaining to the Alpha 1(S) configuration have been made. Additional sections have been added to both the Physician's Manual and the Patient User Manual to appropriately address the osseointegrated Alpha 1(M) configuration. The changes are summarized as follows:

1.1.1. Addition of new Warnings and Cautions related to the Alpha 1(M) Configuration

1.1.2. Addition of sterilization instructions and cycle parameters relating to pre-implant sterilization of the Magnetic Implant

1.1.3. Addition of surgical implantation and explantation instructions and diagrams have been added addressing the placement and removal of the Magnetic Implant

1.1.4. Addition of instruction for attaching the Sound Processor to the Magnetic Implant

1.2. In addition to the revised Patient User Manual and Physician's Manual, the label for the Magnetic Implant is included in this section.

1.3. The primary device label has been modified to clearly indication which device configuration is included in the packaging, Alpha 1(S) or osseointegrated Alpha 1(M)

2. Index of Attachments in this section

2.1. Physician's Manual

2.2. Patient User Manual

2.3. Magnetic Implant Package Label

2.4. Revised Primary Device Labels

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Physician's Manual

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Physician Manual

Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems

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Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 About this Manual

This Physician Manual provides a description of the Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. This manual provides the information necessary for the physician to prescribe the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems to the appropriate patient population. Please read this manual thoroughly before prescribing the system.
A Patient Instruction Manual is included with each **Alpha I (S)** & **Alpha I (M)** Bone Conduction Hearing System and should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

2 Introduction

Warnings and Cautions Overview

The following section contains a description of all physician related Warnings and Cautions associated with the Otomag Bone Conduction Hearing Systems.

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Additional patient and use related Warnings and Cautions can be found in the Patient User Manual. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to physician instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warnings

Warning	▪ Thoroughly read the Physician Manual and the Patient Manual before prescribing the Otomag System. ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Precautions

Caution	▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual.

Product Description

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag System is configured in either of two configurations. The first configuration is the Alpha 1 (S), where the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), where the Otomag Sound Processor is attached magnetically to an osseointegrated implanted magnet. The Headband, Softband, or Magnetic Implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patient Selection Criteria

- Patients to be fitted with the Otomag Alpha 1 (S) Sound Processor and its Headband or Softband may be any age.
- Patients to be fitted with the Otomag Osseointegrated Alpha 1 (M) Sound Processor and its Magnetic Implant should be 5 years old or older.
- Patients and/or patient guardians must be able to understand that the Otomag System will not restore hearing to normal and will not prevent additional hearing impairment resulting from conditions such as disease, old age hearing loss, genetic hearing loss, ototoxic drugs or noise induced hearing loss.

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Possible Adverse Effects

General

It is possible that a reaction to the materials of the Headband, Softband, or Magnetic Implant could occur. Such a circumstance may necessitate that use of the device be discontinued. Please report any adverse effects to Sophono, Inc. The address and phone number for Sophono, Inc. are listed at beginning and end of this Physician Manual. If a reaction to the Headband or Softband occurs, Sophono will supply appropriate instructions so that the device can be sent to the laboratory for analysis.

Risks that may occur during surgery:

The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, postcholesteatoma, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, disturbance of taste or balance and noticeable changes in head noise.

⚠	**Warning** ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System.

Risks that may occur after surgery:

Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma and inflammatory reaction.

It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant.

⚠	**Warning** ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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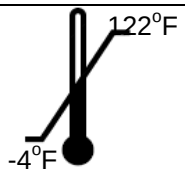
Other Symbols on Equipment and Labeling

Symbol	Description
	Consult Physician Manual
	Batch Code or Lot Number
	Serial Number
	Keep Away From Rain / Keep Dry
	Manufacturer
	MR Unsafe: Device should not be worn when patient is undergoing an MRI
	Product is Latex Free
	Interference may occur in the area of equipment which is labeled with the following symbol.
	Temperature Limitation: The sound processor is designed to operate within the temperature ranges of 41oF (+5oC) to 104oF (+40oC). The processor should not be subject to temperatures below -4oF (-20oC) or above 122oF (+50oC) at any time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 Patient Fitting Procedures

Alpha 1 (S) System: Instructions for Placement of the Softband or Headband and Alpha 1 Sound Processor

	Notes ▪ Record the product and lot or serial numbers for the Alpha 1 Sound Processor in the patient file and send the patient to a qualified audiologist for proper programming of the Alpha 1 Sound Processor.

The Otomag Softband is an elastic Softband similar to a sweat band used in sports. The Alpha 1 (S) Sound Processor magnetically adheres to the Softband via a magnetic pad sewn into the band. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by an audiologist.

- To use the Otomag Softband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Softband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Softband around the patient's head, quite loosely at first by slipping the end of the band through the slot next to the magnetic pad and attaching the mating Velcro ® loops and hooks to each other.
- Place the magnetic pad against the mastoid or other boney location.
- Tighten the Softband by adjusting the Velcro® strap until it is close-fitting enough to ensure effective sound transmission, but not tight enough to cause discomfort. The Softband is too loose if it slips off of the head, can be rotated easily around the head or no sound transmission can be heard. The Softband is too tight if the patient complains of pain or discomfort while wearing the Softband. Make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

	Warning ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

The Otomag Headband is a springy Headband, similar to that used for earphone devices. It comes in one size and is not adjustable. The Alpha 1 (S) Sounds Processor magnetically adheres to the Headband via a magnetic pad fitted to the Headband. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by the audiologist.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- To use the Otomag Headband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Headband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Headband on the patient's head and place the magnetic pad against the mastoid or other boney location.

The choice of a Headband or Softband is a matter of patient preference.

Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

	Warning ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Immediately seal the autoclave pouch.
- Drying of the device is not required.

	Caution ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be sterilized a single time by prevacuum or gravity steam sterilization (autoclaving). The following sterilization parameters have been validated for sterilization of the implant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Limitations on Reprocessing: Single Sterilization Only

Presterilization Decontamination / Cleaning / Disinfection: None Required

Cycle Type: Prevacuum or Gravity

Sterilization Time: 15 minutes minimum

Sterilization Cycle Temperature: 132 degrees C / 270 degrees F

Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)

Storage in Sterile State: Not Allowed – Sterilization immediately pre-implant only

Pre-Surgical Training Requirements

Before attempting to implant the Otomag Implant, surgeons are required to complete training provided by Sophono, Inc. During the training they will receive guidance regarding the procedure, a thorough understanding of the device and surgical procedure and other important information. Contact Sophono Customer Services at the contact number listed in Section 6 of this manual to arrange training.

Surgical Risks

The implantation of the Otomag Implant requires a surgical procedure involving the removal of tissue and bone. As with any surgical procedure involving a general anesthetic, certain risks exist. Those risks include the risk of infection from poor hygiene or non-sterile technique, irritation of tissues during the implantation procedure, unintended cuts and abrasions, and irritation of tissues due to unintended exposure to implant materials. The implant is made of materials considered to be hypo-allergenic but in the case of unintended damage to the device, a patient could come in contact with substances that could generate an adverse reaction.

Surgical Implantation Steps

Step 1 - Making The Incision

The proper position for the implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant will be placed. The incision must be large enough to allow placement of the implant. See Figure 1.

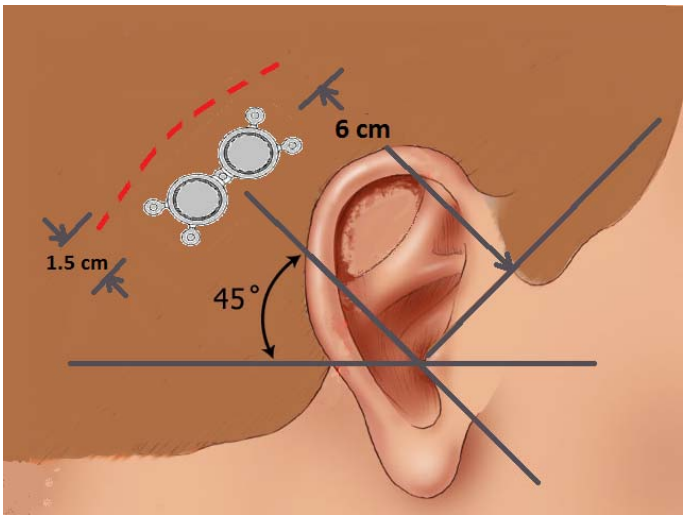

Figure 1 : Incision Location

Step 2 - Create a bone bed (optional)

The implant is approximately 2.6 mm thick and optimal tissue thickness over the implant is 4mm to 5 mm. Bone beds are recommended for the implant if the tissue thickness over the implant is less than 3 mm.

To create a bone bed, mark the position of the implant magnets on the bone and drill the bone bed to a depth of approximately 3 mm. The implant magnets have a diameter of 10 mm.

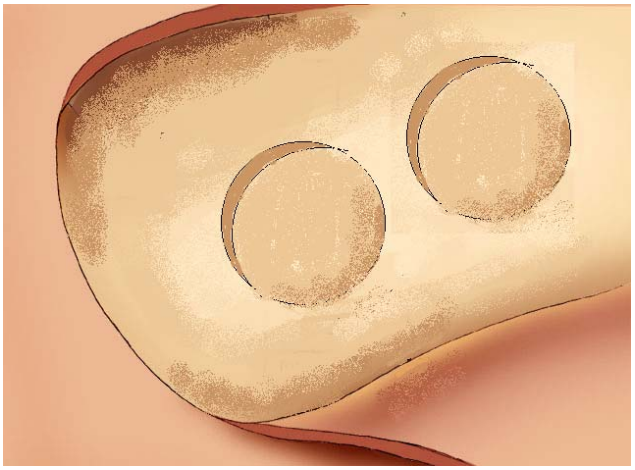

Figure 2: Bone Beds

Step 3 - Implant Placement

Place the implant with the magnets in the bone beds (if created) or with the magnets face up such that the bracket legs are flush to the skull. Place one screw in each of the bracket holes to securely attach the implant to the skull.

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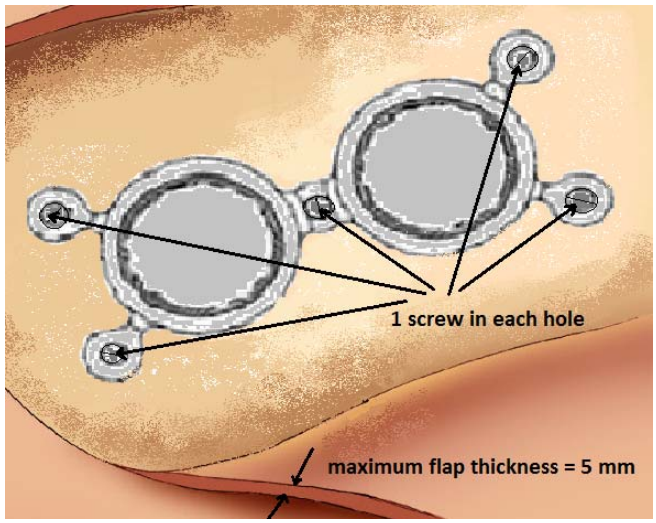

Figure 3: Implant Installation Diagram

Step 4 - Tissue Thinning and Closing the Incision

If the tissue flap is thicker than 6 mm, thin down a 10 mm wide strip of tissue to 5 mm directly over the implant magnets. Suture the incision closed.

Implant Surgical Removal Steps

Step 1 - Making The Incision

The implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant has been placed. The incision must be large enough to allow removal of the implant. See Figure 1 above.

Step 2 - Implant Removal

Remove each of the 5 screws holding the magnetic implant in place. It may be necessary to excise bone or tissue growth occurring over the face of the implant. Once the screws are removed the implant can be lifted carefully from the bone or bone beds. Suture incision closed.

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Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system. The Alpha 1 (M) configuration is supplied with three strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid. Choose a magnetic spacer to achieve appropriate sound transmission without being uncomfortable to the patient. The spacers are labeled XX, YY, ZZ to indicate increasing magnetic strength. The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable of if numbness occurs.

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4 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a biocompatible titanium case. Only the titanium case of the implant is in contact with patient tissue.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid: Fotoplast Lacquer 3 (light-curing one-component lacquer)

NO components or packaging for the Otomag Osseointegrated Bone Conduction Hearing System contain latex.

Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction sound processor
- Fully programmable digital hearing system
- programs (programmable by audiologist)
- 4 channels

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- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery

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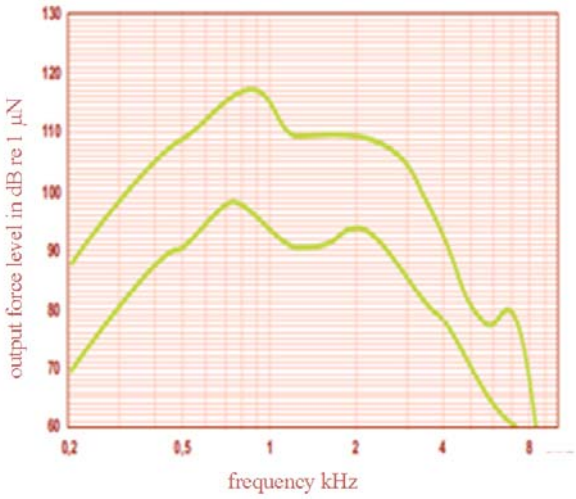
Alpha 1 Sound Processor Performance Data

(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 µN
- Peak Output at 90 dB SPL: 115 dB re 1 µN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 Storage and Handling

Storage

⚠	**Caution** ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -20 C (-4 F) or above +50 C (122 F) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Handling

⚠	**Caution** ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 Professional Support

For more information or to report concerns, contact:

Sophono, Inc.

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Printed in U.S.A.

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Patient User Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Patient User Manual

Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 About this Manual

This Patient Manual provides a description of the Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. Please read this manual thoroughly before using the system.

This Patient Instruction Manual included with each Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing System should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

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2 Introduction

Dear Customer:

Congratulations on the purchase of your new Otomag Bone Conduction Hearing System!

The Otomag Bone Conduction Hearing System includes a family of Sound Processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag Bone Conduction Hearing System is supplied in either of two configurations. The first configuration is the Alpha 1 (S), in which the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), in which the Otomag Sound Processor is attached magnetically to an osseointegrated Magnetic Implant placed behind the patient's ear. The Headband, Softband, or Magnetic Implant holds the Sound Processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for patients with conductive hearing loss, patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and patients who suffer from single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software package allow for programming the Otomag System for individual patient hearing loss.

This Patient Manual will help you quickly gain confidence with your new Otomag Bone Conduction Hearing System. If you have further questions please consult your hearing healthcare provider.

General Information

A hearing device will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of a hearing device does not permit a user to attain full benefit. The use of a hearing device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading.

	Note ▪ **NO** components or packaging of the Otomag Bone Conduction Hearing System contain **latex**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warnings and Cautions Overview

The following section contains a description of all patient related Warnings and Cautions associated with the Otomag Bone Conduction Hearing System. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to patient instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warning	▪ Thoroughly read Patient Manual before using the Otomag Bone Conduction Hearing System. ▪ Rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in personal injury and damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not obtain an Magnetic Resonance Imaging (MRI) procedure while wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire. ▪ Do not attempt to recharge batteries.
Caution	▪ Read this Patient User Manual and keep it available so you can refer to it when needed. ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4 °F (-20 °C) or above 122 °F (+50 °C) at any time. ▪ To avoid damage to the device, do not store the Otomag System near magnets or magnetic devices. ▪ Remove the Sound Processor, Headband and Softband before x-rays of the head and neck

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Caution	▪ Remove the Sound Processor, Headband, and Softband during radiation therapy ▪ Portable and mobile RF (radio frequency) communications equipment can affect the performance of the Sound Processor. ▪ Interference may occur in the area of equipment which is labeled with the following symbol: ▪ Dispose of batteries and electronic items in accordance with your local regulations. ▪ When navigating through security in airports remove the Sound Processor, Headband and Softband and have them screened through the x-ray screening process. The Sound Processor, Headband and Softband contain metal that may activate the airport security metal detectors. ▪ Do not use the Alpha 1 Sound Processor, Headband or Softband while participating in contact sports. Hard physical contact with the device or a blow to the head in the area of the Alpha 1 Sound Processor, Headband or Softband may result in damage to the device or device failure. ▪ Clean the Alpha 1 Processor, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case. ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device. ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor. ▪ Do not expose the Sound Processor to strong sunlight. ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3 Operating Instructions

Insertion of the battery

Size 675 batteries are required for your Alpha I Sound Processor.

See Figure 1 for details. Open the battery compartment (1) with a fingernail and insert the battery (2) so that the plus (+) sign on the battery and the plus (+) sign on the battery compartment are on the same side. Close the battery compartment with a finger. The Sound Processor is now switched on.

⚠	**Caution** ▪ Dispose of batteries and electronic items in accordance with your local regulations.

Switch off your Sound Processor whenever you're not using it by pivoting the battery compartment fully out. This will help preserve battery life. The Alpha 1 has a low battery indicator that generates a tone when it is time to replace the battery. Your hearing healthcare provider can adjust the volume and tone of the low battery indicator for you.

Figure 1. Alpha I Sound Processor

⚠	**Warning** ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals ▪ Do not attempt to recharge batteries. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire

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Start-up and Operation

Switch on the Alpha 1 Sound Processor by pivoting the battery compartment fully in.

Positioning the Sound Processor

Alpha 1 (S)

To place the Alpha 1 (S) Sound Processor, simply guide it into the vicinity of the magnetic pad in the Softband or Headband. The magnetic forces will bring it to its correct position. See Figure 2.

Figure 2. Positioning the Alpha I (S) Sound Processor on the Softband

⚠	**Warning** ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 3.

Figure 3. Positioning the Alpha I (M) Sound Processor on the osseointegrated Magnetic Implant

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⚠	**Caution** ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient.

Volume Control

The volume can be adjusted with the small wheel that is situated on the outside of the Alpha 1 Sound Processor. Using the tip of the index finger, apply slight pressure on the rotary button and simultaneously turn forward to increase volume. Turn the rotary button in the opposite direction to reduce volume.

You can switch off the Sound Processor by opening the battery access door. As soon as you take off the device, switch it off. See Figure 4 for details.

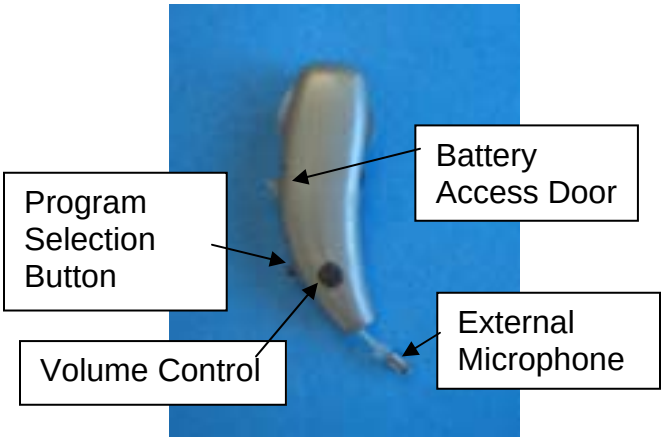


Figure 4. Alpha I Sound Processor

Program Selection Button

The Alpha 1 Sound Processors offer four program settings for different hearing situations. By pressing the small button on the Sound Processor, the programs can be activated. For each activated program you will hear a corresponding signal tone for recognition.

- Program 1: Instrument beeps once
- Program 2: Instrument beeps twice
- Program 3: Instrument beeps three times
- Program 4: Instrument beeps four times

Your hearing healthcare provider will inform you when each of the programs should be used

Removing the Sound Processor

To remove the Alpha 1 Sound Processor, pull **ONLY** on the steel disk. See Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

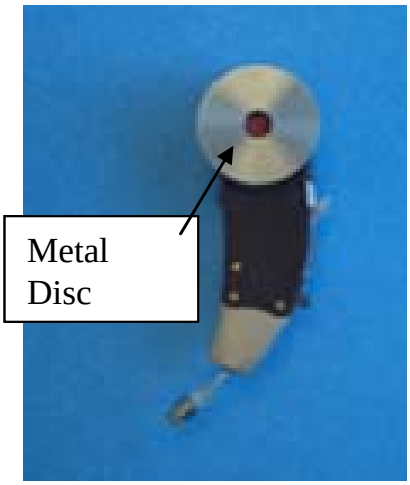


Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

	Note ▪ If you remove the Sound Processor without switching it off, it generates a vibrating tone which leads to high battery consumption. Therefore, always properly switch off the Sound Processor when you are not wearing it.

	Caution ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device.

If Your Sound Processor Does Not Function

Check the following if the Sound Processor is not functioning properly:

- The device is properly switched on and the battery compartment is fully closed
- The battery is not dead
- The battery surface is clean.

If the device still is not functioning properly, see your hearing healthcare provider.

4 Product Maintenance

Cleaning and Care

Sound Processor

- Have your Sound Processor checked at regular intervals as specified by your hearing professional.
- To clean your Sound Processor, wipe it with a soft cloth or a Clorox® type disinfecting wipe
- The battery compartment may be cleaned by wiping it out with a DRY cotton swab or a cotton swab that has been moistened by a Clorox® type disinfecting wipe.

	Note ▪ Remove the Sound Processor, Softband, and Headband during the application of hairspray or styling gels. If hairspray or gel comes in contact with the Sound Processor it may become sticky and difficult to clean

- If the Sound Processor becomes soaked with water:
  - Immediately open the battery door and remove the battery
  - Put the Sound Processor in a container with drying capsules such as Dri-aid kit or similar overnight. Drying kits are available from most hearing care professionals.

	Caution ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case

- The Sound Processor is provided in a plastic case which may be used to store the processor. This case may be cleaned with a Clorox® type disinfecting wipe. Make sure the case is completely dry before storing the Sound Processor in it.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

⚠	**Caution** ▪ The Sound Processor is designed to operate within the temperature ranges of 41°F (+5°C) to 104°F (+40°C). The processor should not be subject to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor ▪ Do not expose the Sound Processor to strong sunlight ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case

Softband and Headband

- The Headband can be cleaned with a Clorox® type disinfecting wipe.
- The Softband may be submerged and hand washed with a mild clothes washing detergent (with or without a small amount of color safe bleach) and air dried or may be cleaned with a Clorox® type disinfecting wipe.

Magnetic Spacer

- The Magnetic Spacer can be cleaned with a Clorox® type disinfecting wipe.

⚠	**Caution** ▪ Clean the Alpha 1 Processor, Magnetic Spacer, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Damage and Replacement

The expected live span for the Sound Processor, Magnetic Spacer, Softband, and Headband is approximately 4 years depending on use, wear, and tear. The Sound Processor will need to be repaired or replaced when it no longer produces adequate vibrations or the sounds become highly distorted. The Softband should be replaced when it becomes damaged or the elastic begins to be stretched out and it can no longer be tightened adequately for sound transmission. The Headband should be replaced when it becomes damaged or no longer has enough spring force to press the magnetic pad against the head for adequate sound transmission. Replacement Headbands and Softbands may be purchased through your hearing healthcare provider from Sophono, Inc.

5 Accessories

If your Alpha 1 Sound Processor has a jack for an FM boot, you may plug the boot of a Phonak MLxi FM receiver into the bottom of the Sound Processor.

If you are concerned about the Alpha 1 Sound Processor falling off your head, a clip and tether are available so that the Sound Processor can be tethered to a garment you're wearing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a Titanium case.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid: Fotoplast Lacquer 3 (light-curing one-component lacquer)

NO components or packaging for the Otomag Bone Conduction Hearing System contain latex.

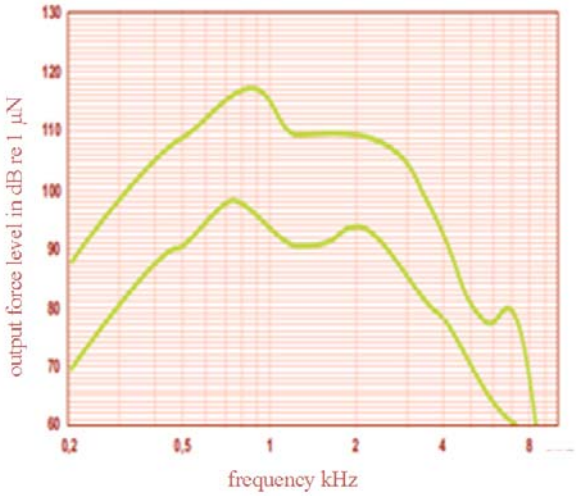
Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction Sound Processor
- Fully programmable digital hearing system
- Programs (programmable by audiologist)
- 4 channels
- 16 frequency bands

- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery)

Alpha 1 Sound Processor Performance Data

(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



Output force level (OFL) at 90 dB SPL – Top Line

Output force level (OFL) at 60 dB SPL – Bottom Line

- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 µN
- Peak Output at 90 dB SPL: 115 dB re 1 µN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

7 Professional Support

For more information or to report concerns contact:

Sophono, Inc.

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Boulder, Colorado 80303
USA
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Manufactured for: Sophono, Inc. 903 Brooklawn Dr., Boulder, Colorado 80303 USA
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Magnetic Implant Package Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sophono

MAGNETIC IMPLANT
REF: 093001

NON STERILE

SN: XXXX-XX
QTY: 1

EFS GmbH & Co. KG
Glasbronnenstr. 6
75449 Wurmberg, Germany
Phone : (+49) 0 2841 8870032
Fax : (+49) 0 2841 8870032

P/N XXXX-XXX

Sophono

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NON STERILE

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Revised Primary Device Labels

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Otomag Alpha 1(S) Bone Conduction Hearing System

Manufacturer:

Otomag GmbH Alte Dorfstrasse 67, 32289 Rödinghausen, Germany. Tel: +49 5746 8504 Fax: +49 5746 8578
Distributed by: Sophono, Inc. 903 Brooklawn Drive, Boulder, CO 80303, USA. Tel: +1 303 564 1663 Fax: +1 720 222 2432

Contents:

1 Alpha 1 (S) Bone Conduction Hearing System
1 Physician Manual
1 Patient Manual

Device Intended for Single Patient Use Only!

PN xxxxxxx SN xxxxxxx LOT xxxxxxx

Made In Germany

Label P/N 3000-03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

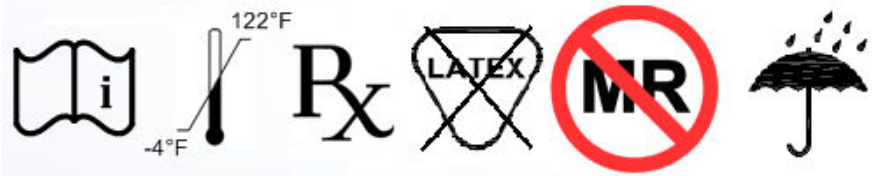
Otomag Osseointegrated Alpha 1(M) Bone Conduction Hearing System

Manufacturer:

Otomag GmbH Alte Dorfstrasse 67, 32289 Rödinghausen, Germany. Tel: +49 5746 8504 Fax: +49 5746 8578
Distributed by: Sophono, Inc. 903 Brooklawn Drive, Boulder, CO 80303, USA. Tel: +1 303 564 1663 Fax: +1 720 222 2432

Contents:

1 **Osseointegrated Alpha 1 (M) Bone Conduction Hearing System**
1 **Magnetic Implant**
4 **Magnetic Spacers (1 Dot to 4 Dot)**
1 **Physician Manual**
1 **Patient Manual**



Device Intended for Single Patient Use Only!

PN XXXXXXX SN XXXXXXX LOT XXXXXXX

Made In Germany

Label P/N 3000-02

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 16: Sterilization and Shelf Life

1. Sterilization

1.1. The Osseointegrated Magnetic Implant is provided clean but not sterile and is intended to be sterilized via gravity or prevacuum steam sterilization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices.

1.2. Attachment 1 to Section 15 – Labeling contains a copy of the revised Physician's Manual which contains details regarding pre-implant sterilization. Refer to pages 11 and 12 of this manual for details.

1.3. Appendix D to the overall submission contains validation protocols and reports for the specified sterilization cycle.

2. Shelf-Life

2.1. Not Applicable. The Osseointegrated Magnetic Implant is not supplied sterile and the materials of the implant case (titanium grades 4 and 5) are not expected to suffer performance degradation over the life of the overall product.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 17: Biocompatibility

1. Introduction

1.1. The only new patient contacting materials present in the Osseointegrated Alpha 1(M) addition to the Otomag Bone Conduction Hearing System are related to the Magnetic Implant and its retention hardware (bone screws).

1.1.1. In accordance with the flowchart shown in Figure 1 below from Attachment C of FDA General Program Memorandum #G95-1 the titanium material used in the implant could follow two available paths through the flow chart. See the highlighted routes through Figure 1.

1.1.1.1. Route 1: The magnetic implant is manufactured by (b)(4) [redacted] (b)(4) [redacted] using the same materials, manufacturing processes, sterilization methods, and body contact types as legally marketed devices both in the US and in Europe. This exact implant is currently being marketed with a CE mark in the EU by Otomag. This path through the flow chart indicates that biocompatibility requirements have been met for the material of the implant case.

1.1.1.2. Route 2: A second available route through the flow chart conservatively assumes that the implant is not exactly the same as a legally marketed device and follows the path that asks if the material “is a polymer” (no), “is the material a metal, metal allow, or ceramic” (yes), “does it contain toxic substances” (no). This path through the flow chart also indicates that biocompatibility requirements have been met for the material of the implant case. The materials specifications for the titanium materials used in the case are contained in Appendix B to the overall submission.

1.1.2. The titanium material used in the magnetic implant is well established as biocompatible and is used in implantable medical devices in similar applications such as cochlear implants and extensively as a material for orthopedic implants.

1.1.3. The bone screws used to anchor the magnetic implant are also titanium. These screws are manufactured by Stryker Leibinger and are a legally marketed device which was cleared under K970912 for use as self threading bone screw.

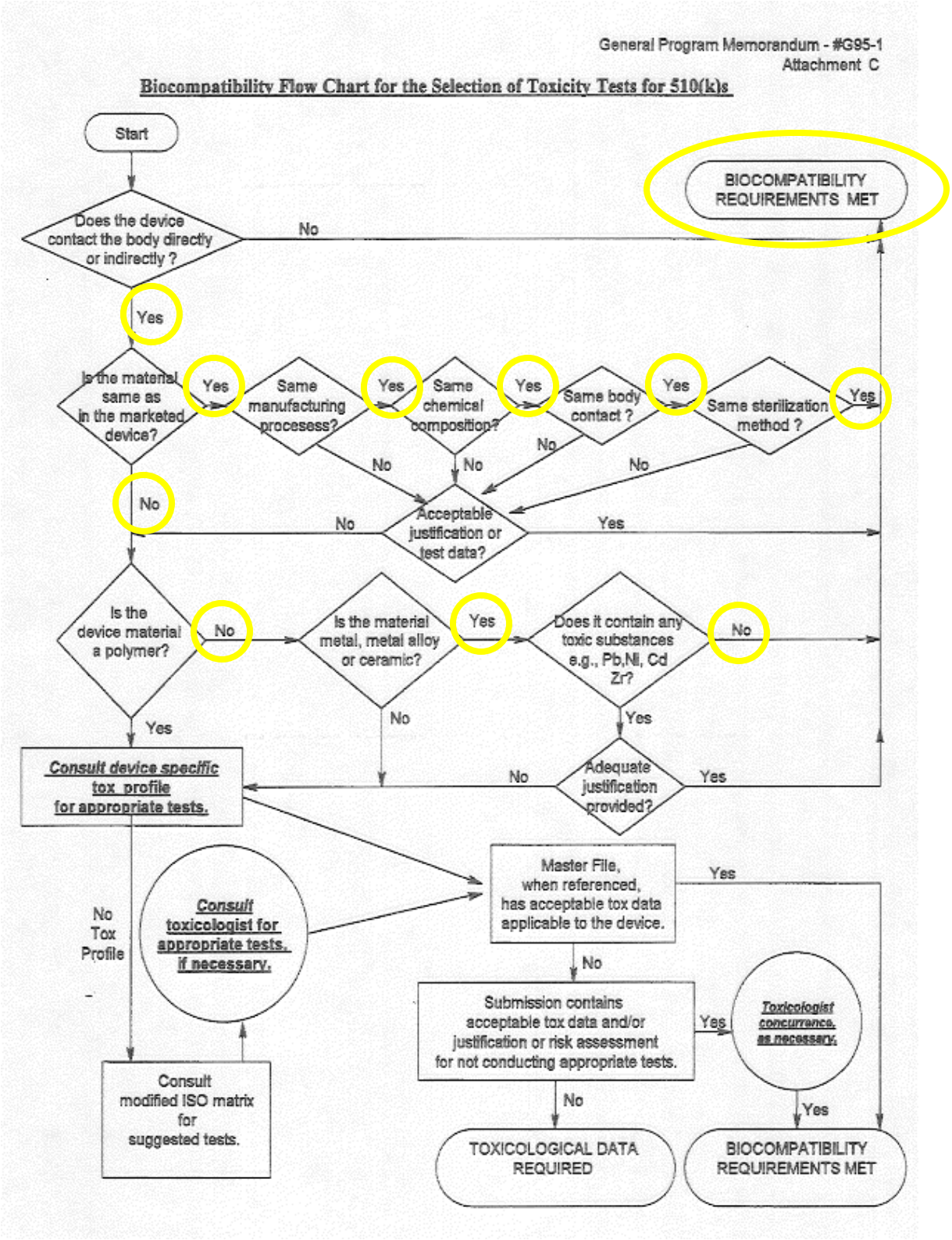


Figure 1: FDA Memorandum #G95-1

Section 18: Software

None of the device changes that are the subject of this 510(k) involved changes to the device software and therefore no additional software testing or software documentation is provided in this submission. All software documents provided in the original 510(k) submission (K100193) continue to be applicable to the modified version of this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 19: Electromagnetic Compatibility and Electrical Safety

The changes made to the Otomag Bone Conduction Hearing System did not involve the electronics or software of the device and therefore there was no need to repeat previously completed EMC and Electrical Safety testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 20: Performance Testing – Bench

1. Introduction

1.1. As a result of the application of risk analysis and the differences identified in the substantial equivalency comparison table, the following verification and validation activities were completed to ensure that the differences between the non-osseointegrated predicate device and the osseointegrated version of the Otomag Bone Conduction Hearing System do not raise new questions of safety and effectiveness.

1.2. Risk Areas identified as a result of risk analysis included:

1.2.1. Material Biocompatibility

1.2.2. Implant Anchoring

1.2.3. Force Application to patient skin / mastoid

1.3. The following section outlines the categories of Verification and Validation testing that were conducted and rationale for those areas where additional testing was unnecessary as a result of the scope of changes.

1.4. Performance Testing:

1.4.1. **Implant Anchoring:** Implant Anchoring using titanium bone screws (Liebinger 4mm facial plating screws) were validated for this use in validation protocol (b)(4) [redacted] to this overall submission.

1.4.2. **Force Application:** Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device. This validation is documented in validation protocol (b)(4) [redacted] to this overall submission.

1.5. Material Biocompatibility:

1.5.1. Refer to Section 17 and Appendix B of the overall submission for information on Biocompatibility.

1.6. Sterilization Validation including Sterile Packaging:

1.6.1. Refer to Section 16 and Appendix D of the overall submission for information on Sterilization Validation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 21: Performance Testing – Animal

Not Applicable: Animal test data is not included as a part of this submission

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 22: Performance Testing – Clinical

Not Applicable: Clinical data is not included as a part of this submission

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Appendix A

ISO 14971:2007: Medical devices – application of risk management to medical devices;

FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices

ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

ISO 14971:2007: Medical devices – application of risk management to medical devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-09-2015

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971 Application of risk management to medical devices - 2007

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-40		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971 Application of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

FDA G95-1 Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Attachment C- Biocompatibility Flow Chart for Selection of Toxicity Tests for 510(k) used to select appropriate testing options

DESCRIPTION

Attachment C is used to determine which testing options/requirements are appropriate

JUSTIFICATION

See above

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-09-2015

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 17665-1 Sterilization of Healthcare Products - Moist Heat - Part 1 ... Development, Validation and Routine Control - 2006

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-261		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
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DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-09-2015

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 17664-1 Sterilization of medical devices: Info. provided by the manuf. for the processing of resterilizable medical devices -'04

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☑
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 17664-1 Sterilization of medical devices: Info. provided by the manuf. for the processing of resterilizable medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

The standard was followed although the device is not intended to be resterilized; it is provided to the end user non-sterile.

DESCRIPTION

Instructions and parameters are provided for proper moist heat sterilization of the device prior to use.

JUSTIFICATION

Information is appropriate for sterilization of the device prior to use.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223 Medical Devices: Symbols to be used with medical device labels, labelling and information to be supplied - 2007

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 5-31		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☑
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
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Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 15223 Medical Devices: Symbols to be used with medical device labels, labelling and information to be supplied

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Appendix B

Magnetic Implant Specification

Material (b)(4) [redacted]

Material [redacted]

Fotoplast Biocompatibility Information

Translation Certificate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Implant Specification

(b)(4) Implant Specification

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Appendix C

(b)(4) - Otomag Magnetic Implant Static Force Verification / Validation Protocol

(b)(4) - Otomag Magnetic Implant Screw Retention Force Validation Protocol

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Verification and Validation Protocol

(b)(4) Verification and Validation Protocol

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Appendix D

(b) (4)

[redacted]

Amended Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Verification and Validation Protocol

(b)(4) Verification and Validation Protocol

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(b)(4) Verification and Validation Protocol

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Otomag Bone Conduction Hearing System 510(k)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix A – Standards Data Reports - FDA Form 3654

Appendix B – Biocompatibility

Appendix C – Bench Performance Testing

Appendix D – Sterilization Validation

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Section 01: Medical Device User Fee Cover Sheet (Form 3601)

See attached Form 3601

770

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
SOPHONO INC 903 Brooklawn Boulder Co 80303 US	Jim Kasic 2.1 E-MAIL ADDRESS jkasic@comcast.net 2.2 TELEPHONE NUMBER (include Area code) 303-5641663
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8585	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD106241

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted]

09-Jul-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Section 02: CDRH Premarket Review Submission Cover Sheet (Form 3514)

See attached Form 3514

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
8/03/2010	MD6050411-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Sophono, Inc.	Establishment Registration Number *(if known)*		
Division Name *(if applicable)*	Phone Number *(including area code)*: 303-546-1663		
Street Address: 903 Brooklawn Drive	FAX Number *(including area code)*: 720-222-2432		
City: Boulder	State / Province: Colorado	ZIP/Postal Code: 80303	Country: USA
Contact Name: James F Kasic II			
Contact Title: President and CEO	Contact E-mail Address: jkasic@comcast.net		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

(b) (4)

[redacted]

PSC Graphics (301) 443-1090 EF

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:

Traditional 510(k) submission for modification to an existing cleared device. The proposed modification does not affect the intended use of the device or alter the fundamental scientific technology of the device. Minor wording changes to indications for use statement are being requested.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LXB	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K100193	1	Otomag Bone Conduction Hearing System	1	Sophono, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Bone Conduction Hearing Aid

	Trade or Proprietary or Model Name for This Device		Model Number
1	Otomag Bone Conduction Hearing System	1	Alpha 1(S) and Alpha 1(M)
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K100193	2	3	4	5	6
7	8	9	10	11	12

Data included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LXB	21 CFR 874.3300	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Ear Nose & Throat

Indications *(from labeling)*

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b) (4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	14971	ISO	Medical Devices: Application of risk management to medical devices	Second Edition	03/01/2007
2	#G95-1	FDA	Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	N/A	05/01/1995
3	17665-1	ISO	Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices	First Edition	08/15/2006
4	17664-1	ISO	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	First Edition	03/01/2004
5	15223-1	ISO	Medical Devices: Symbols to be used with medical device labels, labelling and information to be supplied	First Edition	04/15/2007
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Section 03: Requirements of ClinicalTrials.gov (Form 3674)

See attached Form 3674

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Sophono Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

3. ADDRESS *(Number, Street, State, and ZIP Code)*
903 Brooklawn Drive
Boulder, CO 80303

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 303-546-1663
(Fax) 720-222-2432

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Proprietary Name: Otomag Bone Conduction Hearing System

Classification Name: Bone Conduction Hearing Aid; 21 CFR 874.3300

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
K100193

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Jim Kasic
(Title) CEO

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
903 Brooklawn Drive
Boulder, CO 80303

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 303-546-1663
(Fax) 720-222-2432

15. DATE OF CERTIFICATION

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14.** - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Form FDA 3674 (11/08) (BACK)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

K102199

Sophono

FDA CDRH DMC

510(k) Cover Letter

AUG 04 2010

Received

Date of Submission: August 3, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Submission for Changes to Otomag Bone Conduction Hearing System

Dear Madam/Sir:

Sophono Inc. hereby submits this Traditional 510(k) for modifications made to a previously cleared device. The modification described adds a new configuration into the Otomag Bone Conduction Hearing System family. The new configuration (Alpha 1(M)) uses an implantable magnet as a fixation system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193 – Otomag Bone Conduction Hearing System – May 18, 2010.

The addition of the Alpha 1(M) configuration of the product requires no change in intended use of the device, but does require minor wording changes to the Indications for Use statement. In addition, this new configuration introduces new design specifications and new materials to the product as well as revisions to product labeling. Modifications do not affect the fundamental scientific technology of the device.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Confidentiality:

Please be aware that Sophono Inc. considers our intent to market the Otomag Bone Conduction Hearing System, and the information provided in support of this premarket notification, to be confidential commercial information and afforded such protection under 21 CFR 807.95.

Material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and, therefore, non-discloseable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

Electronic Copy:

Please be aware that this submission contains one (1) paper copy with signatures and (1) electronic copy that is an exact duplicate of the paper copy created in accordance with instructions on FDA's website. The electronic copy has been placed along with a second paper copy of the cover letter in the binder being submitted to FDA.

If any additional information is required, or the Agency has questions regarding the contents of the submission, please contact our submission correspondent, Clay Anselmo. His contact information is included below. We are looking forward to working with the agency and will promptly respond to any requests or questions you may have.

Sincerely,

James F Kasic II
President and CEO
Sophono, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Submitter/Manufacturer Name and Street Address:	Sophono, Inc. 903 Brooklawn Drive Boulder, CO 80303 Ph: 303-546-1663 Fax: 720-222-2432 jkasic@comcast.net
Official Submission Contact:	(b) (4) [redacted]
Establishment Registration Number:	Not Yet Assigned
Type of Submission:	Traditional 510(k)
Trade Name:	Otomag Bone Conduction Hearing System
Common Name:	Bone Conduction Hearing Aid
Classification Name:	874.3300 – Hearing Aid
Classification:	Class II
Device Classification Panel:	Ear, Nose and Throat
Device Product Code:	LXB
Basis for Submission:	Device Changes: Indications Statement, Technical Specification Changes, Material Changes, Labeling Changes
Identification of the legally marketed devices (predicate):	Prior version of Otomag Bone Conduction Hearing System cleared in K100193.
Compliance with special controls, mandatory performance standards or radiation device standards:	• Not Applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cited Voluntary Standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic?		√
Is the device provided sterile?		√
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?	√	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 05:

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet	✓		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet	✓		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D	✓		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E	✓		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G	✓		
Class III Summary and Certification	Class III Summary and Certification Form			✓
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators Financial Disclosure by Clinical Investigators	✓		
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations FDA Standards program Declaration of conformity Required Elements for Declaration of Conformity to Recognized Standard	✓		
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Title	Related Information	Present	Inadequate	N/A
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)	✓		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H	✓		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	✓		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993,	✓		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	✓		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; EMC - Requirements and Tests (Second Edition, 2001)	✓		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			✓
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators			✓
FORM FDA 3654 *Standards Data Report for 510(k)s -*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**	✓		
Kit Certification	Device Advice			✓

Last Updated: 9/3/08 – Brandi Stuart

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 06: Indications for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number: _____

Device Name: Otomag Bone Conduction Hearing System

Indications for Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 07: 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary: Otomag Bone Conduction Hearing System

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

Submitter: Sophono, Inc.

Establishment Registration Number: Not Yet Assigned

Contact Information:

Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
Ph: 303-546-1663
Fax: 720-222-2432
Contact: Jim Kasic
Email: jkasic@comcast.net

Date Prepared: July 27, 2010

Name of Device: Otomag Bone Conduction Hearing System

Common Name: Bone Conduction Hearing System

Classification Name: Hearing Aid

Device Classification:

- Classification: II
- Classification Panel: Ear, Nose and Throat
- Regulation Number: 874.3300
- Product Code: LXB

Predicate Device:

Otomag Bone Conduction Hearing System, Unmodified Version – K100193

Device Description:

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Osseointegrated Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an osseointegrated implanted magnet assembly. This configuration of the system is based on osseointegration of the implant through which living tissue integrates with the titanium implant causing the implant to be integrated into the bone. The magnetic field holds the sound processor

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agains the head and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Technological Characteristics:

The technological characteristics of the Osseointegrated version of the Otomag Bone Conduction Hearing System are equivalent to those of the predicate device (non-Osseointegrated version). Items that are identical between the Osseointegrated version and the predicate are:

- Overall Device Performance
- Fundamental Technology (bone conduction)
- Software

Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Through non-clinical performance testing and evaluation, the identified technological differences do not raise new questions of safety and effectiveness.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;

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- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Performance Standards:

The design of the Otomag Bone Conduction Hearing System conforms to the following voluntary standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Non-Clinical Performance Testing:

The Otomag Bone Conduction Hearing System has been subjected to extensive safety, performance testing, and verification / validation. Testing of the Otomag Bone Conduction Hearing System included various device performance tests and software validation tests designed to ensure that the device meet all of its functional specifications and is fit for its intended use. Tests have also been performed to ensure the device complies with industry and safety standards. The testing information presented in this submission demonstrates the device's performance is substantially equivalent to the predicate device.

Conclusion:

Based on the non-clinical performance testing, the Osseointegrated version of the Otomag Bone Conduction Hearing System is as safe and effective and considered to be substantially equivalent to the previously 510(k) cleared non-Osseointegrated version of the device (K100193).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 08: Declarations of Conformity and Summary Reports

1. Conformity with Standards

1.1. The Otomag Bone Conduction Hearing System and its development process conforms with all applicable requirements of the following National and International Standards.

1.1.1. ISO 14971:2007: Medical devices – application of risk management to medical devices;

1.1.2. FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

1.1.3. ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices

1.1.4. ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

1.1.5. ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

1.2. FDA Form #3654 has been completed for each of the standards referenced above. These forms are included in Appendix A to the overall submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 09: Truthful and Accuracy Statement

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President and CEO of Sophono Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

James Kasic II
President and CEO

7/26/2010
Date

*Premarket Notification [510(k)] Number _____

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10: Class III Summary and Certification

The Otomag Bone Conduction Hearing System is a Class II device. This section is not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 11: Financial Certification or Disclosure Statement

No information from clinical studies is submitted in this application. Therefore no financial certification or disclosure statement is required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 12: Executive Summary

1. INTRODUCTION

1.1. The following section contains the Executive Summary for the Otomag Bone Conduction Hearing System, including the Osseointegrated Alpha 1(M) version. This 510(k) is being submitted to add the Osseointegrated Alpha 1 (M) configuration to the existing product family.

2. DEVICE DESCRIPTION

2.1. The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Osseointegrated Alpha 1 (M).

2.1.1. In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

2.1.2. In the Otomag Osseointegrated Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted Osseointegrated magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. The pressure applied by the magnetic attraction between the implant and the sound processor is equivalent to that in the Alpha 1 (S) configuration.

2.2. The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

3. INDICATIONS FOR USE

3.1. The Indications for Use for the Osseointegrated device are identical to the predicate cleared in K100193.

3.2. The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

3.2.1. Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

3.2.2. Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.2.3. Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

4. CONTRAINDICATIONS

4.1. Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

4.1.1. A hearing loss of sudden onset;

4.1.2. A rapidly progressing hearing loss;

4.1.3. Pain in either ear;

4.1.4. Tinnitus of sudden recent onset, or unilateral tinnitus;

4.1.5. Unilateral or markedly asymmetrical hearing loss of unknown origin;

4.1.6. Vertigo (e.g. dizziness)

5. SUBSTANTIAL EQUIVALENCE

5.1. The changes to the device that are the subject of this 510(k) relate to the addition of another device configuration to the product family. The additional configuration, called Osseointegrated Alpha 1(M) includes a Magnetic Implant that is placed in bone beds behind and above the patient's ear to provide for attachment of the sound processor without the use of the headband or softband. This change impacts detailed engineering specifications, labeling and patient contact materials, but does not alter the overall performance of the device. Due to the specificity of the Indications for Use statement for the prior version of the device, minor wording changes are also required.

5.2. The following table summarizes and compares data on the Otomag Bone Conduction Hearing System cleared in K100193 (predicate device) to the Osseointegrated Alpha 1 (M) device that is the subject of this 510(k) submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Osseointegrated Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	Identical
Class	Class II	Class II	Identical
Product Code	LXB	LXB	Identical
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Osseointegrated Bone Conduction Hearing System	Comparison
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical
Power Supply	Zinc-air battery	Zinc-air battery	Identical
Sound Processing	Digital	Digital	Identical
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical
Frequency Processing Range	125 – 8kHz	125 – 8kHz	Identical
Max Gain (60dB SPL)	38 dB	38 dB	Identical
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	29 dB	Identical
Material of sound processor coupling	Stainless Steel Disc	Stainless Steel Disc	Identical
Accessories/Options	Direct audio input via FM jack	Direct audio input via FM jack	Identical
Patient Contact Materials for Biocompatibility Purposes	Fotoplast-Lac	Fotoplast-Lac Titanium Grades 4 and 5 (Magnetic Implant)	See discussion below
Sterilization	No sterile components	Steam sterilization of surgical implant	See discussion below
Manufacturer	Otomag GmBH	Otomag GmBH	Identical
Peak Output at 90 dB SPL	115 dB	115 dB	Identical

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Osseointegrated Bone Conduction Hearing System	Comparison
Frequency range per ANSI S3.22-2009	280-5000 Hz	280-5000 Hz	Identical
Total harmonic distortion per ANSI S3.22-2009	<3%	<3%	Identical
Equivalent input noise:	17 dB SPL	17 dB SPL	Identical
Battery current drain	0.95 mA	0.95 mA	Identical
Processor:	16 Band, 4 Channel WDRC	16 Band, 4 Channel WDRC	Identical
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical
Compression Attack Time (minimum)	0.25 ms	0.25 ms	Identical
Compression Release Time (maximum)	8192 ms	8192 ms	Identical
Patient Volume Control Wheel	38 dB range	38 dB range	Identical
Power Supply	1.3 V, #675 Zinc Air Battery	1.3 V, #675 Zinc Air Battery	Identical
Force Application Methods	Headband or Softband	Headband or Softband (Alpha 1(S) Version) Osseointegrated Magnetic Implant (Alpha 1(M) Version)	Substantially Equivalent – See discussion below

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6. DISCUSSION OF DIFFERENCES

6.1. The differences in specifications identified in the comparison table above between the predicate Otomag Bone Conduction Hearing device and the Otomag Osseointegrated device as reflected in the above SE table are the following. A detailed discussion of each device change is contained in Section 13 – Device Description / Description of Changes.

6.1.1. Indications for Use:

6.1.1.1. The changes in the Indications For Use statement simply add the additional Osseointegrated Magnetic Implant version of the product to the overall statement including an age limitation for use of the Osseointegrated Magnetic Implant configuration (Osseointegrated Alpha 1(M)) to patients 5 years of age or older. These changes do not impart a new intended use for the product and do not raise new questions of safety and effectiveness.

6.1.2. Patient Contact Materials:

6.1.2.1. The Magnetic Implant (includes attachment screws) constitute new patient contacting materials. The implant is made of Titanium Grades 4 and 5. This material is a biocompatible metal alloy not containing toxic substances. The addition of new patient contact materials that are biocompatible does not raise new questions of safety and effectiveness.

6.1.3. Sterilization:

6.1.3.1. The Magnetic Implant is provided clean but not sterile and intended to be sterilized via gravity or prevacuum steam sterlization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The addition of an appropriately specified and validated sterilization cycle does not raise new questions of safety and effectiveness.

6.1.4. Force Application Method:

6.1.4.1. The new Osseointegrated Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 4 different strength magnetic spacers provided with the product. Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device.

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6.1.4.2. The approach of using a magnetic implant to attach the sound processor has been previously employed by another family of bone conduction hearing devices. The Xomed Audiant Bone Conductor cleared in K855059 and K861971 employs this same technology for the attachment of the sound processor.

7. APPLICATION OF DESIGN CONTROLS

7.1. In accordance with 21 CFR 820.30 all the changes described in this submission were subject to the Design Control Program and Associated Procedures of both Sophono and Otomag. The major elements of the Design Control System applied to these changes included:

7.1.1. Design and Development Planning
7.1.2. Development of Design Outputs
7.1.3. Risk Analysis / Risk Management
7.1.4. Verification and Validation
7.1.5. Design Review
7.1.6. Design Transfer

8. SUMMARY OF PERFORMANCE TESTING

8.1. As a result of the application of risk analysis and the differences identified in the substantial equivalency comparison table, the following verification and validation activities were completed to ensure that the differences between the non-osseointegrated predicate device and the Osseointegrated version of the Otomag Bone Conduction Hearing System do not raise new questions of safety and effectiveness.

8.2. Risk Areas identified as a result of risk analysis included:

8.2.1. Material Biocompatibility
8.2.2. Implant Anchoring
8.2.3. Force Application to patient skin / mastoid
8.2.4. Sealing of Magnetic Implant

8.3. The following section outlines the categories of Verification and Validation testing that were conducted and rationale for those areas where additional testing was unnecessary as a result of the scope of changes.

8.4. **Performance Testing:**

8.4.1. **Implant Anchoring:** Implant Anchoring using titanium bone screws (Liebinger 4mm facial plating screws) were validated for this use in validation protocol (b)(4) contained in Appendix C to this overall submission.

8.4.2. **Force Application:** Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device. This validation is documented in validation protocol (b)(4) contained in Appendix C to this overall submission.

8.4.3. **Sealing of Magnetic Implant:** The two halves of the titanium casing are welded together, cleaned and 100% leak tested. Each of these processes has been appropriately validated by the manufacturer (Eberle, EFS GmBH).

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8.4.4. **Sound Processor:** The sound processor itself was not modified and therefore additional performance testing of this part of the device was not necessary

8.4.5. **Vibration Transmission:** The method, mechanics, and materials used to transmit vibration from the sound processor to the patient are unchanged in the Osseointegrated Alpha 1(M) configuration. The metal disc and magnetic spacers used in the Osseointegrated Alpha 1(M) configuration are identical in material and vibration application method to the Fotoplast encased magnets used in Alpha 1(S) configuration of the device (headband and softband versions). As a result, no additional performance testing related to these characteristics was required for the Osseointegrated Alpha 1(M) configuration.

8.5. **Sterilization Validation including Sterile Packaging:**

8.5.1. The sterilization process specified in the Physician's Manual was validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The validation was performed by Nelson Laboratories and the protocol and final report documenting this validation is contained in Appendix D to this overall submission. In addition, the Physician's Manual contains the information required by ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

8.6. **Biocompatibility Testing:**

8.6.1. In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible.

8.7. **Software:**

8.7.1. No changes were made to either the embedded software in the sound processor or the fitting software associated with the device; therefore no software testing is associated with this modification to the device.

8.8. **Electrical Safety Testing:**

8.8.1. The changes made to the modified version of the device have no effect/impact on electrical safety, and therefore no additional electrical safety testing was required.

8.9. **EMC Testing:**

8.9.1. The changes made to the modified version of the device have no effect/impact on EMC performance, and therefore no additional EMC testing was required.

8.10. **Animal / Clinical Testing**

8.10.1. Animal and Clinical studies were not deemed necessary to validate the changes in the Osseointegrated Alpha 1(M) version of the device.

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9. CONCLUSION

9.1. The results of analyses, evaluation, and testing of the Otomag Bone Conduction Hearing System demonstrate that the Osseointegrated device is substantially equivalent to the prior cleared version of the device both in Intended Use and technological characteristics. The changes to the device do not raise new questions of safety and effectiveness and have been appropriately validated through the application of Otomag's and Sophono's design control programs.

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Section 13: Device Description / Description of Changes

1. General Introduction

1.1. The following section contains both a detailed description of the device in its various configurations as well as a detailed description of the planned changes to the device which are the subject of this 510(k).

1.1.1. The changes described in section 9 below introduce a new configuration into the Otomag Bone Conduction Hearing System family. The new osseointegrated configuration (Alpha 1(M)) uses an implantable magnet encased in titanium as a retention system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193.

1.1.2. The addition of the Alpha 1(M) configuration of the product requires no change in intended use of the device, but does require minor wording changes to the Indications for Use statement. In addition, this new configuration introduces new material, performance and design specifications to the product as well as revisions to product labeling. No changes to software or to the sound processor are being made as a part of introducing this additional configuration.

1.2. The content of the Device Description sections below (sections 2-8) are intended to fulfill the device description requirements from 21 CFR 807.87. Section 9 is intended to describe in detail each planned device change.

2. Device Introduction

2.1. The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and the osseointegrated Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

2.1.1. In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

2.1.2. In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. Vibration is not primarily transmitted through the magnetic implant.

2.2. The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

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3. Indications For Use:

3.1. The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

3.1.1. Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

3.1.2. Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

3.1.3. Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

4. Classifying Regulation and Product Code

4.1. Regulation Number: 21 CFR 874.3300

4.2. Product Code: LXB

5. Detailed Device Description

5.1. Device and Company Nomenclature

5.1.1. The Otomag Alpha 1 Sound Processor may also be called the Alpha 1 Sound Processor, the Sound Processor, or Alpha 1. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.2. The Otomag Alpha 1(S) Configuration may also be called the Alpha 1(S) or 1(S) configuration. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.3. The Otomag Osseointegrated Alpha 1(M) Configuration may also be called the Alpha 1(M) or 1(M) configuration. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.4. Sophono, Inc. (b)(4) [redacted] (b)(4)

5.2. Description of the Alpha 1(S) Configuration

5.2.1. In the Alpha 1(S) configuration, the Sound Processor can be used with a

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headband or softband. Both the headband and softband are equipped with magnets encapsulated by Fotoplast (plastic) materials.

5.2.2. For this configuration, a metal disc is screwed into the Alpha 1 Sound Processor (Figure 3). The magnets within on the headband or softband magnetize to the Alpha 1 Sound Processor metal disc (Figure 1, Boxes B, D, E).

5.2.3. The softband holds the Alpha 1 to the side of the head by adjusting its elastic band and securing the fit with a Velcro closure (Figure 1, Boxes A-D). The headband holds the Alpha 1 to the side of the head by means of a springy metal bow (Figure 1, Boxes E & F). The figure shows the headband and softband with and without the Alpha 1 Sound Processor attached via the magnets.

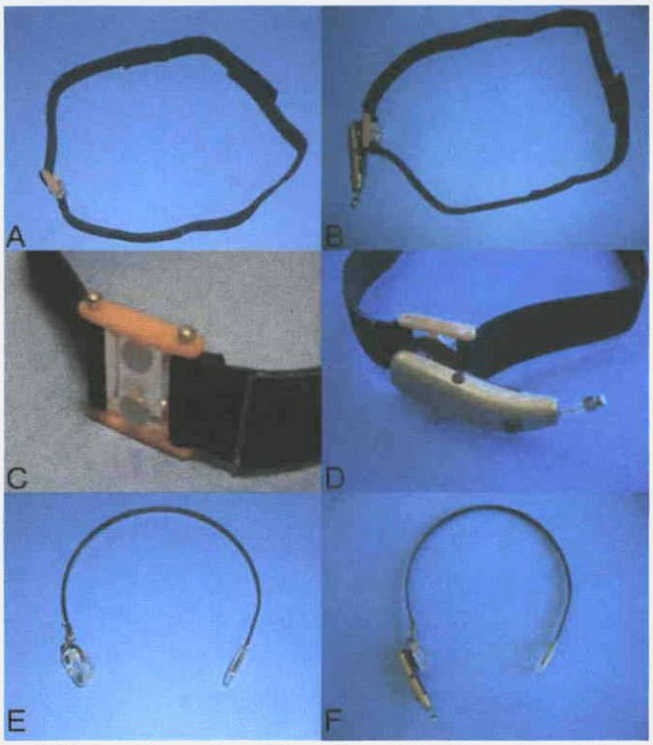

Figure 1: Alpha 1(S) Configuration / Headband, Softband, and Sound Processor

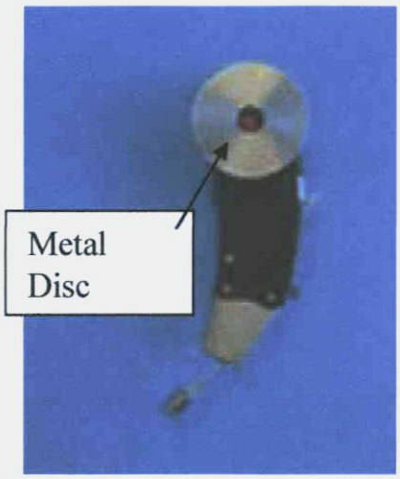

Figure 2: Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment to Headband / Softband

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5.3. Description of the Osseointegrated Alpha 1 (M) Configuration (Addition to Product Family)

5.3.1. In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Osseointegrated Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 3 below shows the details of the configuration.

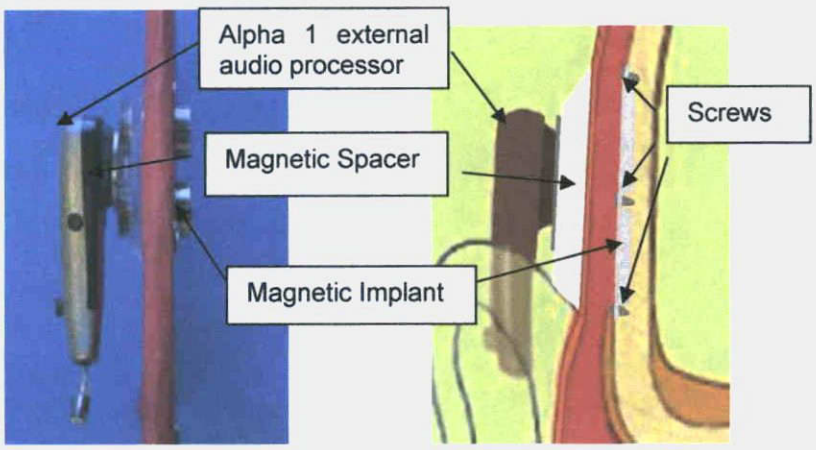

Figure 3: Alpha 1 (M) Magnetic Implant System

5.3.2. For this configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

5.3.3. To ensure that appropriate pressure is applied between the sound processor and the patient's skin / bone, various strengths of magnetic spacers are available (4 sizes – (b)(4) [redacted].

5.3.4. The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical impant site. See the Physician's Manual in Section 15 of the overall submission for detailed implantation instructions.

5.4. Description of the Otomag Alpha 1 Sound Processor

5.4.1. A key component of the Otomag System is the Alpha 1 Sound Processor, which is similar to a behind the ear air conduction hearing with a traditional bone conduction vibrator. The Alpha 1 Sound Processor utilizes proprietary software. The Alpha 1 Sound Processor is available for left or right sides with or without an external microphone, and with or without an FM jack.

5.4.2. The Alpha 1 Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone (Figure 4) within a plastic housing. The microphone opening is situated in the bottom of the housing and the vibrator in the upper part of the

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housing. The volume control with integrated switch and the battery compartment are accessible to the patient on the housing. The programming socket is situated beneath a cover. The programming socket is used for initial programming of the hearing device, as well as when adjustments are needed. No part of the sound processor has prolonged user contact.

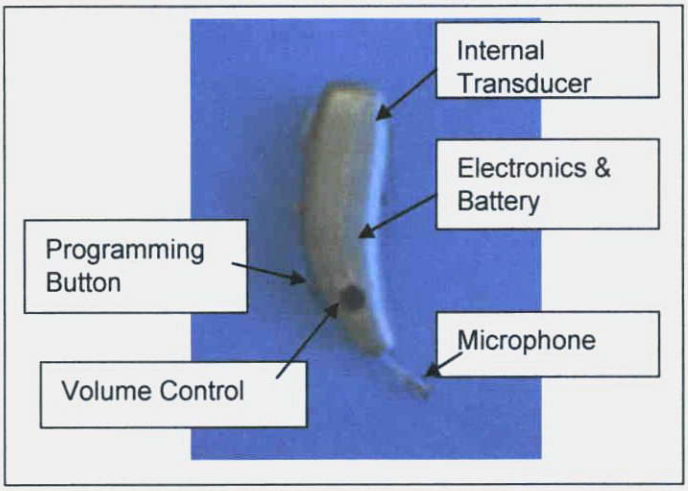

Figure 4: Alpha 1 Sound Processor

5.4.3. Sound Processor Circuit Description

5.4.3.1. (b)(4) [redacted]

5.4.3.2. As an alternative to sound reception with the microphone, an electromagnetic signal can also be received by means of an FM link on those Alpha 1 Sound Processors that have an FM jack. The jack is compatible with the Phonak MLxi FM receiver boot.

5.4.3.3. The housing and transducer are the same as is used in the Starkey Laboratories Viennatone bone conduction sound processor.

5.4.4. Gravity 2 Software Description

5.4.4.1. The Otomag Gravity 2 Fitting Software is based on the (b)(4) [redacted]

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(b)(4)

5.4.4.2. [redacted]

5.4.4.3. The design of the Otomag Alpha 1 Sound Processor requires that it is a four-channel bone conduction sound processor whose signal processing is implemented by a digital signal processor (DSP). (b)(4) [redacted]

(b)(4)

[redacted]

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(b)(4) [redacted]

5.5. Osseointegrated Magnetic Implant

5.5.1. The implant consists of two Samarium Cobalt (b)(4) [redacted] The implant is manufactured for (b)(4) [redacted]. Validation documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in Appendix C to the overall submission. Biocompatibility information, including material specifications for the implant can be found in Appendix B to the overall submission. (b)(4) [redacted]

5.5.2. The magnetic implant is placed in 3 mm deep bone beds as shown in Figure 6 and Figure 7. The implant is secured using 4 mm titanium facial plating screws.

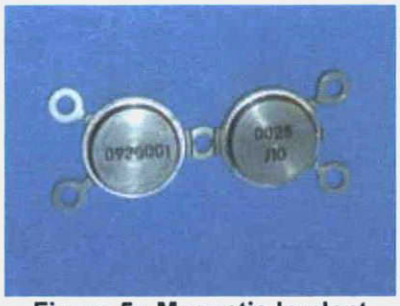

Figure 5: Magnetic Implant

Figure 6: Bone Beds

5.5.3. The magnetic implant is supplied to the physician clean but non-sterile, in sealed packaging to prevent contamination. The device is intended to be steam sterilized at the healthcare facility prior to implantation. Instructions and requirements for performing steam sterlization are included in the Physician's Manual contained in Section 15 to the overall submission.

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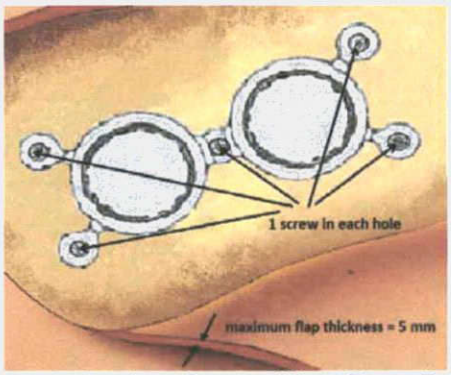

Figure 7: Implant Secured into Bone Beds

5.6. Magnetic Spacer

5.6.1. The spacer consists of a (b)(4) [redacted] 100% Fotoplast S IO. (b)(4) [redacted] as shown in Figure 8 and Figure 9. Both plastic materials are those commonly used for the production of custom ear molds. Complete material specifications can be found in Appendix B to the overall submission. Four magnetic strengths of the spacer are available to accommodate for variations in skin thicknesses and holding requirements to obtain approximately 2.5 N to 5.4 N of holding force.

Figure 8: Magnetic Spacer

Figure 9: Sound Processor Attached to Magnetic Spacer

6. Patient-Contacting Components and Materials

6.1. The components of the Otomag System that are patient contacting are the Fotoplast components on the headband / softband, the Fotoplast Magnetic Spacer, and the

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titanium magnetic implant. All materials used in the Alpha 1 device are materials commonly used in medical devices in the same applications (external tissue contact, implant). Biocompatibility information for these materials is contained in Section 17 and Appendix B of the overall submission. Each Magnetic Implant is cleaned to remove any manufacturing process contaminants.

6.2. Fotoplast-Lac and Fotoplast S IO

6.2.1. The Fotoplast S IO is the material that directly encapsulates the magnets in the softband and headband (b)(4) [redacted] (b)(4) [redacted] Fotoplast-Lacquer 3 material is in direct skin contact with healthy skin behind the ear, at the site of bone conduction. Both materials have been found biocompatible for their intended use. These materials are commonly used to fabricate hearing aid earmolds and thus have years of use in the ear canal without biocompatibility problems.

6.3. Titanium

6.3.1. In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible and is used in many medical implant applications.

6.3.2. The bone screws used to anchor the magnetic implant are also titanium. These screws are manufactured by Stryker Leibinger and are a legally marketed device which was cleared under K970912 for use as self threading bone screw.

7. Kit Configurations

7.1. The Otomag System will be available in two kit configurations (e.g., Alpha 1 (S) with appropriate means of attachment, Alpha 1 (M) with appropriate magnetic spacers) or the components may be ordered separately. Each kit or component will be labeled appropriately and will include the Patient User Manual and / or the Physician Instructions for Use as appropriate.

7.2. Each Alpha 1 Sound Processor will be available in right or left sided versions, with either an internal or external microphone, and with or without an FM jack. Alpha 1 Sound Processor configurations are show in Table 3.

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Table 3		
Sound Processor Configurations		
Right sided	Internal Microphone	With FM Jack
	External Microphone	
Left sided	Internal Microphone	
	External Microphone	
Right sided	Internal Microphone	Without FM Jack
	External Microphone	
Left sided	Internal Microphone	
	External Microphone	

7.3. An example of a component that is likely to be sold separately is an Alpha 1 (S) Sound Processor. Because it will not be known if the patient prefers a softband or headband, the Alpha 1 (S) will likely be shipped separately from the softband or headband.

7.4. Sophono, Inc. will also distribute to qualified hearing healthcare providers the Otomag Gravity 2 Fitting Software.

8. Specifications and Characteristics

8.1. Device Technical Specifications

8.1.1. Alpha 1 Sound Processor Specifications

8.1.1.1. Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB

8.1.1.2. Maximum Gain at 60 dB SPL: 38 dB

8.1.1.3. Peak Output at 90 dB SPL: 115 dB

8.1.1.4. Frequency range per ANSI S3.22-2009: 280-5000 Hz

8.1.1.5. Frequency processing range: 125-8000 Hz

8.1.1.6. Total harmonic distortion per ANSI S3.22-2009: <3%

8.1.1.7. Equivalent input noise: 17 dB

8.1.1.8. Battery current drain: 0.95 mA

8.1.1.9. Processor: 16 Band, 4 Channel WDRC

8.1.1.10. Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz

8.1.1.11. Compression Attack Time: 0.25 ms

8.1.1.12. Compression Release Time: 8192 ms

8.1.1.13. Patient Volume Control Wheel: 38 dB range

8.1.1.14. Power Supply: 1.3 V, #675 Zinc Air Battery

8.1.2. Magnetic Spacer Specifications

8.1.2.1. Magnetic Field Force: (b)(4) [redacted]

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(b)(4))

8.1.2.2. Spacer Sizes: (b)(4) [redacted]

8.1.2.3. Patient Contact Material: Fotoplast LAC

8.1.3. Magnetic Implant Specifications

8.1.3.1. Magnetic Field Force (b)(4) [redacted]
(b)(4) [redacted]

8.1.3.2. Implant Retention Force: (b)(4) [redacted]

8.1.3.3. Patient Contact Materials: (b)(4) [redacted]

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9. Description of Changes

9.1. The following section contains a summarized description of the changes to the device that include Indications for Use, additional hardware, and labeling. It should be noted that the changes described below do not constitute a change in intended use of the device, or the fundamental scientific principles of the device.

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C1	Indications for Use	Minor wording change in the Indications for Use statement to add the term "..or magnetic implant" to the end of the first paragraph. The new paragraph now reads: "The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband, Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:..." In addition, the following paragraph was removed because it was redundant with the first paragraph: "The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband."	None: Changes in Indications for Use statement are minor and do not result in a new Intended Use for the device. Specific impacts of design changes associated with this Indications for Use change are analyzed in each additional line item in this table.	None

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Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C2	**Force Application Method**	Addition of the magnetic spacer in 4 strengths, to be used in conjunction with the magnetic implant, to mimic the pressure applied by the softband or headband. Spacers are chosen by the fitting physician, based on tissue thickness, to ensure an application force of between approximately 2.5 [redacted] (b) (4) Material of the magnetic spacer is identical to the skin contact materials present in the headband and the softband (Fotoplast Lacquer 3). Part of the function of the magnetic spacer is identical to the prior version of the device which utilized a magnetic field to hold the sound processor to the headband or softband. In addition to holding the Sound Processor, the magnetic spacer additionally holds the Sound Processor assembly (Sound Processor and magnetic spacer) to the patient's skin through the creation of an attractive magnetic field.	None: • Patient Contact materials for this component are identical to the prior version of the device • The switch from pressure application via the headband or softband to an attractive magnetic field does not impact risk assessment as long as forces are equivalent	Otomag Softband, Headband, and Magnetic Implant Static Force Verification / Validation Protocol, DG-35: Validation showed magnetic attachment mechanism via magnetic implant is equivalent to headband / softband versions of the device.

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Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C3	**Force Application Method / Patient Contact Materials**	Addition of the magnetic implant, to be used in conjunction with the magnetic spacer, to mimic the pressure applied by the softband or headband. Patient contact material of the magnetic implant is Titanium. Magnets are hermetically sealed within the titanium case. The magnet is of similar design and the same construction methods as is used in currently available cochlear implants. Screws used to anchor the implant in the bone beds are included with the device and are 4 mm titanium bone screws manufactured by Stryker Leibinger and cleared under K970912.	The addition of the implanted magnet raises the following new risks not present in the prior version of the device • Biocompatibility related the implant As discussed immediately above, the switch from pressure application via the headband or softband to an attractive magnetic field does not impact risk assessment as long as forces are equivalent	• See Appendix B for Biocompatibility information for the magnetic implant • Otomag Softband, Headband, and Magnetic Implant Static Force Verification / Validation Protocol, [redacted] (b)(4) Validation showed magnetic attachment mechanism via magnetic implant is equivalent to headband / softband versions of the device. • Otomag Magnetic Implant Screw Retention Force Validation Protocol, DG-36: Showed the retention force of the 5 retention screws far exceeds the forces applied to the implant during operation.

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Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C4	Labeling	Primary Device Labeling has been modified to include clear identification of which configuration of the device is included (Alpha 1(S) or Osseointegrated Alpha 1(M)) Physician's Manual has been revised to include implant and explant instructions, magnetic spacer fitting instructions, and additional Warnings / Cautions related to the magnetic implant. Users Manual has been revised to include additional user instructions for placement of the Sound Processor with the magnetic implant, and additional Warnings / Cautions related to the magnetic implant. A label has been developed for the magnetic implant packaging to correctly identify this portion of the device.	None: Additional instructions are intended to ensure safe, effective use of the device. New Warnings and Cautions are included as a result of detailed risk analysis. The labeling changes themselves only serve to lower overall risk associated with the device	None

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Section 14: Substantial Equivalence Discussion

1. INTRODUCTION

1.1. Section 14 of this Traditional 510(k) identifies the predicate device and provides a detailed comparison between the modified device that forms the subject of this Traditional 510(k) and the predicate device in order to demonstrate the substantial equivalence of the two devices.

2. PREDICATE DEVICE

2.1. The predicate device for the osseointegrated version of the Otomag Bone Conduction Hearing System is the non-osseointegrated version of this device. The device changes presented in this 510(k) do not substantially alter the device with regards to the following:

- 2.1.1. Intended Use
- 2.1.2. Fundamental Technological Characteristics
  - 2.1.2.1. Device Performance
  - 2.1.2.2. Operating Principles
- 2.1.3. Target User and Patient Populations
- 2.1.4. Use Environment

2.2. The changes to the device that are the subject of this 510(k) relate to the addition of another device configuration to the product family. The additional configuration, called Alpha 1(M), includes an osseointegrated Magnetic Implant that is placed in bone beds behind and above the patient's ear to provide for attachment of the sound processor without the use of the headband or softband. This change impacts detailed engineering specifications and patient contact materials, but does not alter the overall performance of the device. Due to the specificity of the Indications for Use statement for the prior version of the device, minor wording changes are also required.

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3. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

3.1. The following table summarizes and compares data on the Otomag Bone Conduction Hearing System cleared in K100193 (predicate device) to the osseointegrated device that is the subject of this 510(k) submission.

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	Identical
Class	Class II	Class II	Identical
Product Code	LXB	LXB	Identical
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	Identical
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical
Power Supply	Zinc-air battery	Zinc-air battery	Identical
Sound Processing	Digital	Digital	Identical
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical
Frequency Processing Range	125 – 8kHz	125 – 8kHz	Identical
Max Gain (60dB SPL)	38 dB	38 dB	Identical
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	29 dB	Identical
Material of sound processor coupling	Stainless Steel Disc	Stainless Steel Disc	Identical
Accessories/Options	Direct audio input via FM jack	Direct audio input via FM jack	Identical
Patient Contact Materials for Biocompatibility Purposes	Fotoplast-Lac	Fotoplast-Lac Titanium Grade 4 and 5 (Magnetic Implant)	See discussion below

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Sterilization	No sterile components	Steam sterilization of surgical implant	See discussion below
Manufacturer	Otomag GmBH	Otomag GmBH	Identical
Peak Output at 90 dB SPL	115 dB	115 dB	Identical
Frequency range per ANSI S3.22-2009	280-5000 Hz	280-5000 Hz	Identical
Total harmonic distortion per ANSI S3.22-2009	<3%	<3%	Identical
Equivalent input noise:	17 dB SPL	17 dB SPL	Identical
Battery current drain	0.95 mA	0.95 mA	Identical
Processor:	16 Band, 4 Channel WDRC	16 Band, 4 Channel WDRC	Identical
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical
Compression Attack Time (minimum)	0.25 ms	0.25 ms	Identical
Compression Release Time (maximum)	8192 ms	8192 ms	Identical
Patient Volume Control Wheel	38 dB range	38 dB range	Identical
Power Supply	1.3 V, #675 Zinc Air Battery	1.3 V, #675 Zinc Air Battery	Identical
Force Application Methods	Headband or Softband	Headband or Softband (Alpha 1(S) Version) Osseointegrated Magnetic Implant (Alpha 1(M) Version)	Substantially Equivalent – See discussion below

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4. DISCUSSION OF DIFFERENCES

4.1. The differences in specifications identified in the comparison table above between the predicate Otomag Bone Conduction Hearing device and the modified Otomag device as reflected in the above SE table are the following. A detailed discussion of each device change is contained in Section 13 – Device Description / Description of Changes.

4.1.1. **Indications for Use:**

4.1.1.1. The changes in the Indications For Use statement simply add the additional Magnetic Implant version of the product to the overall statement including an age limitation for use of the Osseointegrated Magnetic Implant configuration (Alpha 1(M)) to patients 5 years of age or older. These changes do not impart a new intended use for the product and do not raise new questions of safety and effectiveness.

4.1.2. **Patient Contact Materials:**

4.1.2.1. The Magnetic Implant contains new patient contacting materials. The implant is made of Titanium Grades 4 and 5. In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible. The addition of new patient contact materials that are biocompatible does not raise new questions of safety and effectiveness.

4.1.3. **Sterilization:**

4.1.3.1. The Magnetic Implant is provided clean but not sterile and intended to be sterilized via gravity or prevacuum steam sterilization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The addition of an appropriately specified and validated sterilization cycle does not raise new questions of safety and effectiveness.

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4.1.4. **Force Application Method:**

4.1.4.1. The new osseointegrated Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 4 different strength magnetic spacers provided with the product. Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device.

4.1.4.2. The approach of using a magnetic implant to attach the sound processor has been previously employed by another family of bone conduction hearing devices. The Xomed Audiant Bone Conductor cleared in K855059 and K861971 employs this same technology for the attachment of the sound processor.

5. CONCLUSION

5.1. The Intended Use of the osseointegrated version of the Otomag Bone Conduction Hearing System remains the same as the predicate device (non-osseointegrated version). Performance data demonstrate that the modified device meet or exceed the applicable requirements.

5.2. The osseointegrated version of the Otomag Bone Conduction Hearing System is substantially equivalent to the predicate Otomag device cleared in K100193 and that the differences between the two devices:

5.2.1. Do not raise any new issues of safety and effectiveness

5.2.2. Do not amount to a change in the "fundamental scientific technology" of the device

5.2.3. Do not present any adverse health effect or safety risks to patients when used as intended.

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Section 15: Labeling

1. Introduction

1.1. In conjunction with the addition of the osseointegrated Alpha 1(M) configuration of the Otomag Bone Conduction Hearing System, labeling updates were made. As a part of these updates the original manuals have been reorganized and reformatted to better and more clearly present the original information. No substantive changes to the original labeling pertaining to the Alpha 1(S) configuration have been made. Additional sections have been added to both the Physician's Manual and the Patient User Manual to appropriately address the osseointegrated Alpha 1(M) configuration. The changes are summarized as follows:

1.1.1. Addition of new Warnings and Cautions related to the Alpha 1(M) Configuration

1.1.2. Addition of sterilization instructions and cycle parameters relating to pre-implant sterilization of the Magnetic Implant

1.1.3. Addition of surgical implantation and explantation instructions and diagrams have been added addressing the placement and removal of the Magnetic Implant

1.1.4. Addition of instruction for attaching the Sound Processor to the Magnetic Implant

1.2. In addition to the revised Patient User Manual and Physician's Manual, the label for the Magnetic Implant is included in this section.

1.3. The primary device label has been modified to clearly indication which device configuration is included in the packaging, Alpha 1(S) or osseointegrated Alpha 1(M)

2. Index of Attachments in this section

2.1. Physician's Manual

2.2. Patient User Manual

2.3. Magnetic Implant Package Label

2.4. Revised Primary Device Labels

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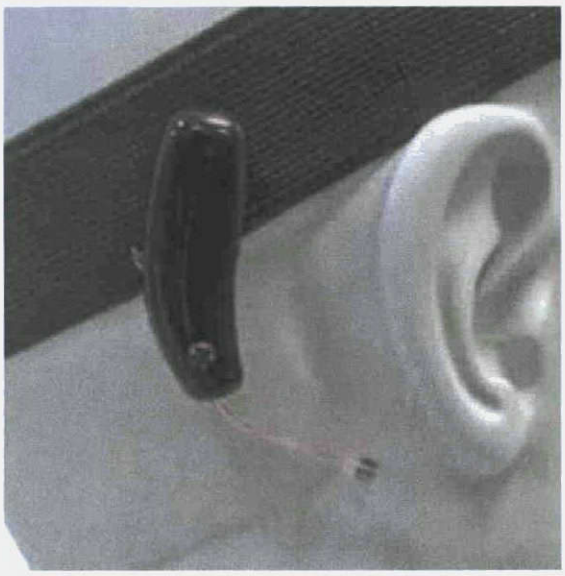
Sophono

Physician Manual



Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems

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Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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1 About this Manual

This Physician Manual provides a description of the Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. This manual provides the information necessary for the physician to prescribe the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems to the appropriate patient population. Please read this manual thoroughly before prescribing the system.
A Patient Instruction Manual is included with each **Alpha I (S)** & **Alpha I (M)** Bone Conduction Hearing System and should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

2 Introduction

Warnings and Cautions Overview

The following section contains a description of all physician related Warnings and Cautions associated with the Otomag Bone Conduction Hearing Systems.

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Additional patient and use related Warnings and Cautions can be found in the Patient User Manual. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to physician instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warnings

Warning	▪ Thoroughly read the Physician Manual and the Patient Manual before prescribing the Otomag System. ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection.

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Precautions

Caution	▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual.

Product Description

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag System is configured in either of two configurations. The first configuration is the Alpha 1 (S), where the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), where the Otomag Sound Processor is attached magnetically to an osseointegrated implanted magnet. The Headband, Softband, or Magnetic Implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

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Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patient Selection Criteria

- Patients to be fitted with the Otomag Alpha 1 (S) Sound Processor and its Headband or Softband may be any age.
- Patients to be fitted with the Otomag Osseointegrated Alpha 1 (M) Sound Processor and its Magnetic Implant should be 5 years old or older.
- Patients and/or patient guardians must be able to understand that the Otomag System will not restore hearing to normal and will not prevent additional hearing impairment resulting from conditions such as disease, old age hearing loss, genetic hearing loss, ototoxic drugs or noise induced hearing loss.

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Possible Adverse Effects

General

It is possible that a reaction to the materials of the Headband, Softband, or Magnetic Implant could occur. Such a circumstance may necessitate that use of the device be discontinued. Please report any adverse effects to Sophono, Inc. The address and phone number for Sophono, Inc. are listed at beginning and end of this Physician Manual. If a reaction to the Headband or Softband occurs, Sophono will supply appropriate instructions so that the device can be sent to the laboratory for analysis.

Risks that may occur during surgery:

The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, postcholesteatoma, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, disturbance of taste or balance and noticeable changes in head noise.

⚠	**Warning** ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System.

Risks that may occur after surgery:

Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma and inflammatory reaction.

It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant.

⚠	**Warning** ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.

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Other Symbols on Equipment and Labeling

Symbol	Description
	Consult Physician Manual
LOT	Batch Code or Lot Number
SN	Serial Number
	Keep Away From Rain / Keep Dry
	Manufacturer
MR	MR Unsafe: Device should not be worn when patient is undergoing an MRI
LATEX	Product is Latex Free
	Interference may occur in the area of equipment which is labeled with the following symbol.
122°F -4°F	Temperature Limitation: The sound processor is designed to operate within the temperature ranges of 41oF (+5oC) to 104oF (+40oC). The processor should not be subject to temperatures below -4oF (-20oC) or above 122oF (+50oC) at any time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 Patient Fitting Procedures

Alpha 1 (S) System: Instructions for Placement of the Softband or Headband and Alpha 1 Sound Processor

	Notes ▪ Record the product and lot or serial numbers for the Alpha 1 Sound Processor in the patient file and send the patient to a qualified audiologist for proper programming of the Alpha 1 Sound Processor.

The Otomag Softband is an elastic Softband similar to a sweat band used in sports. The Alpha 1 (S) Sound Processor magnetically adheres to the Softband via a magnetic pad sewn into the band. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by an audiologist.

- To use the Otomag Softband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Softband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Softband around the patient's head, quite loosely at first by slipping the end of the band through the slot next to the magnetic pad and attaching the mating Velcro ® loops and hooks to each other.
- Place the magnetic pad against the mastoid or other boney location.
- Tighten the Softband by adjusting the Velcro® strap until it is close-fitting enough to ensure effective sound transmission, but not tight enough to cause discomfort. The Softband is too loose if it slips off of the head, can be rotated easily around the head or no sound transmission can be heard. The Softband is too tight if the patient complains of pain or discomfort while wearing the Softband. Make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

	Warning ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

The Otomag Headband is a springy Headband, similar to that used for earphone devices. It comes in one size and is not adjustable. The Alpha 1 (S) Sounds Processor magnetically adheres to the Headband via a magnetic pad fitted to the Headband. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by the audiologist.

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- To use the Otomag Headband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Headband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Headband on the patient's head and place the magnetic pad against the mastoid or other boney location.

The choice of a Headband or Softband is a matter of patient preference.

Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

⚠	**Warning** ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Immediately seal the autoclave pouch.
- Drying of the device is not required.

⚠	**Caution** ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be sterilized a single time by prevacuum or gravity steam sterilization (autoclaving). The following sterilization parameters have been validated for sterilization of the implant.

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Limitations on Reprocessing: Single Sterilization Only

Presterilization Decontamination / Cleaning / Disinfection: None Required

Cycle Type: Prevacuum or Gravity

Sterilization Time: 15 minutes minimum

Sterilization Cycle Temperature: 132 degrees C / 270 degrees F

Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)

Storage in Sterile State: Not Allowed – Sterilization immediately pre-implant only

Pre-Surgical Training Requirements

Before attempting to implant the Otomag Implant, surgeons are required to complete training provided by Sophono, Inc. During the training they will receive guidance regarding the procedure, a thorough understanding of the device and surgical procedure and other important information. Contact Sophono Customer Services at the contact number listed in Section 6 of this manual to arrange training.

Surgical Risks

The implantation of the Otomag Implant requires a surgical procedure involving the removal of tissue and bone. As with any surgical procedure involving a general anesthetic, certain risks exist. Those risks include the risk of infection from poor hygiene or non-sterile technique, irritation of tissues during the implantation procedure, unintended cuts and abrasions, and irritation of tissues due to unintended exposure to implant materials. The implant is made of materials considered to be hypo-allergenic but in the case of unintended damage to the device, a patient could come in contact with substances that could generate an adverse reaction.

Surgical Implantation Steps

Step 1 - Making The Incision

The proper position for the implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant will be placed. The incision must be large enough to allow placement of the implant. See Figure 1.

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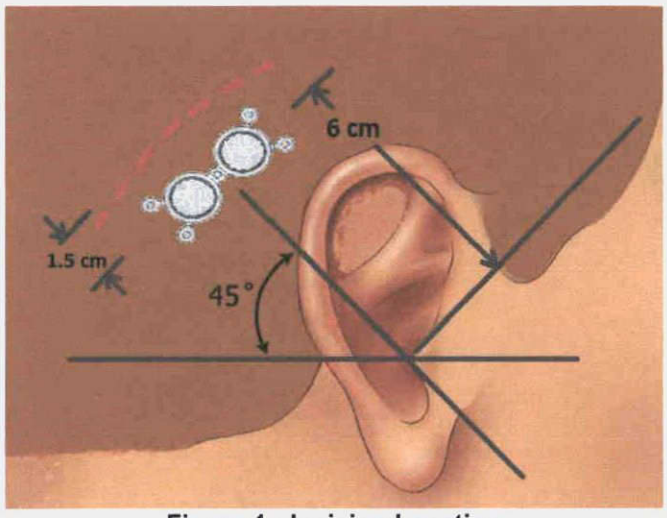

Figure 1 : Incision Location

Step 2 - Create a bone bed (optional)

The implant is approximately 2.6 mm thick and optimal tissue thickness over the implant is 4mm to 5 mm. Bone beds are recommended for the implant if the tissue thickness over the implant is less than 3 mm.

To create a bone bed, mark the position of the implant magnets on the bone and drill the bone bed to a depth of approximately 3 mm. The implant magnets have a diameter of 10 mm.

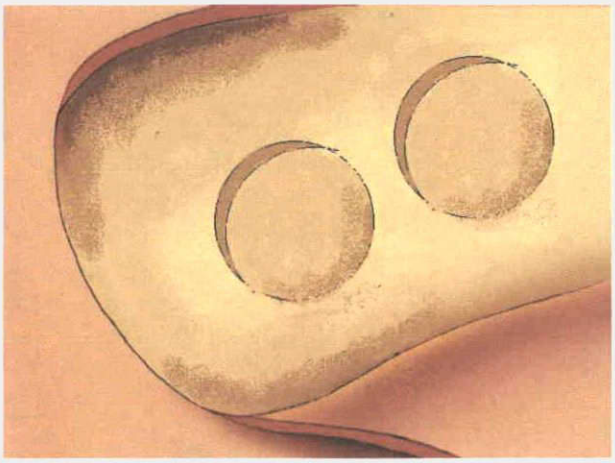

Figure 2: Bone Beds

Step 3 - Implant Placement

Place the implant with the magnets in the bone beds (if created) or with the magnets face up such that the bracket legs are flush to the skull. Place one screw in each of the bracket holes to securely attach the implant to the skull.

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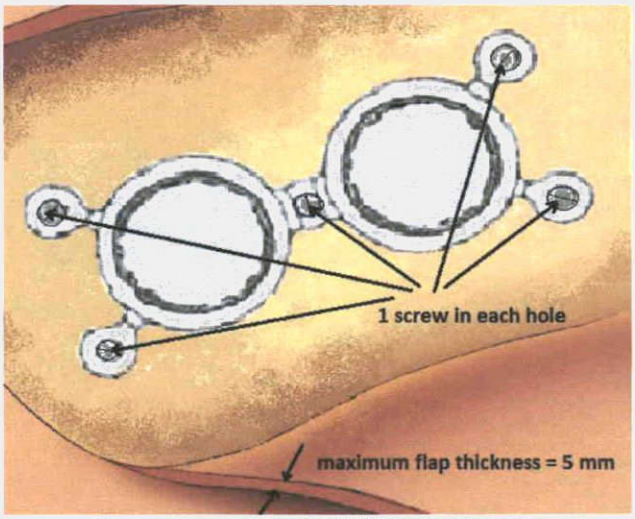

Figure 3: Implant Installation Diagram

Step 4 - Tissue Thinning and Closing the Incision

If the tissue flap is thicker than 6 mm, thin down a 10 mm wide strip of tissue to 5 mm directly over the implant magnets. Suture the incision closed.

Implant Surgical Removal Steps

Step 1 - Making The Incision

The implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant has been placed. The incision must be large enough to allow removal of the implant. See Figure 1 above.

Step 2 - Implant Removal

Remove each of the 5 screws holding the magnetic implant in place. It may be necessary to excise bone or tissue growth occurring over the face of the implant. Once the screws are removed the implant can be lifted carefully from the bone or bone beds. Suture incision closed.

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Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system. The Alpha 1 (M) configuration is supplied with three strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid. Choose a magnetic spacer to achieve appropriate sound transmission without being uncomfortable to the patient. The spacers are labeled XX, YY, ZZ to indicate increasing magnetic strength. The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable of if numbness occurs.

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4 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a biocompatible titanium case. Only the titanium case of the implant is in contact with patient tissue.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid: Fotoplast Lacquer 3 (light-curing one-component lacquer)

NO components or packaging for the Otomag Osseointegrated Bone Conduction Hearing System contain latex.

Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction sound processor
- Fully programmable digital hearing system
- programs (programmable by audiologist)
- 4 channels

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- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery

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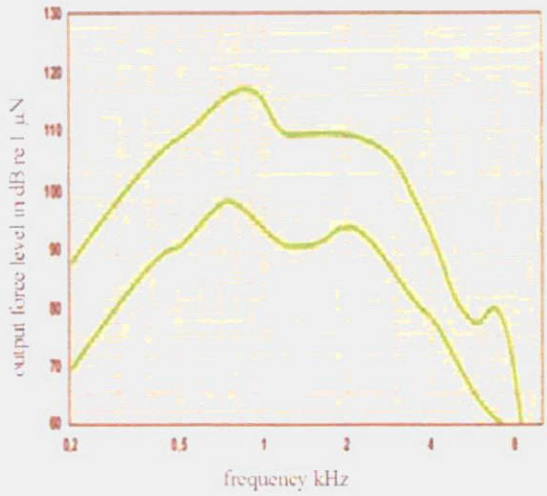
Alpha 1 Sound Processor Performance Data

(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 µN
- Peak Output at 90 dB SPL: 115 dB re 1 µN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

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5 Storage and Handling

Storage

⚠	**Caution** ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -20 C (-4 F) or above +50 C (122 F) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Handling

⚠	**Caution** ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual

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6 Professional Support

For more information or to report concerns, contact:

Sophono, Inc.

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Patient User Manual

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Sophono

Patient User Manual

Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems

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Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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1 About this Manual

This Patient Manual provides a description of the Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. Please read this manual thoroughly before using the system.

This Patient Instruction Manual included with each Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing System should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

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2 Introduction

Dear Customer:

Congratulations on the purchase of your new Otomag Bone Conduction Hearing System!

The Otomag Bone Conduction Hearing System includes a family of Sound Processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag Bone Conduction Hearing System is supplied in either of two configurations. The first configuration is the Alpha 1 (S), in which the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), in which the Otomag Sound Processor is attached magnetically to an osseointegrated Magnetic Implant placed behind the patient's ear. The Headband, Softband, or Magnetic Implant holds the Sound Processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for patients with conductive hearing loss, patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and patients who suffer from single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software package allow for programming the Otomag System for individual patient hearing loss.

This Patient Manual will help you quickly gain confidence with your new Otomag Bone Conduction Hearing System. If you have further questions please consult your hearing healthcare provider.

General Information

A hearing device will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of a hearing device does not permit a user to attain full benefit. The use of a hearing device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading.

	Note ▪ **NO** components or packaging of the Otomag Bone Conduction Hearing System contain **latex**

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Warnings and Cautions Overview

The following section contains a description of all patient related Warnings and Cautions associated with the Otomag Bone Conduction Hearing System. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to patient instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warning	▪ Thoroughly read Patient Manual before using the Otomag Bone Conduction Hearing System. ▪ Rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in personal injury and damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not obtain an Magnetic Resonance Imaging (MRI) procedure while wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire. ▪ Do not attempt to recharge batteries.
Caution	▪ Read this Patient User Manual and keep it available so you can refer to it when needed. ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4 °F (-20 °C) or above 122 °F (+50 °C) at any time. ▪ To avoid damage to the device, do not store the Otomag System near magnets or magnetic devices. ▪ Remove the Sound Processor, Headband and Softband before x-rays of the head and neck

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Caution	▪ Remove the Sound Processor, Headband, and Softband during radiation therapy ▪ Portable and mobile RF (radio frequency) communications equipment can affect the performance of the Sound Processor. ▪ Interference may occur in the area of equipment which is labeled with the following symbol: ▪ Dispose of batteries and electronic items in accordance with your local regulations. ▪ When navigating through security in airports remove the Sound Processor, Headband and Softband and have them screened through the x-ray screening process. The Sound Processor, Headband and Softband contain metal that may activate the airport security metal detectors. ▪ Do not use the Alpha 1 Sound Processor, Headband or Softband while participating in contact sports. Hard physical contact with the device or a blow to the head in the area of the Alpha 1 Sound Processor, Headband or Softband may result in damage to the device or device failure. ▪ Clean the Alpha 1 Processor, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case. ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device. ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor. ▪ Do not expose the Sound Processor to strong sunlight. ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case.

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Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

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3 Operating Instructions

Insertion of the battery

Size 675 batteries are required for your Alpha I Sound Processor.

See Figure 1 for details. Open the battery compartment (1) with a fingernail and insert the battery (2) so that the plus (+) sign on the battery and the plus (+) sign on the battery compartment are on the same side. Close the battery compartment with a finger. The Sound Processor is now switched on.

⚠	**Caution** ▪ Dispose of batteries and electronic items in accordance with your local regulations.

Switch off your Sound Processor whenever you're not using it by pivoting the battery compartment fully out. This will help preserve battery life. The Alpha 1 has a low battery indicator that generates a tone when it is time to replace the battery. Your hearing healthcare provider can adjust the volume and tone of the low battery indicator for you.

Figure 1. Alpha I Sound Processor

⚠	**Warning** ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals ▪ Do not attempt to recharge batteries. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire

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Start-up and Operation

Switch on the Alpha 1 Sound Processor by pivoting the battery compartment fully in.

Positioning the Sound Processor

Alpha 1 (S)

To place the Alpha 1 (S) Sound Processor, simply guide it into the vicinity of the magnetic pad in the Softband or Headband. The magnetic forces will bring it to its correct position. See Figure 2.

Figure 2. Positioning the Alpha I (S) Sound Processor on the Softband

⚠	**Warning** ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 3.

Figure 3. Positioning the Alpha I (M) Sound Processor on the osseointegrated Magnetic Implant

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⚠	**Caution** ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient.

Volume Control

The volume can be adjusted with the small wheel that is situated on the outside of the Alpha 1 Sound Processor. Using the tip of the index finger, apply slight pressure on the rotary button and simultaneously turn forward to increase volume. Turn the rotary button in the opposite direction to reduce volume.

You can switch off the Sound Processor by opening the battery access door. As soon as you take off the device, switch it off. See Figure 4 for details.

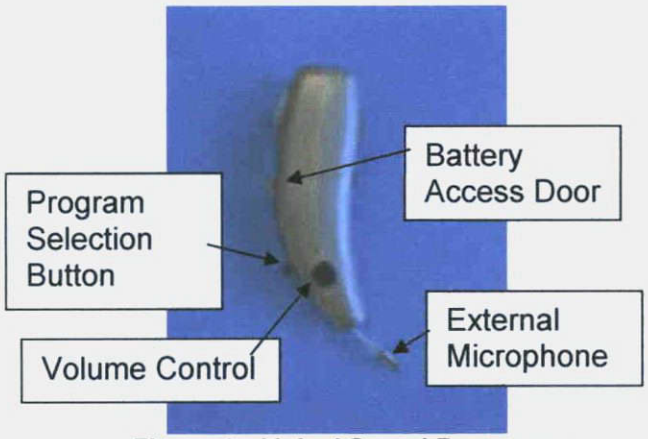

Figure 4. Alpha I Sound Processor

Program Selection Button

The Alpha 1 Sound Processors offer four program settings for different hearing situations. By pressing the small button on the Sound Processor, the programs can be activated. For each activated program you will hear a corresponding signal tone for recognition.

- Program 1: Instrument beeps once
- Program 2: Instrument beeps twice
- Program 3: Instrument beeps three times
- Program 4: Instrument beeps four times

Your hearing healthcare provider will inform you when each of the programs should be used

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Removing the Sound Processor

To remove the Alpha 1 Sound Processor, pull **ONLY** on the steel disk. See Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

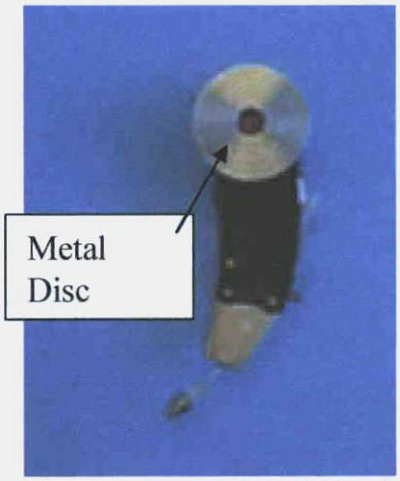

Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

	Note ▪ If you remove the Sound Processor without switching it off, it generates a vibrating tone which leads to high battery consumption. Therefore, always properly switch off the Sound Processor when you are not wearing it.

⚠	**Caution** ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device.

If Your Sound Processor Does Not Function

Check the following if the Sound Processor is not functioning properly:

- The device is properly switched on and the battery compartment is fully closed
- The battery is not dead
- The battery surface is clean.

If the device still is not functioning properly, see your hearing healthcare provider.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 Product Maintenance

Cleaning and Care

Sound Processor

- Have your Sound Processor checked at regular intervals as specified by your hearing professional.
- To clean your Sound Processor, wipe it with a soft cloth or a Clorox® type disinfecting wipe
- The battery compartment may be cleaned by wiping it out with a DRY cotton swab or a cotton swab that has been moistened by a Clorox® type disinfecting wipe.

	Note ▪ Remove the Sound Processor, Softband, and Headband during the application of hairspray or styling gels. If hairspray or gel comes in contact with the Sound Processor it may become sticky and difficult to clean

- If the Sound Processor becomes soaked with water:
  - Immediately open the battery door and remove the battery
  - Put the Sound Processor in a container with drying capsules such as Dri-aid kit or similar overnight. Drying kits are available from most hearing care professionals.

	Caution ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case

- The Sound Processor is provided in a plastic case which may be used to store the processor. This case may be cleaned with a Clorox® type disinfecting wipe. Make sure the case is completely dry before storing the Sound Processor in it.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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⚠	**Caution** ▪ The Sound Processor is designed to operate within the temperature ranges of 41°F (+5°C) to 104°F (+40°C). The processor should not be subject to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor ▪ Do not expose the Sound Processor to strong sunlight ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case

Softband and Headband

- The Headband can be cleaned with a Clorox® type disinfecting wipe.
- The Softband may be submerged and hand washed with a mild clothes washing detergent (with or without a small amount of color safe bleach) and air dried or may be cleaned with a Clorox® type disinfecting wipe.

Magnetic Spacer

- The Magnetic Spacer can be cleaned with a Clorox® type disinfecting wipe.

⚠	**Caution** ▪ Clean the Alpha 1 Processor, Magnetic Spacer, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Damage and Replacement

The expected live span for the Sound Processor, Magnetic Spacer, Softband, and Headband is approximately 4 years depending on use, wear, and tear. The Sound Processor will need to be repaired or replaced when it no longer produces adequate vibrations or the sounds become highly distorted. The Softband should be replaced when it becomes damaged or the elastic begins to be stretched out and it can no longer be tightened adequately for sound transmission. The Headband should be replaced when it becomes damaged or no longer has enough spring force to press the magnetic pad against the head for adequate sound transmission. Replacement Headbands and Softbands may be purchased through your hearing healthcare provider from Sophono, Inc.

5 Accessories

If your Alpha 1 Sound Processor has a jack for an FM boot, you may plug the boot of a Phonak MLxi FM receiver into the bottom of the Sound Processor.

If you are concerned about the Alpha 1 Sound Processor falling off your head, a clip and tether are available so that the Sound Processor can be tethered to a garment you're wearing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or 301-796-8118

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6 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a Titanium case.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid: Fotoplast Lacquer 3 (light-curing one-component lacquer)

NO components or packaging for the Otomag Bone Conduction Hearing System contain latex.

Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction Sound Processor
- Fully programmable digital hearing system
- Programs (programmable by audiologist)
- 4 channels
- 16 frequency bands

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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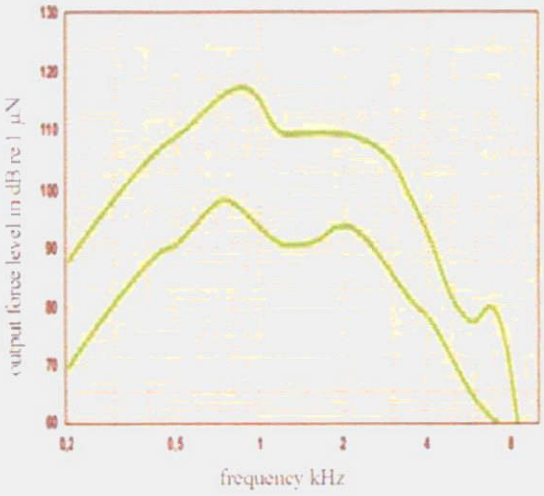
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery)

Alpha 1 Sound Processor Performance Data

(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



Output force level (OFL) at 90 dB SPL – Top Line

Output force level (OFL) at 60 dB SPL – Bottom Line

- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 µN
- Peak Output at 90 dB SPL: 115 dB re 1 µN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

7 Professional Support

For more information or to report concerns contact:

Sophono, Inc.

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postmaster@sophono.com

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+1 (303) 564-1663
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Magnetic Implant Package Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Soghono

MAGNETIC IMPLANT
REF: 093001

NON STERILE

SN: XXXX-XX
QTY: 1

EFS GmbH & Co. KG
Glasbronnenstr. 6
75449 Wurmberg, Germany
Phone : (+49) 0 2841 8870032
Fax : (+49) 0 2841 8870032

P/N XXXX-XXX

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Revised Primary Device Labels

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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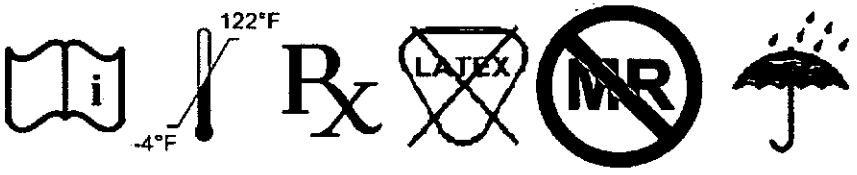
Otomag Alpha 1(S) Bone Conduction Hearing System

Manufacturer:

Otomag GmbH Alte Dorfstrasse 67, 32289 Rödinghausen, Germany. Tel: +49 5746 8504 Fax: +49 5746 8578
Distributed by: Sophono, Inc. 903 Brooklawn Drive, Boulder, CO 80303, USA. Tel: +1 303 564 1663 Fax: +1 720 222 2432

Contents:

1 Alpha 1 (S) Bone Conduction Hearing System
1 Physician Manual
1 Patient Manual



Device Intended for Single Patient Use Only!

PN XXXXXXX **SN** XXXXXXX **LOT** XXXXXXX

Made In Germany

Label P/N 3000-03

Questions? Contact FDA/CDRH/OCE/DIDP at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Page 103 of 192

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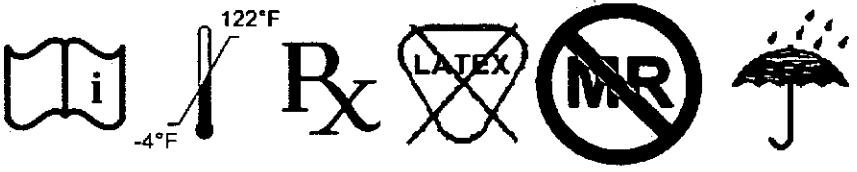
Otomag Osseointegrated Alpha 1(M) Bone Conduction Hearing System

Manufacturer:

Otomag GmbH Alte Dorfstrasse 67, 32289 Rödinghausen, Germany. Tel: +49 5746 8504 Fax: +49 5746 8578
Distributed by: Sophono, Inc. 903 Brooklawn Drive, Boulder, CO 80303, USA. Tel: +1 303 564 1663 Fax: +1 720 222 2432

Contents:

1 Osseointegrated Alpha 1 (M) Bone Conduction Hearing System
1 Magnetic Implant
4 Magnetic Spacers (1 Dot to 4 Dot)
1 Physician Manual
1 Patient Manual



Device Intended for Single Patient Use Only!

PN XXXXXXX SN XXXXXXX LOT XXXXXXX

Made In Germany

Label P/N 3000-02

Questions? Contact FDA/CDRH/OCE/DIDP at CDRH-EOISTATUS@fda.hhs.gov or 301-796-8118

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Section 16: Sterilization and Shelf Life

1. Sterilization

1.1. The Osseointegrated Magnetic Implant is provided clean but not sterile and is intended to be sterilized via gravity or prevacuum steam sterilization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices.

1.2. Attachment 1 to Section 15 – Labeling contains a copy of the revised Physician's Manual which contains details regarding pre-implant sterilization. Refer to pages 11 and 12 of this manual for details.

1.3. Appendix D to the overall submission contains validation protocols and reports for the specified sterilization cycle.

2. Shelf-Life

2.1. Not Applicable. The Osseointegrated Magnetic Implant is not supplied sterile and the materials of the implant case (titanium grades 4 and 5) are not expected to suffer performance degradation over the life of the overall product.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Section 17: Biocompatibility

1. Introduction

1.1. The only new patient contacting materials present in the Osseointegrated Alpha 1(M) addition to the Otomag Bone Conduction Hearing System are related to the Magnetic Implant and its retention hardware (bone screws).

1.1.1. In accordance with the flowchart shown in Figure 1 below from Attachment C of FDA General Program Memorandum #G95-1 the titanium material used in the implant could follow two available paths through the flow chart. See the highlighted routes through Figure 1.

1.1.1.1. Route 1: The magnetic implant is manufactured (b)(4) [redacted] (b)(4) [redacted] using the same materials, manufacturing processes, sterilization methods, and body contact types as legally marketed devices both in the US and in Europe. This exact implant is currently being marketed with a CE mark in the EU by Otomag. This path through the flow chart indicates that biocompatibility requirements have been met for the material of the implant case.

1.1.1.2. Route 2: A second available route through the flow chart conservatively assumes that the implant is not exactly the same as a legally marketed device and follows the path that asks if the material "is a polymer" (no), "is the material a metal, metal allow, or ceramic" (yes), "does it contain toxic substances" (no). This path through the flow chart also indicates that biocompatibility requirements have been met for the material of the implant case. The materials specifications for the titanium materials used in the case are contained in Appendix B to the overall submission.

1.1.2. The titanium material used in the magnetic implant is well established as biocompatible and is used in implantable medical devices in similar applications such as cochlear implants and extensively as a material for orthopedic implants.

1.1.3. The bone screws used to anchor the magnetic implant are also titanium. These screws are manufactured by Stryker Leibinger and are a legally marketed device which was cleared under K970912 for use as self threading bone screw.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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General Program Memorandum - #G95-1
Attachment C

Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s

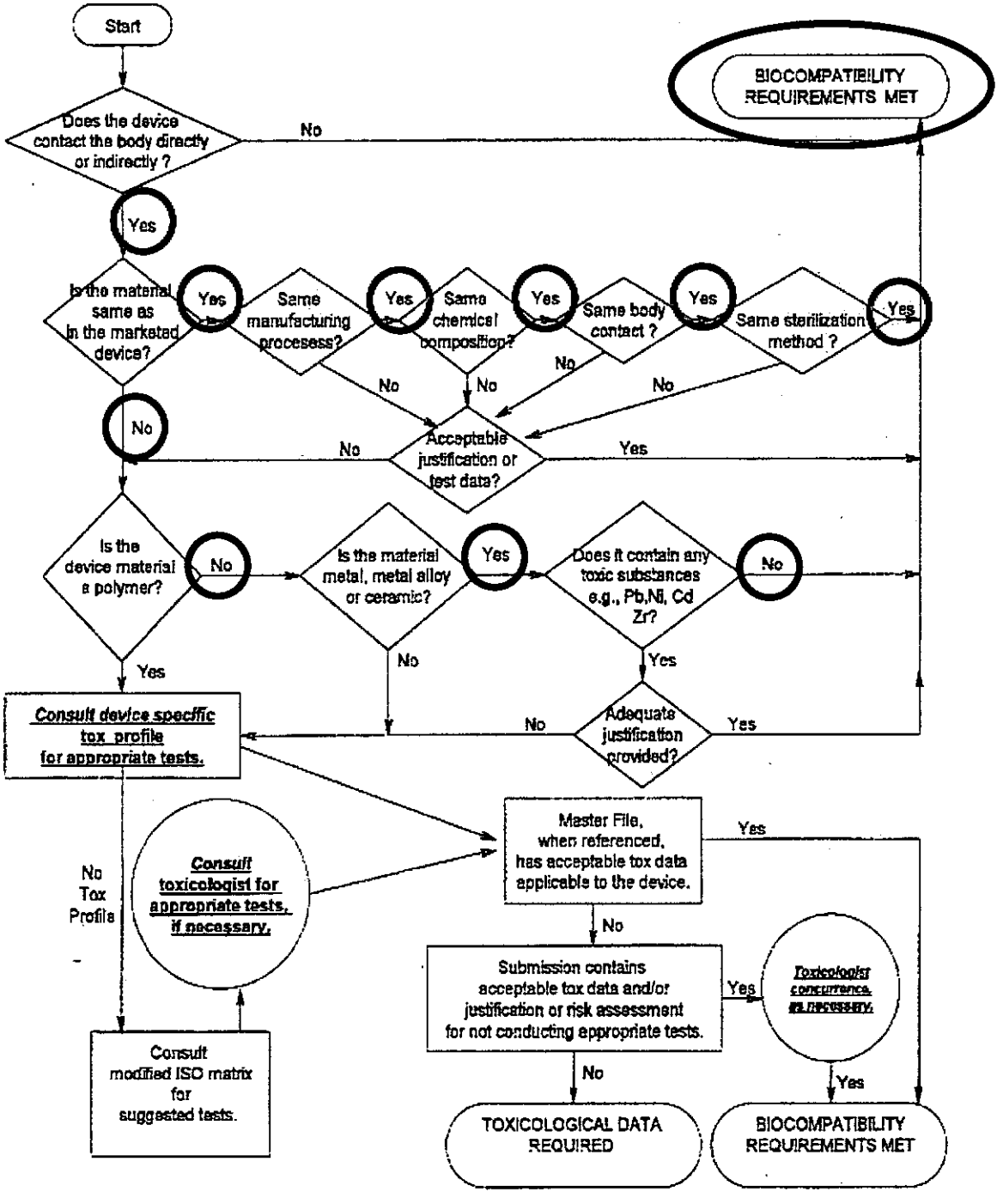

Figure 1: FDA Memorandum #G95-1

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18: Software

None of the device changes that are the subject of this 510(k) involved changes to the device software and therefore no additional software testing or software documentation is provided in this submission. All software documents provided in the original 510(k) submission (K100193) continue to be applicable to the modified version of this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Section 19: Electromagnetic Compatibility and Electrical Safety

The changes made to the Otomag Bone Conduction Hearing System did not involve the electronics or software of the device and therefore there was no need to repeat previously completed EMC and Electrical Safety testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 20: Performance Testing – Bench

1. Introduction

1.1. As a result of the application of risk analysis and the differences identified in the substantial equivalency comparison table, the following verification and validation activities were completed to ensure that the differences between the non-osseointegrated predicate device and the osseointegrated version of the Otomag Bone Conduction Hearing System do not raise new questions of safety and effectiveness.

1.2. Risk Areas identified as a result of risk analysis included:

- 1.2.1. Material Biocompatibility
- 1.2.2. Implant Anchoring
- 1.2.3. Force Application to patient skin / mastoid

1.3. The following section outlines the categories of Verification and Validation testing that were conducted and rationale for those areas where additional testing was unnecessary as a result of the scope of changes.

1.4. Performance Testing:

1.4.1. **Implant Anchoring:** Implant Anchoring using titanium bone screws (Liebinger 4mm facial plating screws) were validated for this use in validation protocol (b)(4) [redacted] to this overall submission.

1.4.2. **Force Application:** Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device. This validation is documented in validation protocol (b)(4) [redacted] to this overall submission.

1.5. Material Biocompatibility:

1.5.1. Refer to Section 17 and Appendix B of the overall submission for information on Biocompatibility.

1.6. Sterilization Validation including Sterile Packaging:

1.6.1. Refer to Section 16 and Appendix D of the overall submission for information on Sterilization Validation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 21: Performance Testing – Animal

Not Applicable: Animal test data is not included as a part of this submission

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 22: Performance Testing – Clinical

Not Applicable: Clinical data is not included as a part of this submission

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix A

ISO 14971:2007: Medical devices – application of risk management to medical devices;

FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices

ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ISO 14971:2007: Medical devices – application of risk management to medical devices

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971 Application of risk management to medical devices - 2007

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-40		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971 Application of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

FDA G95-1 Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Attachment C- Biocompatibility Flow Chart for Selection of Toxicity Tests for 510(k) used to select appropriate testing options

DESCRIPTION

Attachment C is used to determine which testing options/requirements are appropriate

JUSTIFICATION

See above

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 17665-1 Sterilization of Healthcare Products - Moist Heat - Part 1 ... Development, Validation and Routine Control - 2006

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-261		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 17664-1 Sterilization of medical devices: Info. provided by the manuf. for the processing of resterilizable medical devices -'04

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☑
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 17664-1 Sterilization of medical devices: Info. provided by the manuf. for the processing of resterilizable medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

The standard was followed although the device is not intended to be resterilized; it is provided to the end user non-sterile.

DESCRIPTION

Instructions and parameters are provided for proper moist heat sterilization of the device prior to use.

JUSTIFICATION

Information is appropriate for sterilization of the device prior to use.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223 Medical Devices: Symbols to be used with medical device labels, labelling and information to be supplied - 2007

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-31		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☑
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 15223 Medical Devices: Symbols to be used with medical device labels, labelling and information to be supplied

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Appendix B

Magnetic Implant Specification

Material 3_7065 Ti Gr 4

Material 3_7165 Ti6AlV4

Fotoplast Biocompatibility Information

Translation Certificate

898

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Magnetic Implant Specification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Implant Specification

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(b)(4) Implant Specification

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Appendix C

(b) (4) - Otomag Magnetic Implant Static Force Verification / Validation Protocol

(b) (4) - Otomag Magnetic Implant Screw Retention Force Validation Protocol

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)Verification and Validation Protocol

(b)(4)Verification and Validation Protocol

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(b)(4)Verification and Validation Protocol

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Vasant Dasika

Subject: 510(k) Number K102199/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NT	NSE for new technology
☐	NI	NSE for new intended use
☐	NP	NSE for lack of performance data
☐	NN	NSE raises new types of safety and effectiveness questions
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank?* (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

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Neonate/Newborn (Birth to 28 days)	✓
Infant (29 days -< 2 years old)	✓
Child (2 years -< 12 years old)	✓
Adolescent (12 years -< 18 years old) 25 yrs	✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)	✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.

Regulation Number 874.3300

Class* II

Product Code LXB

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) ENTB (Branch Code) 5/23/11 (Date)

Final Review: [signature] (Division Director) 5/23/11 (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K102199/S002

Date: May 18, 2011
To: The Record
From: Vasant K. Dasika, Ph.D.

Office: ODE
Division: DONED

510(k) Holder: Sophono, Inc.
Device Name: Otomag Bone Conduction Hearing System
Contact: Clay Anselmo, President and CEO, Reglera LLC
Phone: 303-223-4303
Fax:
Email: anselmoc@reglera.com

Recommendation: Substantially Equivalent

The prior deficiencies from the January 20, 2011 telephone hold letter, subsequent interactive review items from February to April 2011, and interactive review items from S002 have all been resolved. In summary, the sponsor acceptably responded to FDA concerns in the following four areas:

1. Clinical performance data;
2. Retention/coupling of the sound processor and implant;
3. Adequate transmittance of sound vibration through complete device system; and
4. Sterilization.

See the remainder of this lead review memo for details on how each of the above issues are resolved and for the acceptable rationale provided by the sponsor that the Alpha 1(M) device system is substantially equivalent to the predicate devices.

Review Team

Although all review team members from any review cycle are listed below, only reviewers who had outstanding questions to S001 (or the subsequent interactive material) are identified with a '+' as only these individuals reviewed S002.

Vasant Dasika, Ph.D.	Lead Reviewer & Electrical Engineering+
Angie Khan, M.D.	Clinical+
Frank Curto, M.D.	Clinical
Sue Rudy	Sterility+
Shu-Chen Peng, Ph.D.	Audiology+
Jim Kane, Ph.D.	Audiology
Daniel Clupper, Ph.D.	Materials Science & Mechanical Engineering+

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Vasant Malshet, Ph.D.	Biocompatibility
Nandu Nandkumar, Ph.D.	Branch Chief, ENTB
Eric Mann, M.D., Ph.D.	Clinical Deputy Director, DONED

I. Purpose and Submission Summary

The 510(k) holder would like to introduce a modified Otomag Bone Conduction Hearing System into interstate commerce.

The modification "adds a new configuration into the Otomag Bone Conduction Hearing System family. The new configuration (Alpha 1(M)) uses an implantable magnet as a fixation system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193 – Otomag Bone Conduction Hearing System – May 18, 2010."

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X	X	
Are "cleaning" instructions included for the end user?	X		

Description of the Osseointegrated Alpha 1 (M) Configuration (p. 13-4; 41 of 192 of K102199)
In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Osseointegrated Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 1 below illustrates the configuration; Figure 2 shows the magnetic spacer in isolation; and Figure 3 shows the sound processor attached to the spacer.

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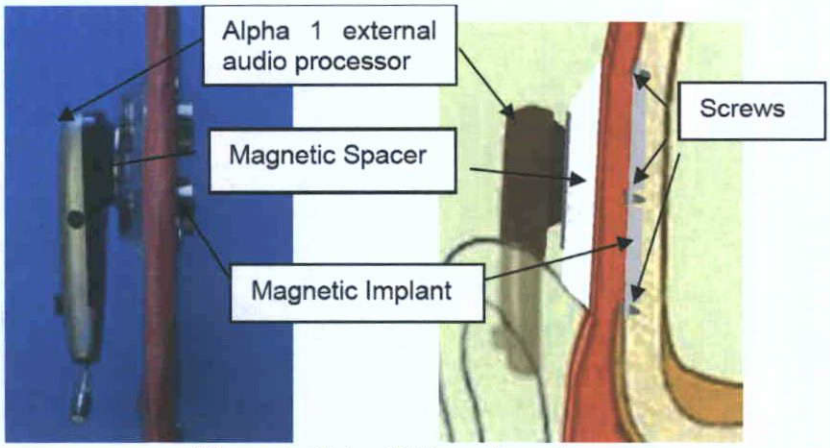

Figure 1. Alpha 1(M) configuration.

Figure 2. Magnetic spacer in Alpha 1(M) configuration.

Figure 3. Sound processor with metal disc attached to magnetic spacer.

For the Alpha 1(M) configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

(b)(4)

[redacted]

Comment (Lead Reviewer): *In S001, the sponsor includes **5** magnetic spacers instead of 4 to provide*

(b)(4)

[redacted]

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(b)(4) [redacted]

The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical implant site.

Osseointegrated Magnetic Implant (p. 13-7; 44 of 192)
The implant consists of two (b)(4) [redacted] magnets hermetically sealed in a titanium housing as shown in Figure 4. The implant is manufactured for Otomag by (b)(4) [redacted] Validation documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in Appendix C to the overall submission. Each implant is welded, cleaned, and 100% leak tested by the manufacturer using formally validated processes.

Figure 4. Magnet implant.

Refer to the review memos of Drs. Clupper and Khan of the original submission (K102199) for additional details about device description. Refer to Ms. Rudy's review memo of the original submission for a table of device components.

IV. Indications for Use

The sponsor provides the following indications for use statement in the original submission (K102199). The indications for use have not changed for S001 or S002.

510(k) Number: K102199

Device Name: Otomag Bone Conduction Hearing System

Indications for Use: The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

• Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

• Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

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• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Drs. Peng and Khan have reviewed the Indications for Use and deem them acceptable.

V. Predicate Device Comparison

The sponsor claims two predicate devices:

- The Otomag Bone Conduction Hearing System, Unmodified Version, Alpha 1(S) in a headband or softband configuration– K100193
- Xomed Audiant Bone Conductor - K855059 / K861971 (added in S001)

The following table from section 14 of S001 compares the subject device with the two predicate devices:

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	874.3300	Identical to both predicates
Class	Class II	Class II	Class II	Identical to both predicates
Product Code	LXB	LXB	LXB	Identical to both predicates
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	The Audient Bone Conductor is a device for Conductive Hearing Loss not correctable by conventional reconstructive surgery	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical to Alpha 1(S) Substantially Equivalent to ABC
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Audiant Bone Conductor is a device for Conductive Hearing Loss not correctable by conventional reconstructive surgery The ABC will, in most cases, essentially close the air-bone gap. The patients hearing acuity with the ABC will be limited to the patients sensorineural acuity (cochlear reserve). In most cases, the ABC patient will not attain hearing thresholds less than (better than) the patients pre-op audiometric bone conduction thresholds. A prospective patients's performance with the ABC can generally be predicted by the results obtained with a conventional Bonde Conduction Hearing Aid. Subjective sound quity and comfort may be higher with the ABC, however. Any prospective ABC patient who has not attempted to utilize a conventional B.C. aid should be allowed a trial evaluation of the same and offered the choice of a B.C. aid or the ABC before implantation. In general, the prospective ABC candidate should meet all of the following criteria: • A high level of commitment and complete understanding of the implications of surgical implantation • Inability or demonstrated unwillingness to utilize a conventionla air or bone conduction hearing aid. A conventional aid should be adequately trialed by	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
		the patient. • A substantial bilateral conductive impairment with adequate sensori-neural acuity. Audiometric bone conduction thresholds in the speech frequencies (500, 1K, 2K) on the implant side should: o Average not more than 25 dB o Contain no individual frequency greater than 40. • Unaided speech reception threshold not less than 40 dB in the imparted ear seech discrimination score of not less than 80%.		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patient's bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patient's bone rather than via the middle ear - a process known as direct bone conduction.	Identical to both predicates
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an external electronic transducer, a battery, volume controls, and an external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical to Alpha 1(S) Substantially Equivalent to ABC
Transducer	Traditional bone conduction transducer	Inductive coupling of an external magnet and coil to an implanted magnet	Traditional bone conduction transducer	Identical to Alpha 1(S)
Power Supply	Zinc-air battery	AA battery	Zinc-air battery	Identical to Alpha 1(S) Substantially Equivalent to ABC
Sound Processing	Digital	Analog	Digital	Identical to Alpha 1(S)
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Simple volume control	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical to Alpha 1(S)
Frequency Processing Range	125 – 8kHz	336– 12kHz	125 – 8kHz	Identical to Alpha 1(S)
Max Gain (60dB SPL)	38 dB	Unavailable	38 dB	Identical to Alpha 1(S)
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	Unavailable	29 dB	Identical to Alpha 1(S)
Accessories/Options	Direct audio input via FM jack	Telecoil	Direct audio input via FM jack	Identical to Alpha 1(S)

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Patient Contact Materials for Biocompatibility Purposes (external device)	Fotoplast-Lac	Biocompatible plastic	Fotoplast-Lac	Identical to Alpha 1(S) Substantially Equivalent to ABC
Patient Contact Materials for Biocompatibility Purposes (external device)	Titanium Grade 2 and 4	Titanium Grade 5 and Silicone Elastomer	Titanium Grade 2 and 4	Identical to Alpha 1(S) Substantially Equivalent to ABC
Sterilization	Steam sterilization of surgical implant	Provided Sterile	Steam sterilization of surgical implant	Identical to Alpha 1(S) Substantially Equivalent to ABC
Peak Output at 90 dB SPL	115 dB	118 dB	115 dB	Identical to Alpha 1(S) Substantially Equivalent ABC
Frequency range per ANSI S3.22-2009	280-5000 Hz	336– 12kHz	280-5000 Hz	Identical to Alpha 1(S) See Discussion Below
Total harmonic distortion per ANSI S3.22-2009	<3%	3-9%	<3%	Identical to Alpha 1(S) Substantially Equivalent to ABC
Equivalent input noise:	17 dB SPL	Unavailable	17 dB SPL	Identical to Alpha 1(S)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Battery current drain	0.95 mA	52 mA	0.95 mA	Identical to Alpha 1(S)
Processor:	16 Band, 4 Channel WDRC	Standard OP Amp	16 Band, 4 Channel WDRC	Identical to Alpha 1(S)
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	None	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical to Alpha 1(S)
Compression Attack Time (minimum)	0.25 ms	1 ms	0.25 ms	Identical to Alpha 1(S) See Discussion Below
Compression Release Time (maximum)	8192 ms	350 ms	8192 ms	Identical to Alpha 1(S) See Discussion Below
Patient Volume Control Wheel	38 dB Range	Unavailable	38 dB Range	Identical to Alpha 1(S)
Force Application Methods	Headband or Softband	Magnetic to implanted magnet	Magnetic to implanted magnet (Alpha 1(M) Version)	Identical to ABC
Connection of implant to the skull	Not Applicable	1 Titanium screw	5 Titanium Screws	Substantially Equivalent – see discussion below

The sponsor claims five major differences between the subject and predicate devices:

1. **Indications for use:** The new Alpha 1(M) configuration is indicated for patients age 5 and older whereas the cleared (S) configuration is indicated for all ages.

2. **New patient contact materials:** The Magnetic Implant in the Alpha 1(M) configuration contains new patient contacting materials: Titanium Grades 4 and 5.

3. **Sterilization:** The Magnetic Implant is provided clean but not sterile and requires sterilization via gravity or prevacuum steam sterilization at the healthcare facility prior to implantation.

4. **Method for coupling sound processor to patient, i.e., "Force Application Method":** The Alpha 1(M) configuration utilizes a magnetic field to apply the necessary force to the patient's mastoid to conduct sound. The force generated by the magnetic field is adjustable through 5 different strength magnetic spacers provided with the product. In contrast, the cleared Alpha 1(S) device uses either elastic material (in the softband version) or spring tension (in the headband version), to couple the sound processor to the patient's head. The predicate therefore uses no implanted components. The sponsor also claims that the Xomed Audiant Bone Conductor also "employs the same technology as the Alpha 1(M) configuration for the attachment of the sound processor."

5. **Connection of the implant to the skull.** Five 4-mm screws are used to hold the Alpha1 (M) implant to the skull while the sponsor claims that the Audiant implant uses one 4 mm length screw.

The sponsor claims that the above differences do not negatively impact safety or effectiveness and do not raise any new safety or effectiveness questions.

The sponsor also (e.g., in S002 in response to deficiency #4 of January 20 AI letter) compares their Alpha1 (M) device with the Cochlear BAHA when used with the implant/abutment even though the BAHA is not identified as a predicate. The sponsor claims that the risks of the Alpha 1 (M) are less than those shown for "legally marketed competitive [bone anchored hearing aid] devices" and that the "significant lifestyle and safety benefits that result with the use of the Alpha 1(M) ... fully outweigh the risks."

VI. Labeling

The sponsor lists 4 labeling materials of the Otomag system that have been revised for the Alpha 1(M) configuration:

1. Physician's Manual
2. Patient User Manual
3. Magnetic Implant Package Label
4. Revised Primary Device Labels

This information was reviewed primarily by Drs. Khan, Peng, and Ms. Rudy and found acceptable. Please refer to the review memos of these reviewers for details.

VII. Sterilization/Shelf Life/Reuse

The sponsor addressed the final sterility related deficiencies (numbered 8 to 12) in S002.

This information was reviewed by Ms. Rudy and was found acceptable. Refer to Ms. Rudy's review memo of S002 and the deficiencies section of this lead review memo for details.

VIII. Biocompatibility

This information was provided in the original submission which Dr. Malshet reviewed and determined that the biocompatibility information is acceptable. Refer to Dr. Malshet's review memo of K102199 for details.

IX. Software

I reviewed this information and accept the sponsor's justification for not providing complete software documentation. The following comment is retained from the lead review memo of K102199:

(b)(4)

[redacted]

X. Electromagnetic Compatibility (EMC) and Electrical, Mechanical and Thermal Safety

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

system in both a skull model and a simulated section of temporal bone. Sound transmission was

(b)(4)

[redacted]

XI. Performance Testing – Bench

Bench performance testing for S002 is summarized in Section X above. Bench performance testing for S001 and the original submission are summarized in the respective review memos.

XII. Performance Testing – Animal

No animal performance-testing data were provided.

Comment (Lead Reviewer): *This is acceptable as the sponsor demonstrates substantial equivalence through the combination of bench performance testing and clinical performance testing.*

XIII. Performance Testing – Clinical

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

The indication statement is the same as the indication for the predicate except for the addition that the (subject) Alpha 1(M) configuration requires a surgically placed implant and is indicated for ages 5 and older only. The Alpha 1(S) configuration predicate does not require an implant and is indicated for all ages.

2. Explain why there is or is not a new effect or safety or effectiveness issue:

The change made in the new indication statement does not raise any new safety of effectiveness issues because the age range has been appropriately specified and deemed acceptable by the clinical reviewers.

3. Describe the new technological characteristics:

New technological characteristics include magnetic coupling of the sound processor to the patient's skull via a magnetic implant and (externally worn) magnetic spacer. The Sophono Alpha 1(S) predicate instead uses a headband or softband to couple the sound processor to that patient's skull and there is no implant. For the Audiant predicate, sound vibration does not actually originate from the exterior sound processor but instead, operates like a decoupled speaker circuit, or more specifically a solenoid and magnet, such that the sound processor emits a modulated magnetic field which induces motion of the implanted magnet. The magnetic coupling and sound-transmission method of the subject device therefore differs from that of each predicate device.

4. Explain how new characteristics could or could not affect safety or effectiveness:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The implanted component in the subject device poses several safety risks, including those relating to potential extrusion and infection. In addition, the safety and effectiveness of the proposed magnetic coupling system have not been established.

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

Bone-conduction hearing-aid devices are not new. Therefore, the general set of safety and effectiveness questions remains constant across various types of devices: adequate and safe coupling/retention and adequate sound transmission.

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The European clinical data together with bench performance data, including those provided during interactive review and in S002, provide reasonable evidence that the subject Alpha 1(M) device is as safe and effective as the Alpha 1 (S) predicate device.

XV. Deficiencies

All 14 deficiencies generated in response to S001 and during subsequent interactive review have been resolved. See attached consults and e-mails from review team members for details regarding acceptance of individual deficiencies. For completeness, all deficiencies from S001 are reproduced below, together with a summary of the sponsor's response and reviewer comment for why each response is accepted.

(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIA-Mail@fda.hhs.gov or 301-796-8118

Summary of Response: Sophono has previously submitted simulated use validation data demonstrating

(b)(4)

[redacted]

The sponsor has provided acceptable justification that the device will stay securely attached for users

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

Response 6: Both the Physician Manual and the Patient Manual already contain Warning statements stating that patients are not to undergo MRI if they have the magnetic implant, and the primary product labeling for the Alpha 1(M) configuration contains the appropriate symbol for the device not being compatible with MRI. As requested by FDA, the MRI warning statements in the previous versions of the manual have been updated to include explantation if MRI is required.

As additionally requested by FDA, the contraindications for the Alpha 1(M) device configuration have been amended to contain statements that specifically state that MRI should not be performed on patients with the magnetic implant and if MRI is absolutely necessary, the explantation is required prior to scanning. The contraindications for the device read as follows. See Appendices 2, 3 and 15 to this response for revised versions of the Physician and Patient Manuals and the 510(k) Summary containing the revised Contraindications.

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- *A hearing loss of sudden onset;*
- *A rapidly progressing hearing loss;*
- *Pain in either ear;*
- *Tinnitus of sudden recent onset, or unilateral tinnitus;*
- *Unilateral or markedly asymmetrical hearing loss of unknown origin;*
- *Vertigo (e.g. dizziness)*

Patients using the Alpha 1(M) configuration of the device, which utilizes a magnetic implant, should not undergo magnetic resonance imaging (MRI) without having the implant removed prior to scanning.

As described in detail in Response 4 above, Sophono strongly believes the benefits of the Alpha 1(M) configuration outweigh the devices risks including children 5 years and older. Our Indications for Use statement regarding this population is consistent with other bone conduction hearing devices that utilize an implant for attachment and we have provided sufficient data showing why the Alpha 1(M) device configuration, based on its design, is likely to have significantly fewer complications than competitive devices.

Comment (Lead Reviewer): *Per Dr. Khan's review, the response is accepted. The rationale is that the thickness of the skull bone is relatively developed to permit safe use of the device for the lower indicated age range of 5 years. It is noted that the age range is the same as that for the (implanted) BAHA device system referred to in the sponsor's response.*

(b)(4)

of S001 insufficiently demonstrate that your device is as safe and effective as the predicate devices

(b)(4)

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

22

(b)(4)

[redacted]

Deficiency 9: Your revised physician instructions (response to deficiency #5c) advise the use of a specific chemical indicator (CI) to be placed inside the sterilization pouch with the implant. We agree with the methods used in your steam sterilization validation study. However, since no specific CI was validated for use, facilities can use any commercially available CI that is labeled for the cycle parameters they are using, and it is not important that they use exactly the brand and catalog number of the CI you have identified. Therefore, please revise your instructions to be more general, simply replacing your specific CI recommendation with a one-line step in the instructions reminding users that a steam indicator strip labeled for the specific cycle parameters should be put into the pouch with the implant.

Response 9: As requested by FDA, the Physician Manual has been revised to contain a single line reminding users that a steam indicator strip labeled for this specific cycle should be put into the pouch with the implant. The revised Physician Manual is contained in Appendix 2 to this response.

Ms. Rudy reviewed this response and finds it acceptable; see Ms. Rudy's review memo for details.

Deficiency 10: You clarify (response to deficiency #7) that your "go, no-go" test devices are used in medical settings for multiple patients. You now advise "prior to using with another patient, the accessories must be cleaned with a Clorox® type disinfecting wipe." Better language for medical settings would be, "...cleaned and disinfected using an EPA-registered hospital disinfectant wipe." Please make this change for accuracy and broadest applicability.

Response 10: As requested by FDA, the Physician's Manual has been revised to read ".....cleaned and disinfected using an EPA-registered hospital disinfectant wipe." The revised Physician Manual is contained in Appendix 2 to this response.

Ms. Rudy reviewed this response and finds it acceptable.

Deficiency 11: You add language after your contraindications in the patient manual (response to deficiency #10b) as reproduced below:

"Note: While the contraindications above may affect the process of hearing aid fitting, it should be noted that the treatment plan for use of the Otomag Alpha 1 sound processor may vary with worsening or improving hearing. Your treatment plan will be determined by your primary care physician."

Primary care physicians are not skilled or credentialed for making or adjusting a treatment plan that would involve the subject device. Please replace "primary care physician" in this note with language such as "your hearing health specialists." Your response to deficiency #13 has the same issue, so please replace the "primary care physician" language there as well.

Response 11: As requested by FDA, the wording in this statement has been revised to specify the language suggested by FDA. This statement now reads:

"Note: While the contraindications above may affect the process of hearing aid fitting, it should be noted that the treatment plan for use of the Otomag Alpha 1 sound processor may vary with worsening or improving hearing. Your treatment plan will be determined by your hearing health specialists."

This revised language has been used in Section 7 (response to previous deficiency 13) as follows:

"If you experience any device related issues, develop unexpected or excessive symptoms, or have general concerns or questions, please contact your hearing health specialists."

The revised Patient Manual is contained in Appendix 3 to this response.

Ms. Rudy reviewed this response and finds it acceptable.

Deficiency 12: Your revised patient manual (Appendix 2) includes magnet information with precautions on page 17 (section 6). All safety precautions should appear at the beginning of the document in a complete list of precautions. You may reiterate any precautions as you wish throughout the document. To place a new precaution on page 17, is to risk that it will never be read or heeded and inappropriately diminishes its importance. Please revise your patient instructions accordingly.

Response 12: The two precautionary statements, from Page 17, section 6 of the Patient Manual referred to in this deficiency are contained in the master list of precautions on pages 7 and 8 of the Patient Manual. These statements are contained in bullet 3 (Caution Section, bottom of page 7) and bullet 2 (Caution Section, top of page 8).

Ms. Rudy reviewed this response and finds it acceptable.

Deficiency 13: In your revised clinician manual, please specify 510(k) numbers (if available) for the recommended craniomaxillofacial titanium self-tapping screws for affixing the implant to the skull.

Response 13: As requested by FDA, the 510(k) numbers for the recommended screws have been added to the Physician Manual. The revised Physician Manual is contained in Appendix 2 to this response.

Ms. Rudy reviewed this response and finds it acceptable.

Deficiency 14: In Section 19 Electromagnetic Compatibility and Electrical Safety of your original

(b)(4)

[redacted]

XVI. Contact History

May 23, 2011: Recommended that the sponsor make changes to patient and physician manuals regarding magnet information and warning/precautions relating to the use of the device system with pacemakers or implantable cardioverter defibrillator devices.

May 20, 2011: Requested and received confirmation from sponsor that titanium welding processes in final device will be same as those tested in submission and used in clinical study. Requested inclusion of precautions/warnings in the Patient Manual given that Apha 1(M) configuration contains an implanted magnetic, metallic component. Sponsor provided revised Patient and Physician manuals the same day.

May 19, 2011: FDA received requested revisions of 510(k) summary. Received requested revision of Physician Manual. Received requested additional information regarding EMC and immunity testing.

May 18, 2011: Requested a detailed breakdown of the ages of the subjects in clinical study. Received this information the next day.

May 11, 2011: Requested and received confirmation from sponsor that all interactive review items have been resolved and will be appropriately referenced in S002.

May 9, 2011: Provided informal feedback to sponsor on vibration test protocol.

May 1, 2011: Interactively received requested vibration test protocol.

April 25, 2011: Sponsor provided informal draft of S002, i.e., their draft response to S001 hold letter.

April 20, 2011: Provided feedback on vibration test protocol, received concurrence from sponsor.

April 18, 2011: Clay Anselmo (sponsor) phoned Lead Reviewer requesting clarification on two of the April 14, 2011 FDA followup questions 2 and 3. Sponsor also asked about general strategy on how to respond. Dasika provided clarification and instructed Anselmo to respond to last official AI letter (to S001) and identify where subsequent interactive review has resolved related concerns.

April 14, 2011: Provided informal comments to sponsor on draft document "(b)(4) [redacted]
(b)(4) [redacted]

March 7, 2011: Received copies of requested articles from sponsor.

March 3, 2011: Received sponsor response to informal interactive review items of February 22, 2011.

February 22, 2011: Following February 15, 2011 teleconference, lead reviewer e-mailed sponsor 3 followup questions, plus an additional deficiency concerning EMC testing of complete device system. Received confirmation same day that sponsor will work on preparing responses.

February 15, 2011: Drs. Nandkumar, Dasika, Clupper, Khan, and Peng held teleconference with sponsor (Jim Kasic and Clay Anselmo). See the attached revised agenda for a list of items discussed.

February 9, 2011: Received expanded agenda and video clips from sponsor for teleconference scheduled for February 15, 2011.

January 24, 2011: Sponsor requested teleconference with FDA. FDA responded same day and asked for detailed agenda.

January 20, 2011: E-mailed sponsor AI letter for S001 containing 13 deficiencies and put submission on hold that day.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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January 16, 2011: Lead Reviewer e-mailed sponsor 14 deficiencies for interactive review. Sponsor provided a response to deficiencies on January 19, 2011.

January 14, 2011: Lead reviewer e-mailed sponsor to request a copy of cited Raicevich et al. (2008) paper. Sponsor provided requested information on same day.

September 23, 2010: Lead Reviewer e-mailed sponsor that additional information is needed to continue review of K102199 and informed the sponsor that the submission will be on hold until the information is provided.

September 22, 2010: Lead Reviewer e-mailed sponsor question to clarify magnetic spacers provided in the sample. Sponsor provided requested clarification the next day.

September 15, 2010: Lead Reviewer requested device sample from sponsor. Sponsor indicated on same day that this was possible and had some clarification questions: purpose, use, and whether sample will be returned. Lead reviewer responded on September 16, 2010. Sample received on September 22, 2010.

August 9, 2010: Lead Reviewer requested e-copy of K102199 from sponsor. Sponsor provided a download link to the submission the same day.

XVII. Recommendation

Substantially Equivalent (SE).

Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB

Reviewer — Date 5/23/11

Branch Chief — Date 5/23/11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dasika, Vasant

From:	(b)(4) [redacted]
Sent:	Monday, May 23, 2011 11:51 AM
To:	Dasika, Vasant; jim.kasic@sophono.com
Cc:	Nandkumar, Srinivas
Subject:	RE: Magnets and pacemakers, ICDs
Follow Up Flag:	Follow up
Flag Status:	Purple
Attachments:	App_3_Patient Manual_Alpha1M (V9)_R1.pdf; App_2_Physicians_Manual_Alpha1M (V10)_R1.pdf

Hi Vasant,

As you requested, the modifications you requested have been made to both the Patient and Physician manuals. The revised versions are attached.

Thanks for all your help and feedback!

Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Monday, May 23, 2011 9:29 AM
To: (b)(4) [redacted]
Cc: Nandkumar, Srinivas
Subject: Magnets and pacemakers, ICDs
Importance: High

Hi Clay-

We recommend that you make the following changes to your labeling:

1) Please remove the sentence, "None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker." from both your patient and clinician manuals.

2) Please add a warning to the patient and physician labeling that the device configurations (both Alpha 1(S) and Alpha 1(M)) contain magnets which could impact the performance of pacemaker or implantable cardioverter defibrillator (ICD) devices. The magnets of the softband/headband of the Alpha 1(S) and the magnetic spacer of the Alpha 1(M) should therefore be kept away from a pacemaker or ICD.

3) Please add a precaution to the patient and physician manual that any patient with a pacemaker or ICD should consult their care provider for safe use of the Otomag system with their cardiac medical device.

Please provide these revised manuals to me within 30 minutes as time is of the essence.

Thank you,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Vasant

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5/23/2011

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Dasika, Vasant

From: (b)(4) [redacted]
Sent: Friday, May 20, 2011 5:10 PM
To: Dasika, Vasant
Subject: RE: warnings and precautions in patient manual
Follow Up Flag: Follow up
Flag Status: Purple
Attachments: App_2_Physicians_Manual_Alpha1M (V9)_R1.pdf; App_3_Patient Manual_Alpha1M (V8)_R1.pdf

Here you go.

Thanks,
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Friday, May 20, 2011 2:44 PM
To: 'Clay Anselmo'
Subject: RE: warnings and precautions in patient manual

hi Clay- A minor clarification:

Insertion of the battery

A Size 675 battery is required for your Alpha I Sound Processor.

Please go ahead and send the revised versions.

thanks,
Vasant

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Friday, May 20, 2011 4:21 PM
To: Dasika, Vasant
Subject: RE: warnings and precautions in patient manual

Will do. Anything else on the manuals before I send the next versions over to you?

Thanks
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Friday, May 20, 2011 2:20 PM
To: 'Clay Anselmo'
Subject: RE: warnings and precautions in patient manual

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Clay- Some suggestionsthat you may consider. Please revise as you see fit.

- The Alpha 1(M) version of this Bone Conduction Hearing system utilizes a metal, magnetic implant. Patients must take care when in the proximity of devices that could influence the implant. Devices such as security systems, metal detectors, radio frequency identification (RFID) systems, and electronic article surveillance (EAS) system may affect or be affected by the implant. You should avoid prolonged exposure to these systems and should not stand near, lean on or linger in the vicinity of such devices.

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Friday, May 20, 2011 4:05 PM
To: Dasika, Vasant
Subject: RE: warnings and precautions in patient manual

Hi Vasant –

Will you please review the following modifications to the Patient Warnings and Cautions to see if it addresses your concerns. I am not sure I completely understood your second request, so please comment.

The MRI warning now reads

- Do not undergo scanning with Magnetic Resonance Imaging (MRI) if you are using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. For patients with the Alpha 1(M) magnetic implant, the implant must be removed prior to scanning.

In addition to the airport security system warning present in the manual I would propose adding the following precaution:

- The Alpha 1(M) version of this Bone Conduction Hearing system utilizes a metal, magnetic implant. Patients must take care when in the proximity of devices that detect or interact with metalic implants. Devices such as security systems, metal detectors, radio frequency identification (RFID) systems, and electronic article surveillance (EAS) system may be affected by the presence of your magnetic implant. You should avoid prolonged exposure to these system and should not stand near, lean on or linger in the vicinity of these devices.

Please let me know if these address your concern.

Thanks
Clay

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Friday, May 20, 2011 1:37 PM
To: 'Clay Anselmo'
Cc: jim.kasic@sophono.com; Nandkumar, Srinivas
Subject: warnings and precautions in patient manual
Importance: High

Hi Clay - Please address the following deficiencies relating to warnings and precautions in your patient manual and send me the revised copy ASAP (by COB Eastern time today or sooner).

1) In the warning for MRI, please specifically add the implant of the Alpha 1(M) configuration needs to be surgically explanted before undergoing an MRI, similar to the statement provided earlier in the contraindications.

2) The current precaution concerning airport security systems does not specifically or sufficiently address the risks associated with the implanted component of the Alpha 1(M) configuration. Please revise/add all appropriate precautions/warnings given that a metallic, magnetic implanted component is part of the Alpha 1(M) configuration. Please ensure that the following are sufficiently addressed: security systems, metal detectors, RFID systems, EAS systems, that users should not linger near or lean on metal detector and anti theft systems, etc.

Thank you for your continued prompt attention to our requests.

Vasant

Vasant K. Dasika, PhD

Biomedical Engineering Scientific Reviewer

Ear, Nose, and Throat Devices Branch

DONED/ODE/CDRH

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10903 New Hampshire Avenue

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Email: Vasant.Dasika@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dasika, Vasant

From: (b)(4) [redacted]
Sent: Thursday, May 19, 2011 11:23 PM
To: Dasika, Vasant
Cc: jim.kasic@sophono.com
Subject: RE: 510(k) summary and Physician manual revisions
Attachments: FDA question EMC 4.pdf

Hi Vasant,

Attached, please find the additional information you requested regarding the Immunity Testing. I am working on the 510(k) summary and will be sending the requested updates shortly.

Thanks,
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Thursday, May 19, 2011 3:50 PM
To: 'Clay Anselmo'
Cc: jim.kasic@sophono.com
Subject: RE: 510(k) summary and Physician manual revisions

Hi Clay- The revised summary is more accurate. (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Thursday, May 19, 2011 5:10 PM
To: Dasika, Vasant
Cc: jim.kasic@sophono.com
Subject: RE: 510(k) summary and Physician manual revisions

Hi Vasant,

I believe the attached version of the 510(k) Summary addresses both your comments and the requirements specified in the link you sent, but please take a quick look and let me know if you need anything more.

Thanks
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Thursday, May 19, 2011 1:43 PM
To: 'Clay Anselmo'
Cc: jim.kasic@sophono.com
Subject: RE: 510(k) summary and Physician manual revisions

hi Clay-

For the 510(k) summary, please actually include more than just a statement on the bench testing. Please describe in sufficient detail the bench testing that was conducted to demonstrate equivalence in terms of both coupling and sound transmission. Note that the 510(k) summary is a stand alone document which should sufficiently describe the device features and testing that supports a substantial equivalence determination.

You can send me a draft version and I can take a look.

Best,
Vasant

ps. Please refer to the following guidance regarding what information to minimally include in the summary (and conclusions section):

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Description of EMC Testing- Alpha 1 Hearing System

EN 60601-1-2: Immunity Standards

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dasika, Vasant

From: Clay Anselmo [anselmoc@reglera.com]
Sent: Thursday, May 19, 2011 3:32 PM
To: Dasika, Vasant
Cc: jim.kasic@sophono.com
Subject: RE: 510(k) summary and Physician manual revisions
Attachments: App_2_Physicians_Manual_Alpha1M (V8)_R1.pdf

Hi Vasant,

Attached is the revised Physician's Manual as you requested. The Symbol for Latex Free and the corresponding row in that table has been removed. The statement regarding the product containing no natural rubber latex remains on page 20 of the Physician Manual and in two locations in the Patient Manual. Please confirm that this is correct.

I will be working on the 510(k) summary now.

Thanks,
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Thursday, May 19, 2011 1:10 PM
To: 'Clay Anselmo'
Cc: jim.kasic@sophono.com; Nandkumar, Srinivas
Subject: 510(k) summary and Physician manual revisions
Importance: High

Hi Clay-

Please address the following points in your 510(k) summary and physician manual. Please provide revised versions of these materials to me by 12 PM Eastern time on Friday May 20, 2011. Please also provide to me the EMC testing clarification that we had requested by tomorrow 10 AM Eastern time at the very latest.

Regards,

Vasant

510(k) Summary:

(b)(4)

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Physician Manual:

Please remove the "latex-free" symbol from p. 8. We request this change because there is no testing that can currently confirm the latex-free claim. The current text, "product contains no natural rubber latex" acceptably communicates that there is no latex in the raw materials and that no latex is added during the manufacturing process. Please ensure that you have records on file to support this statement.

Vasant K. Dasika, PhD

Biomedical Engineering Scientific Reviewer

Ear, Nose, and Throat Devices Branch

DONED/ODE/CDRH

US FDA

10903 New Hampshire Avenue

WO66, Room 2443

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Dasika, Vasant

From: (b)(4) [redacted]
Sent: Thursday, May 19, 2011 11:40 AM
To: Dasika, Vasant
Cc: jim.kasic@sophono.com
Subject: RE: AI Response Submitted

Hi Vasant,

(b)(4) [redacted]

Does this adequately answer your question? The immunity data is coming your way shortly.

Thanks,
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Wednesday, May 18, 2011 10:13 AM
To: 'Clay Anselmo'
Cc: jim.kasic@sophono.com
Subject: RE: AI Response Submitted

(b)(4) [redacted]

It also looks like revision of your 510(k) summary will likely be necessary. I will contact you shortly with specific items and will appreciate your prompt attention to these requests.

Regards,

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Vasant

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Thursday, May 12, 2011 11:12 AM
To: Dasika, Vasant
Subject: RE: AI Response Submitted

Hi Vasant,

I tried to compress the file, so let's see if this goes through as a single document before I tried to split it up. Please let me know if you get this.

Thanks,
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Wednesday, May 11, 2011 6:55 PM
To: 'Clay Anselmo'
Cc: jim.kasic@sophono.com
Subject: RE: AI Response Submitted
Importance: High

Hi Clay- Thank you for your e-mail. Unfortunately I was unable to access the yousendit link (may be due to a firewall issue). Could you please e-mail the submission to me in parts with each part as large a file as your mail system permits? I believe that the mail system on my end permits receipt of large attachments (>20 MB).

Regards,
Vasant

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Wednesday, May 11, 2011 4:05 PM
To: Dasika, Vasant
Cc: jim.kasic@sophono.com
Subject: AI Response Submitted

Hi Vasant,

Our response went to the Document Mail Center via Fed-X today. I uploaded an electronic copy for you via YOUSENDIT. You should be receiving an email with a link to download very shortly. I just wanted to say thank you again for all the interactions on this submission. You have been very helpful.

Thanks
Clay

Clay Anselmo
President and CEO
Reglera LLC
(303) 223-4303 (Direct)
(303) 832-6700 (Fax)
(303) 907-2955 (Cell)

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Dasika, Vasant

From: Clay Anselmo [anselmoc@reglera.com]
Sent: Monday, April 25, 2011 5:04 AM
To: Dasika, Vasant
Cc: jim.kasic@sophono.com
Subject: Draft Jan 20, 2011 AI Response
Flag Status: Purple
Attachments: App_2_Physicians_Manual_Alpha1M (V7)_R2.pdf; App_3_Patient Manual_Alpha1M (V7) _R2.pdf; Sophono_510k_ AI3_Response.doc

Hi Vasant,

(b)(4)

[redacted]

We really appreciate your willingness to work with us. Any comments / suggestions you have would be much appreciated.

Thanks,
Clay

Clay Anselmo
President and CEO
Reglera LLC
(303) 223-4303 (Direct)
(303) 832-6700 (Fax)
(303) 907-2955 (Cell)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dasika, Vasant

From: Clay Anselmo [anselmoc@reglera.com]
Sent: Wednesday, April 20, 2011 1:00 PM
To: Dasika, Vasant
Subject: RE: K102199 follow up after teleconference

Will do.

Thanks,
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Wednesday, April 20, 2011 10:59 AM
To: 'Clay Anselmo'
Cc: Nandkumar, Srinivas; jim.kasic@sophono.com
Subject: RE: K102199 follow up after teleconference

Hi Clay- Thank you for your e-mail. We have an additional request, when you provide the bench testing results as part of your complete response, please be sure to provide sufficiently detailed pictures and diagrams illustrating the test setup and test apparatus.

thanks,
Vasant

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Monday, April 18, 2011 9:20 PM
To: Dasika, Vasant
Cc: Nandkumar, Srinivas; jim.kasic@sophono.com
Subject: RE: K102199 follow up after teleconference

Hi Vasant,

I wanted to say thanks again for your time this morning. We really appreciate your willingness to work with us on this 510(k). Based on our conversation, please see our response to your informal questions. We are moving forward with the testing with these modifications and should be complete by the end of the week.

Q1 – We agree with your comments and will modify the acceptance criteria for the protocol as suggested.

Q2 - (b)(4) [redacted]
(b)(4) [redacted]

Q3 - (b)(4) [redacted]
(b)(4) [redacted]

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(b)(4) [redacted]

Q4 – The protocol contained a typo in sections 9.9 and 9.12 as you note. The protocol is being corrected for each of these configurations to read simply "spring force".

Sincerely,
Clay Anselmo

Clay Anselmo
President and CEO
Reglera LLC
(303) 223-4303 (Direct)
(303) 832-6700 (Fax)
(303) 907-2955 (Cell)

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Thursday, April 14, 2011 10:17 AM
To: 'Clay Anselmo'
Cc: Nandkumar, Srinivas; jim.kasic@sophono.com
Subject: RE: K102199 follow up after teleconference
Importance: High

hi Clay,

We have reviewed your March 3, 2011 responses to our February 22, 2011 teleconference followup questions. The following four informal comments relate to document (b)(4) [redacted]

(b)(4) [redacted]

Regards,
Vasant

1. In 7.2, you state (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2. (b)(4) [redacted]

3. (b)(4) [redacted]

4. (b)(4) [redacted]

Vasant K. Dasika, PhD

Biomedical Engineering Scientific Reviewer

Ear, Nose, and Throat Devices Branch

DONED/ODE/CDRH

US FDA

10903 New Hampshire Avenue

WO66, Room 2443

Silver Spring, MD 20993

Phone: (301) 796-6860

Fax: (301) 847-8126

Email: Vasant.Dasika@fda.hhs.gov

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From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Thursday, March 03, 2011 8:16 PM
To: Dasika, Vasant
Cc: Jim Kasic

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Subject: RE: K102199 follow up after teleconference

Dear Vasant,

(b)(4) [redacted]

Thanks for all your help!
Best Regards,
Clay

Clay Anselmo
President and CEO
Reglera LLC
(303) 223-4303 (Direct)
(303) 832-6700 (Fax)
(303) 907-2955 (Cell)

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Tuesday, February 22, 2011 12:58 PM
To: anselmoc@reglera.com
Cc: jim.kasic@sophono.com;Nandkumar, Srinivas
Subject: K102199 follow up after teleconference
Importance: High

Hi Clay,

Following our February 15, 2011 teleconference, please address the following points:

1) (b)(4) [redacted]
(b)(4) [redacted]

2) (b)(4) [redacted]
(b)(4) [redacted]

3) (b)(4) [redacted]
(b)(4) [redacted]

Please also add the following deficiency to the list specified in our January 20, 2011 request-for-additional-information letter. When you respond to that letter, please address the below deficiency in addition to all of the deficiencies specified in the letter.

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

In summary, please respond as soon as possible to items 1 to 3 listed above (these items follow from our teleconference). For the additional deficiency concerning EMC and electrical safety, please provide your response when you respond to our January 20, 2011 letter.

Please contact me if you have any questions.

Kind Regards,
Vasant

Vasant K. Dasika, PhD
Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA
10903 New Hampshire Avenue
WO66, Room 2443
Silver Spring, MD 20993

Phone: (301) 796-6860
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Email: Vasant.Dasika@fda.hhs.gov

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Agenda for Feb 15, 2011 teleconference

(b)(4)

[redacted]

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Dasika, Vasant

From: Clupper, Daniel C
t: Friday, May 20, 2011 12:31 PM
To: Dasika, Vasant
Subject: RE: K102199/S002 Sophono lead review memo and SE decision

Vasant,
This is reasonable.
Thanks,
Dan

From: Dasika, Vasant
Sent: Friday, May 20, 2011 12:09 PM
To: Nandkumar, Srinivas; Khan, Anjum; Clupper, Daniel C
Subject: K102199/S002 Sophono lead review memo and SE decision
Importance: High

Hi- Attached please find the lead review memo for Sophono. It is basically ready and I am in the process of double checking and documenting the contact history. Angie/Dan, to make sure all our bases our covered, could you both please take a look at the deficiencies below in the memo and the reviewer comments to make sure the justification is reasonable? Please then provide any edits to me or your confirmation. You have both previously reviewed the key information interactively, but I just want everything documented in the lead review memo for the record.

Also if you have any comments on the attached 510(k) summary, please let me know.

Nandu- Please review also; I will be in within the hour to print and package the file.

Angie - Deficiencies 1, 2, 4, 6, 7b (deficiencies start on page 11).

Dan - Deficiencies 1, 3, 4, 5

Thanks!!
Vasant << File: K102199 S002 Lead Review memo.doc >> << File: 510(k) Summary (V7) DRAFT.pdf >>

Vasant K. Dasika, PhD
Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Dasika, Vasant

From: Clupper, Daniel C
Sent: Friday, May 20, 2011 11:40 AM
To: Dasika, Vasant
Subject: RE: K102199/S002 manufacturing question

Vasant,

That's adequate. (b)(4) [redacted]

(b)(4) [redacted]

Thanks,
Dan

From: Dasika, Vasant
Sent: Friday, May 20, 2011 11:31 AM
To: Clupper, Daniel C
Subject: FW: K102199/S002 manufacturing question

hi Dan- Please see the sponsor's response below.
thanks,
Vasant

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Friday, May 20, 2011 11:29 AM
To: Dasika, Vasant
Subject: RE: K102199/S002 manufacturing question

Vasant,

(b)(4) [redacted]

Thanks
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Friday, May 20, 2011 9:06 AM
To: 'Clay Anselmo'
Cc: jim.kasic@sophono.com
Subject: K102199/S002 manufacturing question
Importance: High

Hi Clay- Could you please answer the following question ASAP?

Thanks,
Vasant

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
ODE / DONED / ENTB
WO66 Rm 2574
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

TO: **Vasant Dasika, PhD – team leader**

FROM: Susan Rudy, MSN, CRNP, CORLN S. Rudy CRNP 5/19/2011
Nurse Consultant and Family Nurse Practitioner, ENTB

DATE: 5/19/2011

RE: K102199 / S002 Sophono Otomag Bone Conduction System Alpha 1(M)
Sterility / Labeling review of May 10, 2011 responses to FDA Deficiencies

RECOMMENDATION: SE after a final labeling change

History:

I have provided all sterility reviews for this file, the original, S001 and S1/A1.

Disposition of Sterility / Labeling –related Deficiency Responses

Deferred to other reviewers:

#8a – Validation for functionality after repeated cycles of steam sterilization – or change in labeling. Engineering is needed for validation data in Appendix 1.

Fully accepted:

#8b – Labeling change to specify storage of sterilized implant in sterilization pouch (not screw-top cylinder).
#9 – Labeling change to use chemical indicator compatible with sterilization cycle parameters.
#10 Labeling change for hospital disinfectant wipe language
#11 Labeling change from "primary care physician" to "hearing health specialists."
#12 Labeling change to include a master list of warnings and precautions at the beginning of the document
#13 Labeling change to include 510(k) numbers for self-tapping screws

Appendix 2, Physician Manual, begins on ecopy p. 38

Review of the manual confirms that the changes agreed upon were made.

The Sponsor should spell check the Physician manual as it contains errors e.g., Magentic instead of magnetic (p.4).

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The "latex-free" symbol should be removed from p. 8. Current Agency thinking is that the symbol is misleading because there is currently no testing that can confirm the latex-free claim. The current text, "product contains no natural rubber latex" is acceptable to communicate that there is no latex in the raw materials and no latex is added during the manufacturing process, if you have records on file to support the statement.

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Dasika, Vasant

From: Peng, Shu-Chen
Sent: Monday, April 11, 2011 2:27 PM
To: Dasika, Vasant
Subject: RE: K102199/S001 Sophono : FW: K102199 follow up after teleconference

Hi Vasant,

(b)(4)

[redacted]

Thanks,

Shu-Chen

From: Dasika, Vasant
Sent: Monday, March 21, 2011 12:58 PM
To: Peng, Shu-Chen
Subject: K102199/S001 Sophono : FW: K102199 follow up after teleconference

hi Shu-Chen- Pls see below mail and attachment for what to look at from an audiological perspective.

FYI, Here is Angie's minor clinical deficiency per her review of the European clinical data:

(b)(4)

[redacted]

Please contact me with questions. We can discuss tomorrow.

Thanks!
Vasant

From: Dasika, Vasant
Sent: Friday, March 04, 2011 4:56 PM
To: Khan, Anjum; Peng, Shu-Chen; Clupper, Daniel C
Cc: Nandkumar, Srinivas
Subject: FW: K102199 follow up after teleconference

Hi- Sophono provides their response to our follow-up requests post the teleconference.

The responses require review as follows:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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#1, Appendix 2, Dasika will review and check in with Clupper as needed.

#2, Discussion about European data and Appendix 2- Khan and Peng, as response contains both clinical and audiological information.

#3, Clupper, can check in with Dasika as needed.

(b)(4)

[redacted]

Thanks!
Vasant

Vasant K. Dasika, PhD

Biomedical Engineering Scientific Reviewer

Ear, Nose, and Throat Devices Branch

DONED/ODE/CDRH

US FDA

10903 New Hampshire Avenue

WO66, Room 2443

Silver Spring, MD 20993

Phone: (301) 796-5365

Fax: (301) 847-8126

Email: Vasant.Dasika@fda.hhs.gov

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Dasika, Vasant

From: Clupper, Daniel C
t: Friday, March 25, 2011 3:47 PM
To: Dasika, Vasant
Subject: K102199

Attachments: K102199 - March 3_Materials Sci & Engr Review.doc

Vasant,

Comments for K102199 are attached.

Thanks,
Dan

K102199 -
3_Material

Daniel C. Clupper, Ph.D.
Biomedical Engineer
ENT Devices Branch
DONED/ODE/CDRH
(1) 796-5620

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K102199 – Materials Science and Engineering Review

To: Vasant K. Dasika, Ph.D.
Team Leader, DONED/ENTB

From: Daniel C. Clupper, Ph.D.
Biomedical Engineer, DONED/ENTB

Date: March 25, 2011

Device: Otomag (Sophono, Inc.)

Question 3 from Sophono's letter dated March 3, 2011 is the subject of this review.

Question 3: (b)(4) [redacted]

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(0.013Kg) can easily be converted into an acceleration force required to dislodge the processor as follows:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Daniel C. Clupper, Ph.D.
Biomedical Engineer
DONED/ENTB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dasika, Vasant

From: Khan, Anjum
Sent: Thursday, March 24, 2011 4:25 PM
To: Dasika, Vasant
Subject: RE: K102199 Sophono response to clinical interactive deficiency

Vasant, I am ok with this information. I do not have any further questions for them. Thanks, Angie

---

From: Dasika, Vasant
Sent: Wednesday, March 23, 2011 4:15 PM
To: Khan, Anjum
Subject: K102199 Sophono response to clinical interactive deficiency

Hi Angie-

This e-mail response just arrived from Sophono. Your original question follows the response. Whenever you have a few minutes, please review the response and let me know if it is acceptable or if additional information is needed.

Thanks!

Vasant

Hello Vasant,

(b)(4)

[redacted]

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Monday, March 21, 2011 11:29 AM
To: anselmoc@reglera.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Cc: jim.kasic@sophono.com
Subject: RE: K102199 follow up after teleconference

Hi Clay,

Please address the following:

In your response to item 2 of our February 22, 2011 interactive request for additional information, you

(b)(4) [redacted]

Kind Regards,

Vasant

Vasant K. Dasika, PhD

Biomedical Engineering Scientific Reviewer

Ear, Nose, and Throat Devices Branch

DONED/ODE/CDRH

US FDA

10903 New Hampshire Avenue

WO66, Room 2443

Silver Spring, MD 20993

Phone: (301) 796-6860

Fax: (301) 847-8126

Email: Vasant.Dasika@fda.hhs.gov

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Sophono Otomag Bone Conduction
K102199
Sophono

510 (k) REVIEW (K102199)
(Response to Additional Information Request)

Date: 03-13-11

To: Vasant Dasika, PhD
Engineering Reviewer, ENTB/DONED/ODE

From: Anjum Khan, M.D., MPH
Medical Officer, ENTB/DONED/ODE

Cc: Srinivas Nandkumar, M.D., Ph.D.
Branch Chief, ENTB/DONED/ODE

Subject: Otomag Bone Conduction Hearing System

Purpose:

This is a review of response from the sponsor following a conference call requesting clinical information in addition to other requests. My review is limited to evaluation of Sponsor's Response to Question #2 (Appendix 2).

Question 2:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

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Sophono Otomag Bone Conduction
K102199
Sophono

Patient Population and Demographics:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dasika, Vasant

From: Clay Anselmo [anselmoc@reglera.com]
Sent: Thursday, March 03, 2011 8:16 PM
To: Dasika, Vasant
Cc: Jim Kasic
Subject: RE: K102199 follow up after teleconference
Follow Up Flag: Follow up
Flag Status: Purple
Attachments: Sophono_510k_ AI3_Supl_Response.pdf

Dear Vasant,

The attached document contains our response to the 3 questions posed in the email below. Please don't hesitate to call or email if you have questions related to this information.

(b)(4)

[redacted]

Thanks for all your help!

Best Regards,

Clay

Clay Anselmo
President and CEO
Reglera LLC
(303) 223-4303 (Direct)
(303) 832-6700 (Fax)
(303) 907-2955 (Cell)

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Tuesday, February 22, 2011 12:58 PM
To: anselmoc@reglera.com
Cc: jim.kasic@sophono.com;Nandkumar, Srinivas
Subject: K102199 follow up after teleconference
Importance: High

Hi Clay,

Following our February 15, 2011 teleconference, please address the following points:

1) Please provide your proposed protocol for bench testing of the complete device system (including the implant).

2) Please provide a complete summary of the (European) clinical data that you referenced

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during our teleconference.

3) (b)(4) [redacted]
(b)(4) [redacted]

Please also add the following deficiency to the list specified in our January 20, 2011 request-for-additional-information letter. When you respond to that letter, please address the below deficiency in addition to all of the deficiencies specified in the letter.

(b)(4) [redacted]

Please contact me if you have any questions.

Kind Regards,
Vasant

Vasant K. Dasika, PhD
Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA
10903 New Hampshire Avenue
WO66, Room 2443
Silver Spring, MD 20993

Phone: (301) 796-6860
Fax: (301) 847-8126

Email: Vasant.Dasika@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sophono

March 3, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Room 2443

Attn: **Vasant K. Dasika, PhD**
Email: Vasant.Dasika@fda.hhs.gov

Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for Additional Information dated September 23, 2010

510(k) Applicant / Manufactured by:
Jim Kasic
President and CEO
Sophono Inc.
3022 Sterling Cr,
Boulder, CO 80301

510(k) Contact / Submission Correspondent:
Clay Anselmo
Reglera LLC
555 Zang Street
Lakewood, CO 80228 USA
Phone (Mobile): 303-907-2955
Fax: 303-832-6700
Email: **anselmoc@reglera.com**

Dear Dr. Dasika,

We received FDA's email request for additional information from February 22, 2011 in response to the conference call held on February 15, 2011. To address the requests for additional information in this email, we are providing the following information in response for your review.

The attached information reflects our response to the 3 requests presented in this email. In addition, we have added FDA's request for immunity testing per IEC 60601-1-2 for the Alpha 1(M) configuration of the device to the AI request sent to Sophono on January 20, 2011.

If you have any questions or if further information is needed, please feel free to contact me at any time using the contact information contained above. We greatly appreciate your time and attention to this matter.

Sincerely,

Clay Anselmo,
Submission Correspondent
Reglera LLC.

cc: Jim Kasic., Sophono Inc.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Question 1: Please provide your proposed protocol for bench testing of the complete device system (including the implant).

Response 1: As requested, a draft Protocol outlining the planned approach for performance testing the complete Alpha 1(M) device is included in Appendix 1 to this response. This protocol defines and compares three different device configurations for the purpose of demonstrating that the magnetic implant and the generation of retention force via magnetic field does not adversely affect the performance of the device when compared to the Alpha 1(S) configuration of the device.

Question 2: Please provide a complete summary of the (European) clinical data that you referenced during our teleconference.

(b)(4)

[redacted]

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Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

Question 3:

Response 3:

[redacted]

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

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Index of Appendices

Appendix 1 – (b)(4), Vibration Transfer Comparative Study – (b)(4) [redacted]

Appendix 2 – Summary of Available European Clinical Data

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Appendix 1

(b)(4) Additional Information/Testing

(b)(4) Additional Information/Testing

(b)(4) Additional Information/Testing

(b)(4) Additional Information/Testing

(b)(4) Additional Information/Testing

(b)(4) Additional Information/Testing

(b)(4) Additional Information/Testing

(b)(4) Additional Information/Testing

(b)(4) Additional Information/Testing

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Vasant Dasika

Subject: 510(k) Number K102199/S1

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold)

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: ENT B 1/20/11

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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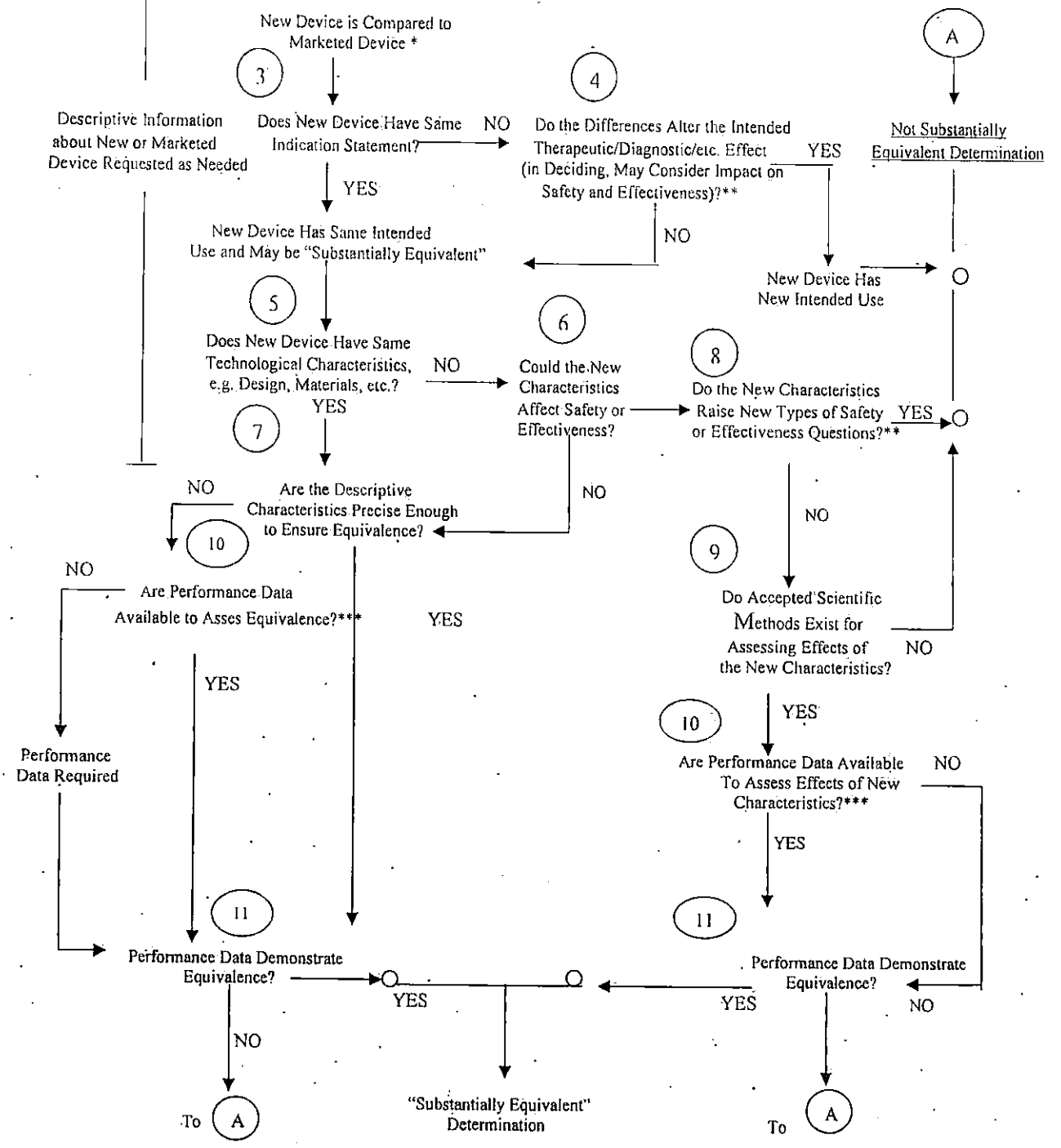
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), but 510(k) Summary's CDRH-recommendations or guidance.

Questions? Contact FDA/CDRH/OEIDD at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K102199/S001

Date: January 20, 2010
To: The Record
From: Vasant K. Dasika, Ph.D.

Office: ODE
Division: DONED

510(k) Holder: Sophono, Inc.
Device Name: Otomag Bone Conduction Hearing System
Contact: Clay Anselmo, President and CEO, Reglera LLC
Phone: 303-223-4303
Fax:
Email: anselmoc@reglera.com

Recommendation: Telephone Hold

Major deficiencies

- No clinical performance data were provided. The sponsor's justification for using bench testing in lieu of clinical performance data is unacceptable as the bench testing does not validate realistic in vivo use nor take into account the implant.
- Safe and effective coupling forces of magnets have not been shown. Sponsor's justification for safe coupling strengths depends on extrapolated references. It is unclear that

All review team members from either cycle are listed below.

Review Team

Vasant Dasika, Ph.D.	Lead Reviewer & Electrical Engineering
Angie Khan, M.D.	Clinical#
Frank Curto, M.D.	Clinical*
Sue Rudy	Sterility
Shu-Chen Peng, Ph.D.	Audiology
Jim Kane, Ph.D.	Audiology*
Daniel Clupper, Ph.D.	Materials Science & Mechanical Engineering
Vasant Malshet, Ph.D.	Biocompatibility**
Eric Mann, M.D., Ph.D.	Clinical Deputy Director, DONED***
Nandu Nandkumar, Ph.D.	Branch Chief, ENTB***

*no review memo was requested from Dr. Kane. The Lead Reviewer discussed with Dr. Kane this submission (S001) and Dr. Kane recommends that a clinical study is conducted. Dr Kane also edited the hold letter that was e-mailed to the sponsor on January 20, 2011. Also, no review memo was requested from Dr. Curto. During discussion with both Dr. Khan and the Lead Reviewer, Dr. Curto recommended that a clinical study be conducted given potential concerns about skin damage and necrosis.

**Dr. Malshet finds the biocompatibility information acceptable from the original submission; thus no review memo is provided from Dr. Malshet for S001.

Questions? Contact FDA/CDRH/OSEL/DCD Lead-Review-Mem@fda.hhs.gov or 301-796-8118

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***In discussion, Drs. Mann and Nandkumar have recommended the need for a clinical study to support the safety and efficacy of the Alpha 1(M) configuration of the device, which contains a new implant.

#Although Dr. Khan's review memo of S001 does not state additional concerns, Dr. Khan has reviewed the Deficiency letter of January 20, 2011 and agrees with contents.

I. Purpose and Submission Summary

The 510(k) holder would like to introduce a modified Otomag Bone Conduction Hearing System into interstate commerce.

The modification "adds a new configuration into the Otomag Bone Conduction Hearing System family. The new configuration (Alpha 1(M)) uses an implantable magnet as a fixation system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193 – Otomag Bone Conduction Hearing System – May 18, 2010."

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X	X	
Are "cleaning" instructions included for the end user?	X		

The following device description is excerpted from the review memos of Drs. Clupper and Khan:

Description of the Osseointegrated Alpha 1 (M) Configuration (p. 13-4; 41 of 192 of K102199)
In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Osseointegrated Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 1 below shows the details of the configuration; Figure 2 shows the magnetic spacer in isolation; Figure 3 shows the sound processor attached to the spacer.

For the Alpha 1(M) configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

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To ensure that appropriate pressure is applied between the sound processor and the patient's skin / bone, various strengths of magnetic spacers are available (b) (4) [redacted]

(b)(4) [redacted]

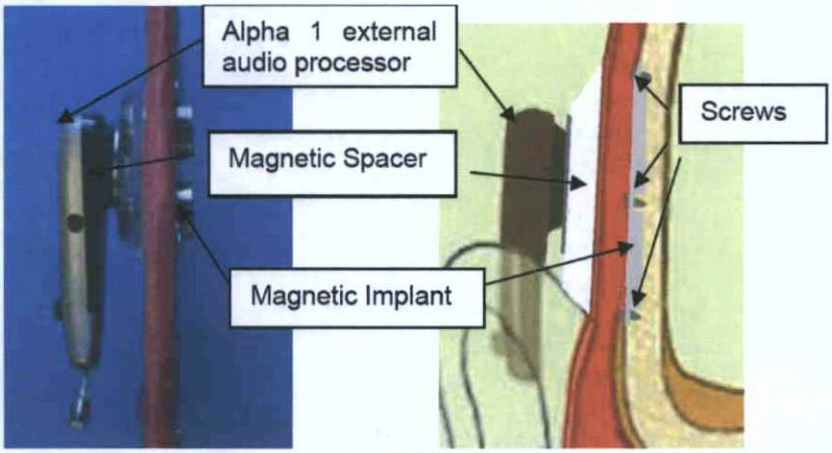

Figure 1. Alpha 1(M) configuration.

Figure 2. Magnetic spacer in Alpha 1(M) configuration.

Figure 3. Sound processor with metal disc attached to magnetic spacer.

The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical implant site.

Osseointegrated Magnetic Implant (p. 13-7; 44 of 192)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The implant consists of two (b)(4) magnets hermetically sealed in a titanium housing as shown in Figure 4. The implant is manufactured for (b)(4) [redacted]. Validation documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in Appendix C to the overall submission. Each implant is welded, cleaned, and 100% leak tested by the manufacturer using formally validated processes.

Figure 4. Magnet implant.

Please refer to the review memos of Drs. Clupper and Khan of the original submission (K102199) for additional details about device description. Please refer to Ms. Rudy's memo from her review of the original submission for a table of device components.

IV. Indications for Use

The sponsor provides the following updated indications for use in S001. In S001, it is noted that all references to "osseointegrated" have been removed from the Indications for Use and from the labeling. See Dr. Khan's review memo of S001 for details and review of a related deficiency.

510(k) Number: K102199

Device Name: Otomag Bone Conduction Hearing System

Indications for Use: The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

• Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

• Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

V. Predicate Device Comparison

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

This section has been updated in S001 as follows:

In S001, the sponsor claims two predicate devices (only one predicate K100193 was claimed in the original submission):

- The Otomag Bone Conduction Hearing System, Unmodified Version, Alpha 1(S) in a headband or softband confiburation– K100193
- Xomed Audiant Bone Conductor - K855059 / K861971 (**added in S001)**

The following in section 14 of S001 provided by the sponsor compares the subject device with the two claimed predicate devices:

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	874.3300	Identical to both predicates
Class	Class II	Class II	Class II	Identical to both predicates
Product Code	LXB	LXB	LXB	Identical to both predicates
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	The Audiant Bone Conductor is a device for Conductive Hearing Loss not correctable by conventional reconstructive surgery	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical to Alpha 1(S) Substantially Equivalent to ABC
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Audiant Bone Conductor is a device for Conductive Hearing Loss not correctable by conventional reconstructive surgery The ABC will, in most cases, essentially close the air-bone gap. The patients hearing acuity with the ABC will be limited to the patients sensorineural acuity (cochlear reserve). In most cases, the ABC patient will not attain hearing thresholds less than (better than) the patients pre-op. audiometric bone conduction thresholds. A prospective patients's performance with the ABC can generally be predicted by the results obtained with a conventional Bonde Conduction Hearing Aid. Subjective sound quity and comfort may be higher with the ABC, however. Any prospective ABC patient who has not attempted to utilize a conventional B.C. aid should be allowed a trial evaluation of the same and offered the choice of a B.C. aid or the ABC before implantation. In general, the prospective ABC candidate should meet all of the following criteria: • A high level of commitment and complete understanding of the implications of surgical implantation. • Inability or demonstrated unwillingness to utilize a conventionla air or bone conduction hearing aid. A conventional aid should be adequately trialed by	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz) • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
		the patient. • A substantial bilateral conductive impairment with adequate sensori-neural acuity. Audiometric bone conduction thresholds in the speech frequencies (500, 1K, 2K) on the implant side should: o Average not more than 25 dB o Contain no individual frequency greater than 40. • Unaided speech reception threshold not less than 40 dB in the impanted ear seech discrimination score of not less than 80%.		

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patient's bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patient's bone rather than via the middle ear - a process known as direct bone conduction.	Identical to both predicates
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an external electronic transducer, a battery, volume controls, and an external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical to Alpha 1(S) Substantially Equivalent to ABC
Transducer	Traditional bone conduction transducer	Inductive coupling of an external magnet and coil to an implanted magnet	Traditional bone conduction transducer	Identical to Alpha 1(S)
Power Supply	Zinc-air battery	AA battery	Zinc-air battery	Identical to Alpha 1(S) Substantially Equivalent to ABC
Sound Processing	Digital	Analog	Digital	Identical to Alpha 1(S)
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Simple volume control	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical to Alpha 1(S)
Frequency Processing Range	125 – 8kHz	336– 12kHz	125 – 8kHz	Identical to Alpha 1(S)
Max Gain (60dB SPL)	38 dB	Unavailable	38 dB	Identical to Alpha 1(S)
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	Unavailable	29 dB	Identical to Alpha 1(S)
Accessories/Options	Direct audio input via FM jack	Telecoil	Direct audio input via FM jack	Identical to Alpha 1(S)

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Patient Contact Materials for Biocompatibility Purposes (external device)	Fotoplast-Lac	Biocompatible plastic	Fotoplast-Lac	Identical to Alpha 1(S) Substantially Equivalent to ABC
Patient Contact Materials for Biocompatibility Purposes (external device)	Titanium Grade 2 and 4	Titanium Grade 5 and Silicone Elastomer	Titanium Grade 2 and 4	Identical to Alpha 1(S) Substantially Equivalent to ABC
Sterilization	Steam sterilization of surgical implant	Provided Sterile	Steam sterilization of surgical implant	Identical to Alpha 1(S) Substantially Equivalent to ABC
Peak Output at 90 dB SPL	115 dB	118 dB	115 dB	Identical to Alpha 1(S) Substantially Equivalent ABC
Frequency range per ANSI S3.22-2009	280-5000 Hz	336– 12kHz	280-5000 Hz	Identical to Alpha 1(S) See Discussion Below
Total harmonic distortion per ANSI S3.22-2009	<3%	3-9%	<3%	Identical to Alpha 1(S) Substantially Equivalent to ABC
Equivalent input noise:	17 dB SPL	Unavailable	17 dB SPL	Identical to Alpha 1(S)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-510kMemo@fda.hhs.gov or 301-796-8118

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Battery current drain	0.95 mA	52 mA	0.95 mA	Identical to Alpha 1(S)
Processor:	16 Band, 4 Channel WDRC	Standard OP Amp	16 Band, 4 Channel WDRC	Identical to Alpha 1(S)
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	None	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical to Alpha 1(S)
Compression Attack Time (minimum)	0.25 ms	1 ms	0.25 ms	Identical to Alpha 1(S) See Discussion Below
Compression Release Time (maximum)	8192 ms	350 ms	8192 ms	Identical to Alpha 1(S) See Discussion Below
Patient Volume Control Wheel	38 dB Range	Unavailable	38 dB Range	Identical to Alpha 1(S)
Force Application Methods	Headband or Softband	Magnetic to implanted magnet	Magnetic to implanted magnet (Alpha 1(M) Version)	Identical to ABC
Connection of implant to the skull	Not Applicable	1 Titanium screw	5 Titanium Screws	Substantially Equivalent – see discussion below

In S001, the sponsor claims five major differences between the subject and predicate devices:

1. **Indications for use:** The new Alpha 1(M) configuration is indicated for patients age 5 and older whereas the cleared (S) configuration is indicated for all ages.

2. **New patient contact materials:** The Magnetic Implant in the Alpha 1(M) configuration contains new patient contacting materials: Titanium Grades 4 and 5.

3. **Sterilization:** The Magnetic Implant is provided clean but not sterile and requires sterilization via gravity or prevacuum steam sterilization at the healthcare facility prior to implantation.

4. **Method for coupling sound processor to patient, i.e.,** (b)(4) [redacted] (b)(4)

5. **Connection of the implant to the skull.** Five 4-mm screws are used to hold the Alpha1 (M) implant to the skull while the sponsor claims that the Audiant implant uses one 4 mm length screw.

The sponsor claims that the above differences do not negatively impact safety or effectiveness and do not raise any new safety or effectiveness questions.

The review team has identified several deficiencies stemming from differences between the subject and predicate devices, including concerns about the safety and efficacy of the magnetic coupling method of the subject device, surgical risks, and sterility concerns. A clinical study is therefore recommended.

See the review memo of Dr. Clupper, this review memo, the edited deficiency letter by Dr. Kane, and notes at the beginning of this review memo regarding discussion and review team members for details.

VI. Labeling

The sponsor lists 4 labeling materials that have been revised for the Alpha 1(M) configuration:

1. Physician's Manual
2. Patient User Manual
3. Magnetic Implant Package Label
4. Revised Primary Device Labels

For S001, this information was reviewed primarily by Drs. Khan and Ms. Rudy. Please refer to the review memos of these reviewers for details, including deficiencies relating to labeling.

VII. Sterilization/Shelf Life/Reuse

This information was reviewed by Ms. Rudy.

For S001, please see Ms. Rudy's review memo for details, including several deficiencies relating to sterilization.

VIII. Biocompatibility

This information was reviewed by Dr. Malshet in the original submission. Dr. Malshet has determined that the information is acceptable. Please see Dr. Malshet's review memo for details.

IX. Software

This following brief review of the software is retained from the Lead Reviewer's review of the original submission (K102199):

Comment (Lead Reviewer): *Changes in this submission relate only to the method of physically coupling the sound processor to the patient, and not in the sound-processor firmware or the clinical programming software. I therefore concur with the sponsor's assessment that, "All software documents provided in the original 510(k) submission (K100193) continue to be applicable to the modified version of this device." Please refer to the lead review memo for K100193 for review of the device software.*

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Comment (lead reviewer): *In review of the original submission, I identified following deficiency which relates to electrical engineering and bench performance testing:*

(b)(4)

[redacted]

(b)(4)

[redacted]

XI. Performance Testing – Bench

In S001, the sponsor provides bench performance testing supporting to validate that go/no-go gauges that have been introduced to verify the radial holding force of the implant.

Dr. Clupper reviewed these data in addition to the other mechanical testing data in S001 and the

(b)(4)

[redacted]

XII. Performance Testing – Animal

No animal performance-testing data were provided.

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Comment (Lead Reviewer): *This is acceptable provided that the sponsor demonstrate substantial equivalence through bench performance testing and, per review of S001, clinical performance testing.*

XIII. Performance Testing – Clinical

No clinical performance-testing data were provided in S001.

(b)(4)

[redacted]

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?		X	If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

The indication statement is the same as the indication for the predicate except for the addition that the (subject) Alpha 1(M) configuration which requires a surgically placed implant, is intended for ages 5 and older only.

2. Explain why there is or is not a new effect or safety or effectiveness issue:

The change made in the new indication statement does not raise any new safety of effectiveness issues because the age range has been appropriately specified per the review of the original submission by the clinical reviewers. Per review of S001, concerns have been raised by the collective review team about young children being implanted with the device and the risk versus benefit for this population, given that MRI needs to be contraindicated. See the January 20, 2011 deficiency letter for details.

3. Describe the new technological characteristics:

New technological characteristics include magnetic coupling of the sound processor to the patient's skull via a magnetic implant and (externally worn) magnetic spacer. The Sophono predicate instead uses a headband or softband to couple the sound processor to that patient's skull and there is no implant. The Audiant predicate does not actually conduct vibration from the exterior sound processor and therefore the magnetic coupling in that device differs from the subject device.

4. Explain how new characteristics could or could not affect safety or effectiveness:

The implanted component in the subject device poses several safety risks, including those relating to potential extrusion and infection. The safety and effectiveness of the coupling system have not been established.

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

Hearing-aid bone-conduction devices are not new. Therefore the general set of safety and effectiveness questions remains constant across various types of devices.

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

Per review of S001, clinical performance data are needed to demonstrate substantial equivalence to the predicate.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" (http://www.fda.gov/cdrh/modact/guidance/1195.html) and "A Suggested Approach to Resolving Least Burdensome Issues" (http://www.fda.gov/cdrh/modact/leastburdensome.html).

See attached e-mailed for final deficiencies conveyed to sponsor.

XVI. Contact History

January 16, 2010: Lead Reviewer e-mailed sponsor 14 deficiencies for interactive review. Sponsor provided a response to deficiencies on January 19, 2011.

January 14, 2010: Lead reviewer e-mailed sponsor to request a copy of cited Raicevich et al. (2008) paper. Sponsor provided requested information on same day.

August 9, 2010: Lead Reviewer requested e-copy of submission from sponsor. Sponsor provided a download link to the submission the same day.

September 15, 2010: Lead Reviewer requested device sample from sponsor. Sponsor indicated on same day that this was possible and had some clarification questions: purpose, use, and whether sample will be returned. Lead reviewer responded on September 16, 2010. Sample received on September 22, 2010.

September 22, 2010: Lead Reviewer e-mailed sponsor question to clarify magnetic spacers provided in the sample. Sponsor provided requested clarification the next day.

September 23, 2010: Lead Reviewer e-mailed sponsor that additional information is needed to continue review of K102199 and informed the sponsor that the submission will be on hold until the information is provided.

XVII. Recommendation

Telephone Hold (TH).

Reviewer — Date 1/20/11

Branch Chief — Date 1/20/11

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Dasika, Vasant

From: Dasika, Vasant
Sent: Thursday, January 20, 2011 3:19 PM
To: jim.kasic@sophono.com; 'Clay Anselmo'
Cc: Nandkumar, Srinivas
Subject: K102199/S001 AI needed

Attachments: K102199 S001 AI needed.pdf

Dear Mr. Kasic,

We have conducted a preliminary review of the above referenced submission and the responses you have provided via interactive review on January 19, 2011. Based on our review of your documents, additional information is needed. Please see the attached letter for details. Please also be advised that your submission will be placed on hold today and will remain on hold until the requested information is provided.

When you do respond with the requested additional information, please provide this information per the instructions in the letter (i.e., submit it to the address stated in the letter). At the same time, please also provide directly to me a complete e-copy of your response. This will greatly facilitate the review process.

Please contact me if you have any questions.

Kind Regards,
' ant

K102199
[needed.pc

Vasant K. Dasika, PhD
Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA
10903 New Hampshire Avenue
WO66, Room 2443
Silver Spring, MD 20993

Phone: (301) 796-6860
Fax: (301) 847-8126

Email: Vasant.Dasika@fda.hhs.gov

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Re: K102199
Trade Name: Sophono Otomag Bone Conduction Hearing System
Dated: December 20, 2010
Received: December 21, 2010

Dear Mr. Kasic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following:

Several safety and effectiveness concerns have not been adequately addressed by the

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[redacted]

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9. Your revised physician instructions (response to deficiency #5c) advise the use of a specific chemical indicator (CI) to be placed inside the sterilization pouch with the implant. We agree with the methods used in your steam sterilization validation study. However, since no specific CI was validated for use, facilities can use any commercially available CI that is labeled for the cycle parameters they are using, and it is not important that they use exactly the brand and catalog number of the CI you have identified. Therefore, please revise your instructions to be more general, simply replacing your specific CI recommendation with a one-line step in the instructions reminding users that a steam indicator strip labeled for the specific cycle parameters should be put into the pouch with the implant.

10. You clarify (response to deficiency #7) that your "go, no-go" test devices are used in medical settings for multiple patients. You now advise "prior to using with another patient, the accessories must be cleaned with a Clorox® type disinfecting

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wipe." Better language for medical settings would be, "...cleaned and disinfected using an EPA-registered hospital disinfectant wipe." Please make this change for accuracy and broadest applicability.

11. You add language after your contraindications in the patient manual (response to deficiency #10b) as reproduced below:

    Note: While the contraindications listed above may affect the process of hearing aid fitting, it should be noted that the treatment plan for use of the Otomag Alpha 1 Sound Processor may vary with worsening or improving hearing. Your treatment plan will be determined by your primary care physician.

    Primary care physicians are not skilled or credentialed for making or adjusting a treatment plan that would involve the subject device. Please replace "primary care physician" in this note with language such as "your hearing health specialists." Your response to deficiency #13 has the same issue, so please replace the "primary care physician" language there as well.

12. Your revised patient manual (Appendix 2) includes magnet information with precautions on page 17 (section 6). All safety precautions should appear at the beginning of the document in a complete list of precautions. You may reiterate any precautions as you wish throughout the document. To place a new precaution on page 17, is to risk that it will never be read or heeded and inappropriately diminishes its importance. Please revise your patient instructions accordingly.

13. In your revised clinician manual, please specify 510(k) numbers (if available) for the recommended craniomaxillofacial titanium self tapping screws for affixing the implant to the skull.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is

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complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at **http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf**

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Vasant K. Dasika, Ph.D. at (301) 796-6860. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
510(k) AUDIOLOGY REVIEW MEMO

From: Shu-Chen Peng, Ph.D., CCC-A
ENTB/DONED/ODE

To: Vasant Dasika, Ph.D., ENTB

CC: Nandu Nandkumar, Ph.D., Branch Chief, ENTB

Subject: **K102199/S001**
Request for Additional Information
Otomag Bone Conduction Hearing System
Sophono

Date: January 12, 2011

Per your request, I have completed the review of the above referenced submission, specifically the sponsor's response to FDA Deficiencies 1 and 2, which arose in my previous audiology review on K100193. The sponsor has properly addressed both questions. Thus, I have no outstanding questions for the sponsor, from the perspective of clinical audiology. In the remainder of this review memo, each question is listed, followed by the sponsor's response and my comment on each response.

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[redacted]

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[redacted]

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[redacted]

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K102199/S001 – Materials Science and Engineering Review Addendum

To: Vasant Dasika, Ph.D.
Team Leader, DONED/ENTB

From: Daniel C. Clupper, Ph.D.
Biomedical Engineer, DONED/ENTB

Date: January 19, 2011

Re: Sophono, Inc. Interactive Response Dated January 18, 2011

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[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

Daniel C. Clupper, Ph.D.
Biomedical Engineer
DONED/ENTB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-2118

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K102199/S001 – Materials Science and Engineering Review

To: Vasant Dasika, Ph.D.
Team Leader, DONED/ENTB

From: Daniel C. Clupper, Ph.D.
Biomedical Engineer, DONED/ENTB

Date: January 14, 2011

Device: Otomag Bone Conduction Hearing System
Model Alpha 1 (M)
(Sophono Inc.)

Regulatory Background
Regulation Number: 21 CFR 874.3300
Product Code: LXB

Indications for Use
The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Device Introduction
The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and the osseointegrated Alpha 1 (M).

This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

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In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. Vibration is not primarily transmitted through the magnetic implant.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Description of the Osseointegrated Alpha 1 (M) Configuration
In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Osseointegrated Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 1 below shows the details of the configuration.

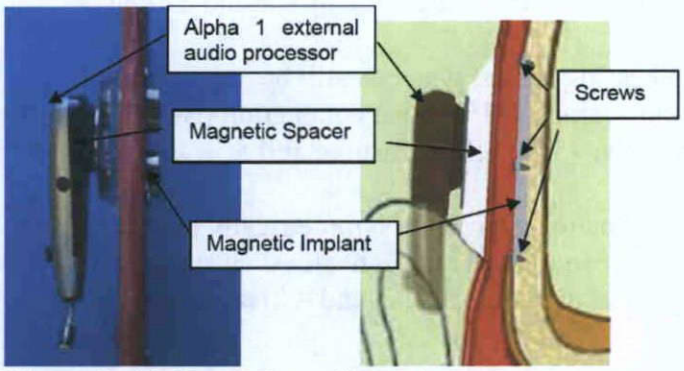

Figure 1. Alpha 1(M) configuration.

For this configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

To ensure that appropriate pressure is applied between the sound processor and the patient's skin / bone, various strengths of magnetic spacers are available (b)(4) [redacted] (b)(4) [redacted]

The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant

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magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical implant site.

Magnetic Implant

The implant consists of two (b)(4) 5 magnets hermetically sealed in a titanium housing as shown in Figures 2 and 3. The implant is manufactured for (b)(4) GmBH. Validation documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in (b)(4)

(b)(4)

(b)(4)

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The magnetic implant is placed in 3 mm deep bone beds as shown in Figure 4. The implant is secured using 4 mm titanium facial plating screws. The device is intended to be steam sterilized at the healthcare facility prior to implantation.

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Figure 4. Bone bed.

Magnetic Spacer

The spacer consists of a (b)(4) [redacted] 100% Fotoplast S IO. (b)(4) [redacted] (b)(4) [redacted] as shown in Figure 5 and Figure 6. Both plastic materials are those commonly used for the production of custom ear molds. Complete material specifications can be found in Appendix B to the overall submission. Four magnetic strengths of the spacer are available to accommodate for variations in skin thicknesses (Fig. 7) and holding requirements to obtain approximately 2.5 N to 5.4 N of holding force.

Figure 5. Magnetic spacer.

Figure 6. Sound processor attached to magnetic spacer.

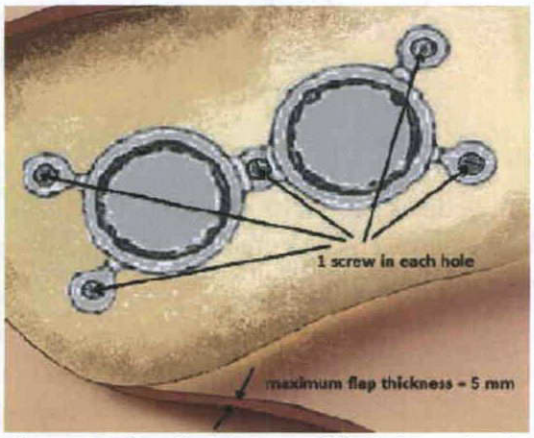

Figure 7. Implant secured into bone bed.

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Previous Deficiencies

Deficiency #4

(b)(4)

[redacted]

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[redacted]

Daniel C. Clupper, Ph.D.
Biomedical Engineer
DONED/ENTB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510 (k) REVIEW (K102199/S001)
(Response to Deficiencies)

Date: 01-13-11

To: Vasant Dasika, PhD
Engineering Reviewer, ENTB/DONED/ODE

From: Anjum Khan, M.D., MPH
Medical Officer, ENTB/DONED/ODE

1.13.11

Cc: Srinivas Nandkumar, M.D., Ph.D.
Branch Chief, ENTB/DONED/ODE

Subject: Otomag Bone Conduction Hearing System

Purpose:

This submission includes Sophono Inc. responses to Agency's Letter dated September 13, 2009.

My review is limited to Deficiencies # 7, 9, 10 and 11.

Review of Deficiencies:

Deficiency 7:

In your Indications for Use statement and many other sections of your submission, you describe that the "Otomag Alpha 1 Sound Processor is to be used with Otomag Headband or Otomag Softband, or with the Otomag Osseointegrated Magnetic Implant." However, from the information provided, it is unclear that the 5, fairly small diameter, bone-anchoring screws fulfill and permit osseointegration. We recommend that you accurately label your device for the mechanism by which it functions (i.e. without osseointegration) or justify why you believe the Magnetic Implant of the Otomag System is an osseointegrated implant.

Sponsor's Response:

As discussed in the response to Deficiency 6 above, Sophono has removed all references to osseointegration throughout the submission. Revised sections of the original submission removing reference to osseointegration are contained in Appendices 1, 2, 3, 4, 5, 10, and 11.

Reviewer's Comment: This response is accepted.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Warning

If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device.

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The modified physician instructions which incorporate the use of these gages are shown below. The concept is quite simple. When the "Go" gage is attached, the magnetic spacer should remain attached to the implant and when the "No-Go" gage is attached the magnetic spacer should pull off of the implant. This method allows the identification of one or more magnetic spacers that apply the force to the skull over the appropriate range. The labeling further instructs the physician to select the lowest strength magnetic spacer that passes both the "Go" and "No-Go" evaluations and provides adequate hearing improvement. This ensures correct function of the device while minimizing pressure to the skin and chances of pain or tissue necrosis. "Go" and "No-Go" gage tools have been added to the device description present in Appendix 3 to this response.

Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system and patient comfort. The Alpha 1 (M) configuration is supplied with five strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid.

The spacers are labeled with "dots" to indicate magnetic strength. Magnetic strength increases based on the number of dots present on the spacer. One dot is the lowest strength and five dots is the highest strength.

Several magnetic spacer strengths may be applicable to an individual patient. To determine the appropriate magnetic spacer for a patient use the "Go" and "No-Go" gages as follows.

Using the "Go" gage to determine the weakest appropriate magnetic spacer

1. Starting with the one dot magnetic spacer, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the magnetic spacer poles align with the implant poles and the strongest magnetic attraction is achieved.

2. Ask the patient to sit upright with their head in a typical vertical position. Attach the "Go" gage clip to the patient's clothing.

3. Hang the "Go" gage disk from the magnetic spacer.

4. If the magnetic spacer detaches from the side of the patient's head, then the spacer is too weak and the process should be repeated with increasing magnetic spacer strengths until the magnetic spacer remains attached to the side of the head while attached to the "Go" gage disk.

5. The lowest dot number magnetic spacer that passes the "Go" test indicates the weakest magnetic spacer strength that should be recommended to the patient.

Using the "No -Go" gage to determine the strongest applicable magnetic spacer

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1. Starting with the lowest dot number magnetic spacer that passes the "Go" test, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the poles align with the implant poles and the strongest magnetic attraction is achieved.

2. Again, ask the patient to sit upright with their head in a typical vertical position. Attach the "No-Go" gage clip to the patients clothing.

3. Hang the "No-Go" gage disk from the magnetic spacer.

4. The magnetic spacer ***should detach*** *from the head from the weight of the disk. If the magnetic spacer detaches from the head then the magnetic spacer is one of the appropriate spacers for the patient.*

5. Repeat this process, increasing magnetic spacer strength one dot at a time until the magnetic spacer ***does not detach*** *from head.*

6. The highest number magnetic spacer that ***detaches*** *from the head using the "No-Go"test indicates the highest magnetic spacer strength that* ***should be used*** *by the patient on a regular basis.*

7. Any magnetic spacer that remains attached during the "No-Go" test is too strong and should not be recommended for patients long term use.

8. If all magnetic spacers used in the "No-Go" test detach when the "No-Go" disc is attached, then all of the spacers tested in the "No-Go" test may be appropriate for the particular patient.

Several spacer magnet strengths may be applicable for an individual patient. The patient should be prescribed the lowest dot magnet strength that is both comfortable, functions correctly and fits with their age and lifestyle.

Warning

- Excessive, long term use of magnetic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test.

Caution

- The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or if pain, numbness, or tingling occurs.

FDA expressed additional concern regarding the effect the magnetic attraction will have on the underlying soft tissue. To address this concern, one must understand the physics of

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the Alpha 1 (M) system in combination with the anatomy and physiology of capillary perfusion.

Skin necrosis occurs from prolonged tissue ischemia. Tissue ischemia occurs due to pressure exceeding the underlying capillary pressure over a prolonged period of time. In the case of the Alpha 1 (M) and (S) systems, tissue ischemia can occur due to the pressure that the spacers place on the tissue if that pressure is excessive.

RAICEVICH et al. (full reference contained in Appendix 6, DG-38, Section 12) studied the pressure of bone conduction devices with respect to conventional external bone vibrator devices, industrial norm standards and the pressure that these devices apply to the skin. Based on his work and others on capillary pressure, he determines that the long-term maximum contact pressure for fitting bone vibrators should not exceed 3.7 kPa. He also notes that most bone vibrators apply too much pressure. Using 3.7 kPa as a target and based on the surface area of the spacer of 665 mm2 the maximum normal direction holding force of magnetic spacer should be less than approximately 2.5 N. (2.5 N/665 mm * 1000 = 3.7 kPa). The fitting instructions and gages supplied with the Alpha 1 (M) configuration are designed to achieve forces at or below 2.5 N.

Reviewer's Comment: Defer to Dr. Dasika for full evaluation of this response. However, I think the warnings are appropriate.

Deficiency 10:

Under the section of Risks that may occur during surgery (Page 68 of 192), you state that "These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, post-cholesteatoma, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, disturbance of taste or balance and noticeable changes in head noise." Please address the following concerns regarding these risks.

a) Although most of your described risks are understandable, please clarify how you expect the risk of "post cholesteatoma" and "Disturbance of taste and balance" to occur in the procedure you propose for the implantation of the magnetic implant, without transgressing the middle ear or in the vicinity of the mastoid area.

b) Your list of risks that may occur during surgery does not include some critical risks of dural exposure, CSF leak, perforation of sigmoid sinus, and subdural hematoma. Please include these potential risks to your list of risks during surgical procedure.

Sponsor's Response 10a:

Sophono agrees with FDA's comments regarding "post cholesteatoma" and "disturbance of taste and balance". The Alpha 1(M) magnetic implant does not transgress the middle ear nor the vicinity of the mastoid area, the risks of "post cholesteatoma" and

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"disturbance of taste and balance" are not likely in this application and have been removed from this labeling. Refer to the text below and Appendix 4 for the revised version of the Physician Manual.

Reviewer's Comment: This response is accepted.

Sponsor's Response 10b:

Per FDA's request, the risks of dural exposure, CSF leak, perforation of sigmoid sinus and subdural hematoma have been added to the Physician Manual. Refer to the text below and Appendix 4 for the revised version of the Physician Manual.

Risks that may occur during surgery:
The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, dural exposure, CSF leak, perforation of sigmoid sinus, subdural hematoma and noticeable changes in head noise.

Reviewer's Comment: This response is accepted.

Deficiency 11:

In the Section of Risks that may occur after surgery (Page 68 of 192), you describe that "Potential risks related to the implant following surgery include infection, reparative granuloma and inflammatory reaction. It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant." This list does not include the risk of skin breakdown or skin necrosis. Please add this risk to the list.

Sponsor's Response:

Per FDA's request, the risks of skin breakdown or skin necrosis have been added to the Physician Manual. Refer to the text below and Appendix 4 for the revised version of the Physician Manual.

Risks that may occur after surgery:
Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma, inflammatory reaction, skin breakdown or skin necrosis.

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Conclusions/Recommendations:

Responses to Deficiencies 7, 10 and 11 are accepted.

I defer to Dr. Dasika for the evaluation of response to Deficiency #9.

I have no further questions for the sponsor.

Anjum Khan, M.D., MPH
Medical Officer, ENTB,DONED,ODE

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
ODE / DONED / ENTB
WO66 Rm 2574
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

TO: **Vasant Dasika, PhD – team leader**

FROM: Susan Rudy, MSN, CRNP, CORLN S. Rudy CRNP 1/19/2011
Nurse Consultant and Family Nurse Practitioner, ENTB

DATE: 1/10/2011 Revised 1/19/2011

RE: **K102199 / S001 & A1 Sophono Otomag Bone Conduction System Alpha 1(M)**
Sterility review for Traditional 510(k)
Includes review of interactive responses received 1/19/2011

RECOMMENDATION: TH

Purpose / History:

The sponsor submits a traditional 510(k) for a modification to an existing cleared device. The modification is to the cleared indications for use statement, introduces new design specifications, new materials and revisions to product labeling. They claim that the scientific technology is unchanged for the device.

I provided the original sterility review dated 9/14/2010. My sterility deficiencies were communicated to the Sponsor as deficiencies #12 – 18.

The S001 documents that informed the review are: Appendices 4, 5, 9, 10, 16, 17

Regulatory:

Product Code LXB
Regulation: 21 CFR 874.3300
Class II
Sophono is a small business in Boulder, CO.

Indications for Use (original application -PDF p.13)

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

• Patients with conductive or mixed hearing losses, who can still benefit from amplification

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of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

• Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

The device is by prescription only.

Device Description

The model Alpha 1(S) was cleared in K100193 using a softband or a headband for the magnetic fixation of the sound processor. The Sponsor now applies for the model Alpha 1(M) using an implantable osseointegrated magnet assembly as the fixation system for the sound processor.

The implant is 2.6mm thick and 10mm diameter

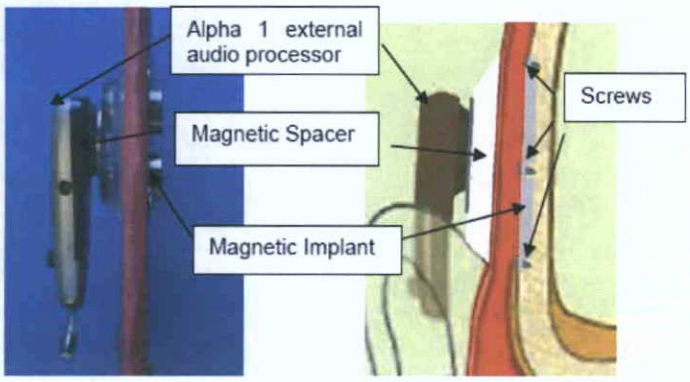

Figure 3: Alpha 1 (M) Magnetic Implant System

From PDF p. 64 S001

7. Kit Configurations

7.1. The Otomag System will be available in two kit configurations (e.g., Alpha 1 (S) with appropriate means of attachment, Alpha 1 (M) with appropriate magnetic spacers) or the components may be ordered separately. Each kit or component will be labeled appropriately and will include the Patient User Manual and / or the Physician Instructions for Use as appropriate.

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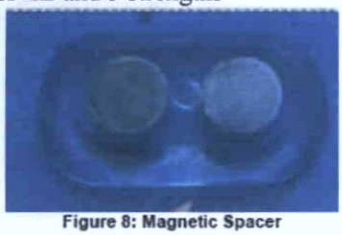
Summary of System Components

Device component	Materials	Spaulding Classification	Reprocessing instructions	Notes
Magnetic implant Synonyms: • Otomag Alpha 1 Sound Processor • Alph 1 Sound Processor • Sound Processor • Alpha 1	Sumarium cobalt sealed in titanium casing	Critical	No cleaning Steam sterilize with gravity or prevacuum cycle in a pouch.	No pre-vacuum validation. No drying validation. Incomplete description of packaging
*5 Titanium bone fixation screws	Third party component.	Critical	Follow OEM instructions for sterilizing.	Stryker Leibinger 1.7mm diameter craniofacial titanium self tapping screws (gold) and 1.7mm diameter self drilling screws (silver) in 4mm lengths. Shaft diameter must be no larger than 1.9mm and screw head size > 2.45mm
*Rescue bone fixation screws	Third party component	Critical	Follow OEM directions for sterilization	1.9mm (purple) diameter, 3mm length
Magnetic spacer in 3 sizes XX, YY, or ZZ and 5 strengths  Figure 8: Magnetic Spacer (shown with sound processor)	Nickel-plated neodymium iron boron magnets encapsulatetd in 100% Fotoplast light-curing plastic covered in a thin layer of Fotoplast Lacquer 3.	Noncritical – patient contacting Advised only for intact skin	Clean with Clorox type disinfectant wipe	S001 Appendix 18
Sound Processor (Previously reviewed by the same team with a disk)			Wipe with a soft cloth or Clean with Clorox type disinfectant wipe Clean battery compartment with dry Q-tip or Q-tip	

S10

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Device component	Materials	Spaulding Classification	Reprocessing instructions	Notes
			moistened with Clorox type disinfectant wipe. Use dry aid kit for excessive moisture exposure.	
Fitting gages (b)(4) [redacted] The gages are discs that are hung from the magnetic spacer as it sits over the implant during the fitting test. Whether or not the weight pulls the spacer free (+ patient comfort) determines which of the 5 spacers should be used.	Used during the fitting test to ensure proper function, pt comfort, and device performance. Wts attach to spacer. Smaller wt ensures minimum attachment force b/w implant & spacer; larger ensure too much force is not applied.	Noncritical-environmental contact Used on multiple patients in a medical setting.	Clean and low-level disinfection with Clorox type wipe or EPA registered hospital disinfectant wipe.	S1 A1
Storage case (Previously reviewed by the same team)		Single patient use Patient will use repeatedly over time Noncritical-environmental contact	Clean with a clorox type disinfectant wipe	
Head band (previously reviewed by the same team		Single patient use Patient will use repeatedly over time Noncritical-environmental contact	Clean with a clorox type disinfectant wipe	
Soft band (previously reviewed by the same team)		Single patient use Patient will use repeatedly over time Noncritical-environmental contact	Submerge and hand wash using mild clothes washing detergent with or without a small amount of color safe bleach, and air dry or clean with a Clorox type disinfectant wipe.	
Retention clip / lanyard (optional)	Attaches to sound processor assembly and to user's clothing – prevents damage if sound	Single patient use Patient will use repeatedly over time	Clorox type disinfectant wipe	

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Device component	Materials	Spaulding Classification	Reprocessing instructions	Notes
	processor assembly dislodges from user.	Noncritical-environmental contact		

*

Craniomaxillofacial Titanium Screws	1.7 mm dia. x 4.0 mm Self Tapping	1.7 mm dia. x 4.0 mm Self Drilling	1.9 mm dia. x 3.0 mm Emergency
Stryker/Leibinger Part Numbers	50-17004	50-17904	50-19004

Device Operation

The headband, softband, or magnetic implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The implant is placed in a surgical procedure under a general anesthetic.

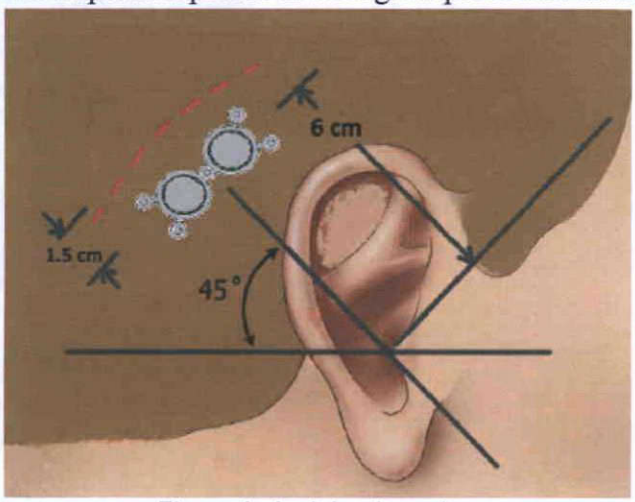

Figure 1 : Incision Location

Optional bone beds are created in the skull in which the magnets sit.

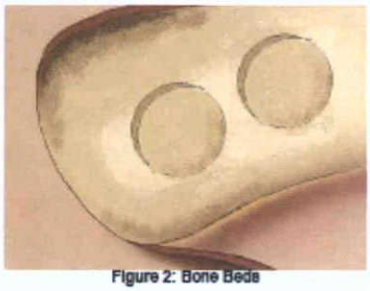

Figure 2: Bone Beds

The implants then sit in the bone beds and are attached to the skull using titanium screws.

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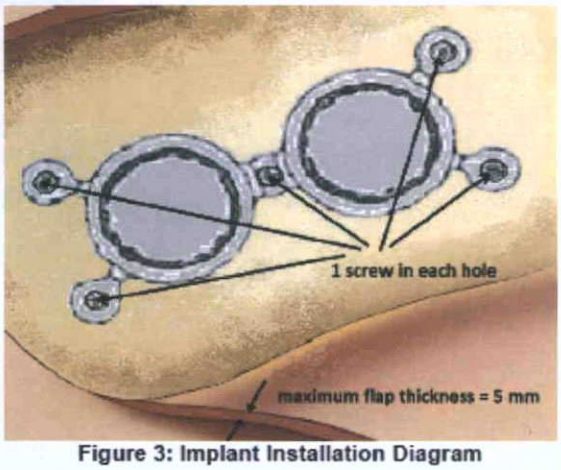

Figure 3: Implant Installation Diagram

Liebinger 4mm facial plating screws (titanium bone screws) for implant anchoring were validated.

Directions for explanting the magnets are also given, which are basically the reverse of implanting.

Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system. The Alpha 1 (M) configuration is supplied with three strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid. Choose a magnetic spacer to achieve appropriate sound transmission without being uncomfortable to the patient. The spacers are labeled XX, YY, ZZ to indicate increasing magnetic strength. The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable of if numbness occurs.

Nature and Duration of Patient Contact

The implant is placed in a surgical procedure under a general anesthetic. It is Spaulding classification "Critical" requiring sterilization prior to implantation.

This would normally be a " Class 1 / clean" wound primarily closed.
It does violate a hair-bearing area.

It is a permanent contact device (> 30 days) per ISO 10993-1.

Materials

Patient contacting materials include Fotoplast-Lac and Titanium Grades 4 and 5 implant. The device is latex free.

Standards PDF p 115 (Appendix A)

Standard # Cited &	Title	FDA Recognized	Declaration of Conformance	Notes

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Date				
ISO 17665-1:2006 with Updated 510(k) sterility review guidance K90-1 and with AAMI TIR 13: 1997 Principles of Industrial Moist Heat Sterilization	Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices	Yes	Yes – without deviations, adaptations or exclusions	Nelson Labs
ISO 17664-1:2004 section 3.10	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	No	Yes- – without deviations, adaptations or exclusions	Third party lab
ISO 15223-1:2007	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Yes	Yes— without deviations, adaptations or exclusions	
AAMI TIR 12: 2004 section 6 with FDA / ODE 1996 guidance on labeling reusable medical devices	Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	No	Yes in S001 without deviations adaptations or exclusions	Cited by Nelson labs
USP 32 <1211>	Sterilization and sterility assurance of compendial articles			Cited by Nelson labs
AAMI ST79: 2006 with A1:2008 & Z3: 2009 Sections 8 & 9	Comprehensive Guiide to steam sterilization and sterility assurance in health care facilities	Yes	Yes in S001 without deviations adaptations or exclusions	Cited by Nelson labs
AAMI ST8: 2008	Hospital Steam Sterilizers	Yes	Yes in S001 without deviations adaptations or exclusions	Cited by Nelson labs
AAMI ST67: 2003 (R2008)	Sterilization of healthcare products – requirements for products labeled "STERILE"	Yes	Yes in S001without deviations adaptations or exclusions	Cited by Nelson labs
EN556-2: 2003	Sterilization of medical devices. Requirements for medical devices to be desiginated "STERILE." Requirements for aseptically processed medical devices			Cited by Nelson labs
AAMI ST77: 2006 Sections	Containment devices for reusable medical device	Yes	Yes in S001 without deviations	Cited by Nelson

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4.4 & 5	sterilization.		adaptations or exclusions	labs
FDA / ODE 1996	Labeling reusable medical devices guidance			Cited by Nelson labs
AAMI ST81: 2004	Sterilization of medical devices: Information to be provided by the manufacturer for the processing	Yes	Yes in S001 without deviations adaptations or exclusions	

Predicate Devices:

K100193 Otomag Bone Conduction Hearing System – Models Alpha 1(S) and Alpha 1(M).

The Xomed Audiant Bone Conductor (K855059 and K861971) use the same technology.

Sterilization and Shelf-Life: (Original app -Section 16; PDF p. 105)

Whereas the Alpha 1(S) configuration had no sterile components, the Alpha 1(M) has a surgical implant that is sterilized by the user facility prior to surgery.

Section 16: Sterilization and Shelf Life

1. Sterilization

1.1. The Osseointegrated Magnetic Implant is provided clean but not sterile and is intended to be sterilized via gravity or prevacuum steam sterilization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices.

1.2. Attachment 1 to Section 15 – Labeling contains a copy of the revised Physician's Manual which contains details regarding pre-implant sterilization. Refer to pages 11 and 12 of this manual for details.

1.3. Appendix D to the overall submission contains validation protocols and reports for the specified sterilization cycle.

2. Shelf-Life

2.1. Not Applicable. The Osseointegrated Magnetic Implant is not supplied sterile and the materials of the implant case (titanium grades 4 and 5) are not expected to suffer performance degradation over the life of the overall product.

Implant Steam Sterilization Validation appears in Attachment D (PDF P. 173-192) and in S001: Appendix 16

Reviewer summary (updated with S001 content):

(b)(4)

[redacted]

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Figure 1: Inoculation site on device

Reviewer comment: While the text description of the device does not clearly identify the test samples as the subject devices, the provided image does.

Reviewer summary continued:
SAL ≥ 10^6
Product inoculation involved wrapping an inoculated suture around a groove of the device.
Devices were placed in a cardinal health pouch (b)(4) [redacted] *)*
Sterilizer was a STERIS (AMSCO) SV-120 K030789
Load configuration: Hospital sized chamber in the cold spot (over the drain)

(b)(4) [redacted]

TABLE 1. Results for the Gravity Half Cycles

IDENTIFICATION	RUN #1	RUN #2	RUN #3
Sample 1	0	0	0
Sample 2	0	0	0
Sample 3	0	0	0
Positive Control	+	+	+
Negative Control	0	0	0
Environmental Control	0	0	0

0 = No Growth
+ = Growth

(b)(4) [redacted]

Reviewer comment: It is not clear if a chemical indicator was used inside the package with the implant.
See deficiency.

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(b)(4)

[redacted]

Proposed Labeling

Physician's Manual (S001 Appendix 4, starts PDF p. 60)

Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

Warning

□ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Immediately seal the autoclave pouch.

Caution

□ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not

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use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be sterilized a single time by prevacuum or gravity steam sterilization (autoclaving). The following sterilization parameters have been validated for sterilization of the implant.

Limitations on Reprocessing: Single Sterilization Only
Presterilization Decontamination / Cleaning / Disinfection: None Required
Cycle Type: Gravity
Sterilization Time: 15 minutes minimum
Sterilization Cycle Temperature: 132 degrees C / 270 degrees F
Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)
Storage in Sterile State: Not Allowed – Sterilization immediately pre-implant Only

Sterilization Pouch Specifications

To ensure the validated parameters are replicated appropriately, the following is to be used to individually pouch each implant prior to performing the sterilization cycle:

Manufacturer: Cardinal Health, http://www.cardinal.com, 800.964.5227

Catalog Number: 92510

Size: 5.5" x 10" Paper Self Seal Pouch

Materials: Arjowiggins 60g/m^2 Paper / CN PET 12/CPP40 Micron

Total Product Area: 0.035 m^2

Paper Area: 0.035 m^2

Ink: Medical Grade

⚠	**Caution** • Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches.

Reviewer comments: This instruction does not allow for placing a chemical indicator into the pouch with the implant which is common practice. See deficiency.

AAMI ST79: 2006 consolidated text advises external and internal monitoring of packages containing implants.

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Table 6—Sterilization process monitoring recommendations

(b)(4)

[redacted]

Spacer instructions from p. 18.

Using the "Go" gage to determine the weakest appropriate magnetic spacer

1. *Starting with the one dot magnetic spacer, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the magnetic spacer poles align with the implant poles and the strongest magnetic attraction is achieved.*
2. *Ask the patient to sit upright with their head in a typical vertical position. Attach the "Go" gage clip to the patient's clothing.*
3. *Hang the "Go" gage disk from the magnetic spacer.*
4. *If the magnetic spacer detaches from the side of the patient's head, then the spacer is too weak and the process should be repeated with increasing magnetic spacer strengths until the magnetic spacer remains attached to the side of the head while attached to the "Go" gage disk.*
5. *The lowest dot number magnetic spacer that passes the "Go" test indicates the weakest magnetic spacer strength that should be recommended to the patient.*

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Using the "No -Go" gage to determine the strongest applicable magnetic spacer

1. *Starting with the lowest dot number magnetic spacer that passes the "Go" test, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the poles align with the implant poles and the strongest magnetic attraction is achieved.*
2. *Again, ask the patient to sit upright with their head in a typical vertical position. Attach the "No-Go" gage clip to the patients clothing.*
3. *Hang the "No-Go" gage disk from the magnetic spacer.*
4. *The magnetic spacer* ***should detach*** *from the head from the weight of the disk. If the magnetic spacer detaches from the head then the magnetic spacer is one of the appropriate spacers for the patient.*
5. *Repeat this process, increasing magnetic spacer strength one dot at a time until the magnetic spacer* ***does not detach*** *from head.*
6. *The highest number magnetic spacer that* ***detaches*** *from the head using the "No-Go" test indicates the highest magnetic spacer strength that* ***should be used*** *by the patient on a regular basis.*
7. *Any magnetic spacer that remains attached during the "No-Go" test is too strong and should not be recommended for patients long term use.*
8. *If all magnetic spacers used in the "No-Go" test detach when the "No-Go" disc is attached, then all of the spacers tested in the "No-Go" test may be appropriate for the particular patient.*

Reviewer comments:
From this description it is clear that the spacers, magnets, gages, and gage clips are used in a medical setting and that not every device used will be delivered to the patient. These devices will touch intact skin. It is not clear how devices tested with a patient but not given to the patient are handled / reprocessed between patients. See deficiency.

Package labels PDF p. 99

Sophono

MAGNETIC IMPLANT
REF: 093001

NON STERILE

SN: XXXX-XX
QTY: 1

EFS GmbH & Co. KG
Glasbronnenstr. 6
75449 Wurmberg, Germany
Phone : (+49) 0 2841 8870032
Fax : (+49) 0 2841 8870032
P/N XXXX-XXX

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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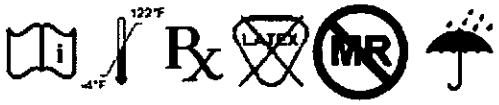
Otomag Alpha 1(S) Bone Conduction Hearing System

Manufacturer:
Otomag GmbH Alte Dorfstrasse 67, 32289 Rödinghausen, Germany. Tel: +49 5745 8504 Fax: +49 5745 8578
Distributed by: Sophono, Inc. 903 Broadlawn Drive, Boulder, CO 80303, USA. Tel: +1 303 564 1653 Fax: +1 720 222 2432

Contents:
1 Alpha 1 (S) Bone Conduction Hearing System
1 Physician Manual
1 Patient Manual



Device Intended for Single Patient Use Only!

PN xxxxxxx SN xxxxxxx LOT xxxxxxx

Made in Germany Label P/N 3000-03

Reviewer comment:
I believe we currently require that the English text be displayed with each international symbol.

Patient User Manual (starts S001 Appendix 5, PDF p. 97)

P. 6 Precautions

- Clean the Alpha 1 Processor, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device.
- To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.
- When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device.
- The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device.

Positioning instructions (p. 10)

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Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 3.

Figure 3. Positioning the Alpha I (M) Sound Processor on the osseointegrated Magnetic Implant

Patient User manual section 4, p. 14 (PDF p. 110) Product maintenance cleaning and care.

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4 Product Maintenance

Cleaning and Care

Sound Processor

- Have your Sound Processor checked at regular intervals as specified by your hearing professional.
- To clean your Sound Processor, wipe it with a soft cloth or a Clorox® type disinfecting wipe
- The battery compartment may be cleaned by wiping it out with a DRY cotton swab or a cotton swab that has been moistened by a Clorox® type disinfecting wipe.

	Note • Remove the Sound Processor, Softband, and Headband during the application of hairspray or styling gels. If hairspray or gel comes in contact with the Sound Processor it may become sticky and difficult to clean

- If the Sound Processor becomes soaked with water:
  - Immediately open the battery door and remove the battery
  - Put the Sound Processor in a container with drying capsules such as Dri-aid kit or similar overnight. Drying kits are available from most hearing care professionals.

	Caution • The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. • To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case

- The Sound Processor is provided in a plastic case which may be used to store the processor. This case may be cleaned with a Clorox® type disinfecting wipe. Make sure the case is completely dry before storing the Sound Processor in it.

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⚠	**Caution** • The Sound Processor is designed to operate within the temperature ranges of 41°F (+5°C) to 104°F (+40°C). The processor should not be subject to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. • Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor • Do not expose the Sound Processor to strong sunlight • Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case

Softband and Headband

- The Headband can be cleaned with a Clorox® type disinfecting wipe.
- The Softband may be submerged and hand washed with a mild clothes washing detergent (with or without a small amount of color safe bleach) and air dried or may be cleaned with a Clorox® type disinfecting wipe.

Magnetic Spacer

- The Magnetic Spacer can be cleaned with a Clorox® type disinfecting wipe.

⚠	**Caution** • Clean the Alpha 1 Processor, Magnetic Spacer, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. • To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

Below from p. 17:

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a Titanium case.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid: Fotoplast Lacquer 3 (light-curing one-component lacquer)

NO components or packaging for the Otomag Bone Conduction Hearing System contain latex.

Reviewer comments:
"mastoid" should be explained.
"latex" should be replaced by "natural rubber latex."
See deficiencies.

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(b)(4)

[redacted]

Reviewer comments:

Current limits are < 0.5 EU / ml or < 20EU / device which the test results appear to meet.
The subject device is not clearly identified in the report.
The device does not appear to be labeled nonpyrogenic.

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See deficiencies.

(b)(4)

[redacted]

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volume and different results. ***See deficiency.***

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Review of Sponsor responses to Deficiencies:

Deficiency 12: You do not address several issues that impact on the potential for surgical site infections postoperatively. Please address the following:

a) Your magnets appear to be implanted in a hair-bearing area. Surgeries in hair-bearing areas are at risk for surgical site infections (Mangram et al., 1999). Your Surgeon's manual does not address the removal of hair from the surgical area preoperatively. Please address this concern.

b) You do not advise any skin preparation (topical antimicrobials) prior to making the skin incision. Please address this concern and revise your Surgeon's instructions if indicated.

c) You do not advise any antibiotic prophylaxis for implanted patients. Please discuss whether antibiotic prophylaxis is recommended with your implants and revise the Surgeon's instructions if indicated.

References:

Fairbanks, D. N. F. (2007). Pocket Guide to Antimicrobial Therapy in Otolaryngology-Head and Neck Surgery (13th Ed.) Alexandria, VA: The American Academy of Otolaryngology-Head and Neck Surgery Foundation. Available from http://www.entnet.org/EducationAndResearch/upload/AAO-PGS-9-4-2.pdf

Mangram, A. J., Horan, T. C., Pearson, M. L., Silver, L. C., Jarvis, W. R., & HICPAC. (1999). Guideline for Prevention of Surgical Site Infection, 1999. Atlanta, GA: USDHHS / PHS / CDC / NCID / HIP. Available from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf

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Response 12: As requested by FDA in Parts a and b of this deficiency, the Physician Manual has been updated to address the removal of hair from the surgical area preoperatively as well as skin preparation (topical antimicrobials) prior to making the skin incision. The following section has been added to the Physician Manual.

Surgical Site Preparation:

The hair should be clipped and the scalp shaved at the incision site immediately before surgery. With the incision site skin free of gross contamination, apply antiseptic (such as iodophors, alcohol-containing products, or chlorhxidine gluconate) in the area of the proposed incision to an area large enough to allow for the extension of the incision or creation of a new incision or drain sites (if necessary).

Although under typical circumstances antibiotic prophylaxis would not be necessary, per the FDA's request in Part (c) of this deficiency, the Physician Manual has been updated to address antibiotic prophylaxis. The following section has been added to the physician manual.

Pre-Surgical Antibiotic Prophylaxis:

Antibiotic prophylaxis should be considered if the surgeon determines that this surgical procedure may be associated with a considerable risk of infection or if a post operative infection would cause a serious hazard to the patient's recovery or well being.

FDA Review of response to Deficiency #12: ACCEPTED.

b. Preoperative hair removal

Preoperative shaving of the surgical site the night before an operation is associated with a significantly higher SSI risk than either the use of depilatory agents or no hair removal.[16,100,166-169] In one study, SSI rates were 5.6% in patients who had hair removed by razor shave compared to a 0.6% rate among those who had hair removed by depilatory or who had no hair removed.[166] The increased SSI risk associated with shaving has been attributed to microscopic cuts in the skin that later serve as foci for bacterial multiplication. Shaving immediately before the operation compared to shaving within 24 hours preoperatively was associated with decreased SSI rates (3.1% vs 7.1%): if shaving was performed >24 hours prior to operation, the SSI rate exceeded 20%.[166] Clipping hair immediately before an operation also has been associated with a lower risk of SSI than shaving or clipping the night before an operation (SSI rates immediately before = 1.8% vs night before = 4.0%).[170-173] Although the use of depilatories has been associated with a lower SSI risk than shaving or clipping,[166,167] depilatories sometimes produce hypersensitivity reactions.[166] Other studies showed that preoperative hair removal by any means was associated with increased SSI rates and suggested that no hair be removed.[100,174,175]

Reference:

Mangram, A. J., Horan, T. C., Pearson, M. L., Silver, L. C., Jarvis, W. R., & HICPAC. (1999). Guideline for Prevention of Surgical Site Infection, 1999. Atlanta, GA: USDHHS / PHS / CDC / NCID / HIP. P. 15.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Available from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf

INFECTION PROPHYLAXIS IN SURGERY.
For CLEAN SKIN-ONLY INCISIONS IN HEALTHY PATIENTS, risk is low, sterile technique is sufficient, and antimicrobial prophylaxis is generally unnecessary.
Microbiology: *Staph. aureus* (including meth-resistant strains: MRSA•), *Staph. epidermidis*
Drug choices (if circumstances deem necessity):
Primary:
IV: cefazolin (Ancef, Kefzol)
1 Gm before anesthesia induction
OR
Oral: cephalexin (Keflex)
500 mg 1 h pre-op
• If MRSA suspected or prevalent: TMP/SMX oral, Vancomycin or Tygecycline IV (p. 49).
Alternative:
IV: clindamycin (Cleocin)
600-900 mg (slow drip) before anesthesia
OR
Oral: clindamycin (Cleocin)
150-300 mg 1 h pre-op

Per Fairbanks, 2007, p. 66-68, "surgery for prosthetic device implantation" may or may not be an indication.

Per Mangram et al, 1999

AMP is sometimes indicated for operations that entail incisions through normal tissue and in which no viscus is entered and no inflammation or infection is encountered. Two well-recognized AMP indications for such clean operations are: (1) when any intravascular prosthetic material or a prosthetic joint will be inserted, and (2) for any operation in which an incisional or organ/space SSI would pose catastrophic risk. Examples are all cardiac operations, including cardiac pacemaker placement,[290] vascular operations involving prosthetic arterial graft placement at any site or the revascularization of the lower extremity, and most neurosurgical operations (Table 4). Some have advocated use of AMP during all operations on the breast.[80,242,]

Deficiency 13: Your implant is steam sterilized by the end user facility immediately prior to surgical implantation. You advise that the user facility does not need to clean the implant and you describe a no-touch technique for transferring the implant from your package to the user facility's sterilization pouch. Your Surgeon's instruction manual (p. 11) mentions a container with a screw cap coming from the manufacturer. Please address the following:

a) Please fully describe your primary, secondary and tertiary packaging for the implant as applicable to complete the record and to assist our evaluation of your user instructions.

b) Please provide assurance that your manufacturing process removes both inorganic and organic residues prior to packaging. This information can be briefly summarized in one or two paragraphs.

c) Please state whether your manufacturing process renders the implant to have less than 0.5 EU / ml or < 20 endotoxin units / device per AAMI ST72: 2002 *Bacterial endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing* or USP <85> *Bacterial Endotoxins Test*. Please address the case of bilateral implants.

d) You describe the recommended sterilization pouch for the end user facility by manufacturer and part number. Please expand this description (Surgeon's manual p. 12) to include the materials and size of the pouch to better assure that the validated conditions are replicable by the end user facility.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Response 13a: Per the FDA's request in Part (a) of this deficiency, the following paragraphs briefly describe the primary, and secondary packaging for the implant. There is currently no tiertiary packaging. In addition, the device description has been updated to contain this information. The revised device description is included in Appendix 3 and the packaging specifications can be found in Appendix 9 of this response.

Primary Packaging

The primary packaging for the Alpha 1 (M) Sound Processor Implantable Device is a high density polyethylene (HDPE) tube (P/N S0072) with a screw top lid supplied by the Implant Vendor (Eberle EFS). The lid is covered with a perforated shrink band to provide a tamper- evident seal. This package is opened by the clinician at the time the implant is transferred into the sterilization pouch described in the labeling. The implant label is placed on the primary package. This label contains key symbols, the words "Non-Sterile", the serial number of the implant, quantity, and manufacturer information.

Secondary Packaging

The secondary packaging consists of a small corrugated box (8"x6"x1.5", P/N S0043) into which the primary packaging is inserted along with a copy of the Physician's Manual. The box is sealed with packaging tape and the shipping contents label is applied to the outside of the box. The exterior label on this package appears as follows:

Otomag Alpha 1(M) Bone Conduction Hearing System (Implant)

Manufacturer:
Otomag GmbH Alte Dorfstrasse 67, 32269 Rödinghausen, Germany. Tel: +49 5746 8504 Fax: +49 5746 6578
Distributed by: Sophono, Inc. 3022 Sterling Circle, Suite 100, Boulder, CO 80301 USA. Tel: +1(720) 407 5160 Fax: 1 720 4075166

Contents:
1 Magnetic Implant
1 Physician Manual

122°F
-4°F
Rx
LATEX
MR

Device Intended for Single Patient Use Only!

Made in Germany

Label P/N S0075-00

FDA review of response to deficiency #13a: PARTIALLY ACCEPTED

The external package label should bear the symbol for "non-sterile."

Response 13b: In response to the FDA's request for additional information in Part (b) of this deficiency, the organic and inorganic residues are removed prior to packaging as part of the manufacturing process. The validation test results attached in Appendix 15 demonstrate that contamination due to the manufacturing processes and handling is being adequately removed. Please note that the first two of these documents are certified translations of the original test reports that were originally written in German. Testing was performed on finished, packaged implants. The testing focused on microbial contamination, particulate contamination, endotoxins, and other process contaminants as listed below:

- Bio burden Level per DIN ISO 11737-1
- Particulate Contamination Level per ISO 8536-4
- Endotoxin/LAL per ANSI/AAMI ST72:2002 and the FDA Guidance documents describing LAL Testing.
- Cytotoxicity Testing per ISO 10993-5

FDA review of response to Deficiency #13b: PARTIALLY ACCEPTED

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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There are two endotoxin testing reports with conflicting information.

Response 13c: As described above, testing has been completed demonstrating that the bacterial endotoxin levels on the finished device are < 0.0050 EU /ml or < 0.12 EU / Device. Refer to Appendix 15 for detailed test results.

FDA review of response to Deficiency #13c: PARTIALLY ACCEPTED.

There are two endotoxin testing reports with conflicting information.

Response 13d: Per the FDA's request in Part (d) of this deficiency, the Physician Manual has been updated to contain additional sterilization pouch information to ensure the validated conditions are replicatable by the end user. The updated Physician Manual is contained in Appendix 4, and the text that was added to address this deficiency is as follows:

Sterilization Pouch Information

To ensure the validated parameters are replicated appropriately, the following is to be used to individually pouch each implant prior to performing the sterilization cycle:

Manufacturer: Cardinal Health, http://www.cardinal.com, 800.964.5227

Catalog Number:	92510
Size:	5.5" x 10" Paper Self Seal Pouch
Materials:	Arjowiggins 60g/m^2 Paper / CN PET 12/CPP40 Micron
Total Product Area:	0.035 m^2
Paper Area:	0.035 m^2
Ink:	Medical Grade

⚠	**Caution** • Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches.

FDA review of response to Deficiency #13d: PARTIALLY ACCEPTED

The external package should bear a chemical indicator which should be described.

Deficiency 14: You advise that titanium screws must be used to fix your implant to the patient's mastoid bone. Please address the following:

a) Please clarify if you supply the titanium screws or if you recommend the use of screws available from another vendor. If the latter, please detail in your Surgeons' instruction manual the material, length, width and any other important features of the screws that should be used. In addition, you should advise users of the exact screws that have been validated as compatible and optimal, by manufacturer, device name, and part number. Your instructions should make it clear that the screws must be sterile and should either provide sterilization instructions or should refer to the original manufacturer's instructions for sterilization, unless the screws are provided sterile from the manufacturer.

b) Most bone screw / implant systems involve "rescue screws." Please advise users what they should do if the initial attempt to place a screw doesn't work, and what the maximum screw size is that can be used with your device.

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Response 14: To address FDA's concern, the information regarding the screws to be used to attach the implant has been supplemented to:

- Fully specify the screws to be used including manufacturer, description, and part number
- Specify that the screws must be sterile and that the physician must follow the manufacturer's instructions related to use and sterilization (if purchased non-sterile)
- Specify an emergency "Rescue" screw to be used in the event of problems with placement of the original screw. This includes information on the maximum screw size that can be used with the implant.

The following additions have been made to the Physician Manual. Please refer to Appendix 4 for a copy of the revised manual. Appendix 14 contains validation protocols and reports related to the screw sizes specified in the revised Physician Manual.

Alpha 1 (M) System: Compatible Screws

	Notes • The Alpha 1 (M) implant requires 5 screws for implantation that are NOT included with the implant.

Screws

The Alpha 1 (M) implant requires 5 screws to be used to affix the implant to the skull. These screws are NOT included as part of the Alpha 1 (M) implant system and must be obtained separately.

The implant bracket holes are sized to accept Stryker/Leibinger 1.7 mm diameter Craniomaxillofacial titanium Self Tapping Screws, (Gold) and 1.7 mm diameter Self Drilling Screws (Silver) in 4 mm lengths and 1.9 mm Emergency Screws (Purple) in 3 mm lengths.

Craniomaxillofacial Titanium Screws	*1.7 mm dia. x 4.0 mm Self Tapping*	*1.7 mm dia. x 4.0 mm Self Drilling*	*1.9 mm dia. x 3.0 mm Emergency*
Stryker/Leibinger Part Numbers	*50-17004*	*50-17904*	*50-19003*

While all screw sizes / types specified above have been validated for this application, the Stryker/Leibinger 1.7mm x 4 mm self drilling screws, part number 50-17904 is considered optimal.

Other commercially available craniomaxillofacial titanium screws may be used as long as the screw shaft diameter is less than 2.0 mm and the screw head size is greater than 2.45 mm. Screw must be 4 mm in length (3mm for emergency screws).

The screws must be sterile prior to implantation. If the screws are not purchased sterile, refer to the screw manufacturer's instructions for sterilization.

	Warning • Purchased screws may be provided non-sterile and if so must be sterilized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection.

	Caution • Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws.

If the initial attempt to place a screw does not work and the screw hole becomes "stripped" emergency "rescue" screws can be threaded into the stripped hole. The largest size screw that can be used is 1.9 mm in diameter.

FDA review of response to deficiency #14: ACCEPTED

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Deficiency 15: You advise users (Surgeon's manual, p. 11) that they must follow your sterilization instructions precisely. Please address the following:

a) You state (Surgeon's manual, p. 12) that either pre-vacuum or gravity steam sterilization can be utilized for an exposure time of 15 minutes minimum at 132 degrees C. While this time and temperature are common hospital gravity steam sterilizer parameters, they are uncommon (and unvalidated per your Nelson Labs report) parameters for prevacuum steam sterilization (per AAMI ST79: 2006 and A1: 2008 and A2: 2009 consolidated text, Tables 4 & 5 *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*). Please remove your recommendation for pre-vacuum steam sterilization, or perform and document a pre-vacuum steam sterilization validation for your implant.

b) Your gravity steam sterilization validation study report does not state the chamber size utilized for the study. Please provide assurance that a hospital-sized sterilization chamber was used, and that neither an industrial-sized, nor a table-top sized chamber were used.

Response 15a: Per the FDA's request in Part (a) of this deficiency, the Physician Manual has been updated to remove the recommendation for pre-vacuum steam sterilization. The updated Physician Manual is contained in Appendix 4, and the text that was added to address this deficiency now reads as follows:

- *Limitations on Reprocessing: Single Sterilization Only*
- *Presterilization Decontamination / Cleaning / Disinfection: None Required*
- *Cycle Type: Gravity*
- *Sterilization Time: 15 minutes minimum*
- *Sterilization Cycle Temperature: 132 degrees C / 270 degrees F*
- *Drying Time: 30 minutes minimum*
- *Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)*
- *Storage in Sterile State: Not Allowed – Sterilization immediately pre-implant only*

FDA review of Response to deficiency #15a: ACCEPTED

Response 15b: In response to FDA's request for additional information in Part b. of this deficiency, the sterilization chamber used for the validation study report has been clarified via an amended Steam Sterilization Validation Report contained in Appendix 16. The chamber that was used in the original study was and FDA cleared, hospital sterilization chamber with the following specifications. Our used of the device in the study was consistent with the cleared intended use of the device:

Manufacturer: Steris (Amsco)

Model Number: SV-120

Size: Size 16" x 16" x 26"

510K Number: K030789

FDA review of response to deficiency #15b: ACCEPTED

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Deficiency 16: You do not recommend (Surgeon's instruction manual, p. 12) or validate (Attachment D) a drying time for your implanted magnets. Please address the following:

a) In your Surgeon's manual (p.11), in the section where you describe the preparation of the implant for sterilization, you state "Drying of the device is not required." This statement seems to be illogically placed and not relevant to the preparation for sterilization, since none of your recommended preparation steps involve making the implant wet. Please justify or delete this statement.

b) Your Nelson Labs sterilization validation protocol (Attachment D) includes a plan and method for validating drying associated with steam sterilization. However, the sterilization validation study report contains no validation of drying, and therefore it appears that a drying validation was not conducted. We believe that a drying validation study is necessary. Please explain the discrepancy between your protocol and validation study report and justify the lack of a drying validation study. Alternatively, please submit the missing drying validation study.

As communicated in "*Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance*" (available at http://www.fda.gov/cdrh/ode/198.pdf), manufacturers are responsible for including at least one validated, technically feasible sterilization method in their product labeling. Each sterilization instruction should include all critical cycle parameters. We regard drying as a critical cycle parameter, because wet instrument pouches exposed to environmental air and surfaces can become contaminated by microbes on strike through (i.e., wicking). Even though your implant is to be sterilized immediately before the surgery, we believe it must go through the drying part of the steam cycle in order to maintain sterility during preoperative handling.

Response 16a: Per the FDA's request in Part (a) of this deficiency, the Physician Manual has been updated to remove the statement "Drying of the device is not required". Refer to the Response to 15(a) above and Appendix 4 to this response for the revised version of the Physician Manual.

FDA review of Response to deficiency #16a: ACCEPTED

Response 16b: Per the FDA's request in Part (b) of this deficiency, a drying validation study was completed and the results of the study are contained in Appendix 17. The study validated a minimum drying time of 30 minutes to achieve the <3% residual moisture (from AAMI TIR 12, 2004). The sterilization cycle in the Physician Manual has been revised to contain the specifications for drying time as shown in the response to Deficiency 15(a) above.

FDA review of Response to deficiency #16b: ACCEPTED

Deficiency 17: Your sound processor uses a magnetic spacer, apparently available in one of "three strengths (XX, YY, & ZZ)" to connect the sound processor with the magnetic implant. Judging by the image of the spacer in the patient manual, the spacer may differ in design and materials compared to its counterpart in the cleared system (K100193). You do not fully characterize the spacer. Please provide a full description of the spacer and specify when and how it is used. In order for us to evaluate whether your cleaning instructions for reuse are adequate, we need to know whether it contacts intact or nonintact skin (e.g., unhealed surgical incision, psoriasis, eczema). If it will contact nonintact skin, it becomes Spaulding classification, "semi-critical" requiring a validated method of high-level disinfection between uses. Alternatively, you should contraindicate its use with non-intact skin.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Response 17: In response to the FDA's questions, the magnetic spacer is fully characterized in the specification document in Appendix 18. In summary, and in addition to the information in the original 510(k) submission, page 45 of 192 (Section 5.6). The Magnetic spacer consists of nickel plated neodymium iron boron magnets encapsulated in 100% Fotoplast ISO, a biocompatible, light-curing plastic and then covered in a thin layer of Lacquer (Fotoplast Lacquer 3, the same materials as the patient spacer of the soft band and headbands cleared in K100193).

As a part of developing our responses to FDA's identified deficiency, Sophono has decided to increase the number of available magnetic spacers to a total of 5. The reason for the addition was to give the physician finer force resolution when selecting the correct magnetic spacer for a given patients. Section 5.3 of the Physician Manual has been revised to warn the physician that magnetic spacers are only for use with intact skin (e.g. no unhealed surgical incision, psoriasis, or eczema). The following information has been added to the Physician Manual:

Placement of the Alpha 1 (M) Audio Processor

Approximately 4 weeks after the incision site has healed and all signs of inflammation are gone, the patient may be fit with the Alpha 1 (M) Audio Processor.

	Warning ▪ Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this warning may result in prolonged healing, further irritation, or infection.

FDA review of response to deficiency #17: PARTIALLY ACCEPTED

The content is still unclear as to whether the devices used for the fitting test are for single or multiple patients. If for multiple patients, they need cleaning and low level disinfection between patients.

Deficiency 18: Your sterility validation contractor, Nelson Labs, cites a number of standards and guidance documents that guide their methods. You submit declarations of conformance for just two of these. You should submit a declaration of conformance form (FDA form 3654) for each standard or guidance cited by Nelson labs.

Response 18: Per the FDA's request in this deficiency, the submission has been updated to include declarations of conformance for the standards cited in the Steam Sterilization Validation Report and copies of our revised Declaration of Conformity and additional Forms 3654 are included in Appendix 10. We now additionally claim limited or full compliance with the following additional standards:

- AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI/ANSI ST8:2008, Hospital steam sterilizers
- AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products – Requirements for products labeled "STERILE"
- AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization
- AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (Added from Response 20)
- ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (Added from Response 20)

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FDA review of response to Deficiency #18: ACCEPTED

New Sterility / Re-use Deficiencies were communicated interactively by V. Dasika to the Sponsor by e-mail as deficiencies #4-14, and the Sponsor submitted responses interactively on 1/19/2011.

FDA Deficiency #4:

4. You provide evidence of bacterial endotoxin testing (S001, Appendix 15). Appendix 15 contains two reports from two different contractors: (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted]. Please address the following concerns:

   a. Neither report clearly identifies the subject device as the device tested and reported.

Response 4a: The initial report dated March 12, 2010 was requested by the implant manufacturer (b)(4) [redacted] (b) [redacted] and its content was supplied in support of the test report requested by Sophono and conducted by Nelson labs. The content of the original report is not within Sophono's control to revise to better clarify the configuration of the device tested. However, the test report created by Nelson Labs was commissioned by Sophono and the part number (b)(4) [redacted] representing the configuration tested was documented in the original report. This part number is reflected in the primary implant label provided to FDA in the original submission package. However, to address FDA's concern, the report has been formally amended by Nelson to contain additional description of the device configuration tested. The device configuration tested was the finished implant as manufactured and packaged by Eberle. This is the exact configuration intended to be marketed by Sophono. A copy of the amended report is contained in Appendix 1 to this response.

FDA review of response to #4a: ACCEPTED

The following new content is in the amended Nelson Labs report.

Note: The devices tested and reported herein, (b)(4) [redacted], are client's subject device, which is the finished packaged magnetic implant supplied in a plastic vial.

   b. Each report uses the LAL kinetic turbidometric method, but each reports a different assay sensitivity (0.001 EU / ml and 0.005 EU / ml respectively)

Response 4b: Regarding the concern about the variation in assay sensitivities, there is no defined requirement in any standard for specific test sensitivity when testing bacterial endotoxins. The test sensitivity, along with the endotoxin release limit, are used to determine the Maximum Valid Dilution (MVD) or maximum amount of extraction volume prior to testing. The calculation for this is as follows:

MVD / Maximum Extraction Volume = Endotoxin Release Limit / Sensitivity

Therefore, the sensitivity across different tests is allowed to vary, as long as the MVD / maximum extraction volume is not exceeded during testing.

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c. Each report uses a different extraction volume (b)(4) [redacted]

Response 4c: Regarding the concern about variation in extraction volumes (b)(4) [redacted], there is not a required extraction volume specified within the 1987 FDA guideline on LAL or any other recent document. The 1987 FDA guideline on LAL suggests an extraction volume of

40mL/Device, which was is the volume that was used in report (b)(4) [redacted]. However, in testing performed under report (b)(4) [redacted], a lower extraction volume was used to achieve a higher sensitivity. In this case, the 24 ml used was sufficient to entirely cover the test articles for the complete duration of the test. Test labs will often use different extraction volumes due to varying device configurations and equipment. The extraction volume has little impact on the evaluation of the endotoxin burden as long as adequate detection sensitivity is maintained.

d. Each report obtains different results, although all are within accepted limits.

Response 4d: We acknowledge FDA's concern, however small variations in endotoxin are expected. In this case, the estimated difference in the two results (b)(4) [redacted] approximately 166 times lower than the acceptance limit, indicating the actual variability in the result is very small. Both test methods yielded results that met acceptance criteria as defined by the 1987 FDA Guideline on LAL, ST 72, and USP <85>.

e. Please clarify if your implant is labeled as non-pyrogenic. If it is, please provide an image or mock-up of the labeling bearing the information. If it is not, please explain the lack of non-pyrogenic labeling. This information should also be framed in the context of the labeling of your predicate devices.

After additional interactive clarification, this deficiency #1e was amended to read:

e) (as amended) You provide your implant component of the device as non-sterile to be sterilized by the end user facility prior to surgery. You request to know if this situation can justify the lack of non-pyrogenic device labeling. If the implant is manufactured and delivered to the end user as non-pyrogenic, please explain why a simple packaging transfer prior to sterilization by the end user will introduce pyrogens. In addition, please discuss the non-pyrogenic labeling (or lack of labeling) of each of your predicate devices as part of your justification if you want to deviate from the standard (AAMI ST72).

Response 4e: To address the deficiency identified by FDA, the primary and secondary labels have been revised to include the statement "Non-Pyrogenic". These labels can be seen in Response 8 within this document. Additionally, the Patient Manual and Physician Manual have been revised to specify the device as Non-Pyrogenic. The updated manuals are contained in Appendices 2 and 3, and the text that was added to address this deficiency is as follows:

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The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via gravity sterilization at the healthcare facility immediately prior to implementation.

Additionally, FDA requested Sophono discuss the labeling of the predicate devices. The primary predicate for this submission, the Alpha 1(S) version of this device does not contain and implant nor other sterile components and therefore the labeling does not contain a statement regarding pyrogenicity. The labeling for the secondary predicate, the Audiant Device, is not currently available through any means available to Sophono. However, Sophono agrees with FDA's recommendation to add non-pyrogenic to the labeling. This is supported by the provided test data, and Sophono does not believe the packaging transfer, as specified in the Physician Manual, will add additional pyrogens.

FDA review of responses to deficiencies #4 b-d: ACCEPTED.

My main point was to detail how these were different studies and to ask which study is final and used for decision-making about labeling. They have complied with the relevant standards and appropriately labeled their implant as non-pyrogenic. The Nelson Labs, US-based study is the final study.

FDA Deficiency #5:

5. Your implant is gravity steam sterilized by the healthcare facility prior to the implant procedure. AAMI ST79: 2006 (consolidated text with A1: 2008 & A2: 2009) Table 6 advises that packages containing implants have both external and internal chemical indicator (i.e., "steam indicator") monitoring. This monitoring is important to use in addition to various other load and sterilizer monitors. Please address the following:

a. Your gravity steam sterilization validation study utilized a Cardinal Health medical grade paper self seal pouch (size 5.5" x 10"). Please describe what external chemical indicator monitoring it contains.

Response 5a: As requested by FDA, Sophono has obtained a description of the chemical indicator used in the gravity steam sterilization validation study. The indicator is manufactured by Cardinal

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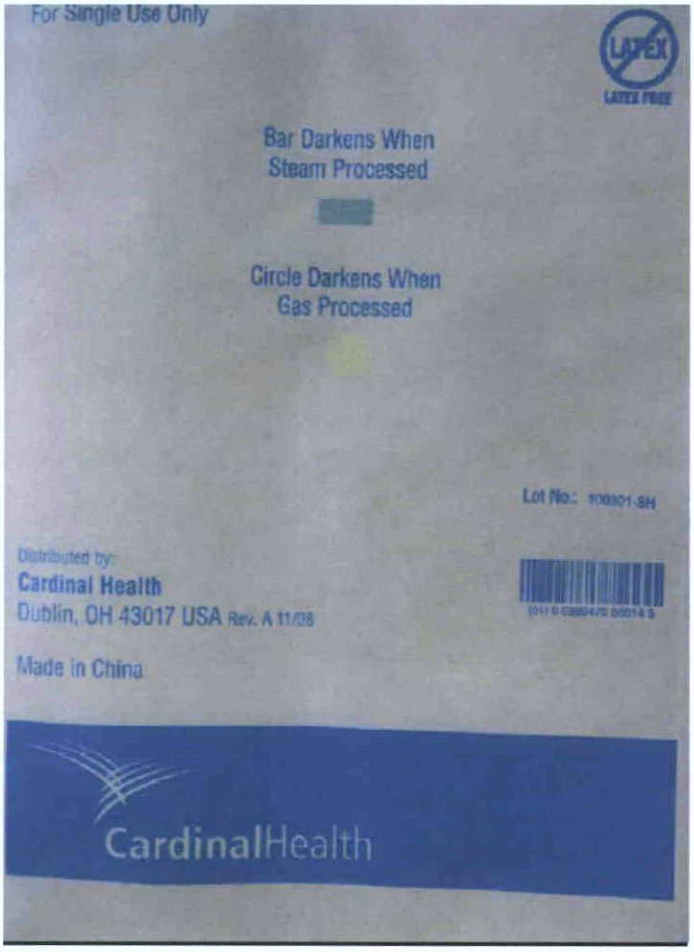
Health and provides clear indication of adequate steam sterilization as shown below. In addition, this pouch also contains a gas indicator. The indicator is a part of the specified sterilization pouch and provides a colored bar that darkens upon complete exposure to steam processing. A picture of the chemical indicator appears as follows:



FDA review of response to #5a: ACCEPTED

b. Please describe the chemical indicator monitor used inside the package during the validation study.

Response 5b: In response to FDA's request for a description of the chemical indicator used during execution of the validation study, a chemical indicator was not used and would not have been appropriate for this study. The validation study was completed using the Overkill Method as described in ISO 17665, which validates a sterilization process utilizing half cycle exposures. As a result of using the Overkill Method, a chemical indicator would not have appropriately indicated completion of the sterilization cycle. Instead of a chemical indicator, a biological indicator (BI) was used to demonstrate completion of the ½ cycle through death of the target organism contained on the BI.

FDA review of response to #5b: ACCEPTED

c. Your latest physician instruction document does not advise users to add a chemical indicator inside the package with the implant. If use of a chemical indicator was not validated, please provide a strong justification for this. Otherwise, please revise your user instruction to include this step.

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Response 5c: As justified in Response 5b, an internal chemical indicator was not used during validation activities. A BI was used to ensure the defined cycle adequately sterilized the device. However, Sophono acknowledges the need for an internal indicator. Sophono has identified an indicator strip manufactured by Steris specifically for use with Sophono's cycle parameters (270F, 15min). The technical information and specification for this strip are contained in Appendix 5

Per FDA's request, the Physician Manual has been revised to include use of this recommended indicator inside the package during sterilization of the implant. The updated Physician Manual is contained in Appendix 3, and the text that was added to address this deficiency is as follows:

FDA review of response to #5c: PARTIALLY ACCEPTED

See new deficiency related to the content below.

Internal Steam Indicator Strip Specifications

Each time an implant is steam sterilized, place a single indicator strip conforming to the following specifications into the inside of the specified pouch. Follow manufacturer's instructions for interpretation of results

Manufacturer: Steris

Description: Verify® Sixcess® 270F 15 Minute Indicator - Long

Catalog Number: PCC031

Cycle Use: 270°F (132°C), 15 minute steam sterilization processes

Type: Single Use Only

FDA deficiency #6:

6. You appropriately do not validate "flash" steam sterilization for your implant. Flash sterilization is not appropriate for implants due to the potentially severe consequences to the patient from placing even a minimally contaminated device in an essentially avascular environment (Rutala et al., 2008, p. 60 and AAMI ST79: 2006 (consolidated text), p. 3). Your latest physician instruction document does not mention flash sterilization. Many metal devices that are sterilized by steam can undergo flash sterilization. To reinforce current knowledge and best practice, we recommend that you add a warning to your physician instructions advising that the implant should not be flash steam sterilized. Facilities should have an adequate supply of devices such that if an implant is dropped or otherwise contaminated, another sterile implant is available for use. In addition, because of this common best practice, your instructions should advise users what they can do with implants that are sterilized to be ready for a case but are not used (i.e., can they be stored and / or can they be repackaged and sterilized again before another case, or must they be discarded).

References:

AAMI ST 79: 2006 with A1: 2008 and A2: 2009 (consolidated text): *Comprehensive guide to steam*

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sterilization and sterility assurance in health care facilities.

Rutala, W.A., Weber D. J., & HICPAC. (2008). *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*. Atlanta, GA: Centers for Disease Control Available from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf

Response 6: Based on the concerns raised by the FDA, Sophono has updated its Physician Manual to include a warning that the implant is not intended to be flash steam sterilized. The updated Physician Manual is contained in Appendix 3, and the text that was added to address this deficiency is as follows:

	Warning ▪ The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device.

Based upon FDA's further comments, a statement has been added to the Instructions for Sterilization section of the Physician Manual recommending the availability of a sterilized backup implant in the event the intended implant becomes contaminated during the implantation procedure. The revised text further instructs the Physician that the unused devices may be stored in the original container or in the sterilization pouch. However, the implant must be repackaged and resterilized just prior to surgical implantation in accordance with the instructions. The text that was added to address these concerns is included within Response 5c.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be re-sterilized by gravity steam sterilization (autoclaving) if it is not used during the implantation procedure. The following sterilization parameters have been validated for sterilization of the implant.

Limitations on Reprocessing: Magnetic implants may be resterilized if not used during the implant procedure. Implants may be stored in the sterilization pouch or the original screw-top cylinder. However, the implant must be transferred to a new sterilization pouch just prior to sterilization and implant.

FDA review of response to #6: PARTIALLY ACCEPTABLE

This raises issues with the non-pyrogenic labeling and with validation of device functionality. See new deficiencies.

7. Your "go, no-go" test devices (spacers, magnets, fitting gages, and gage clips) are used in a medical setting, but are not clearly described as to whether they are for single patient use or multiple patient use. Please clarify their description on this point. If any of these devices can be used with more than one patient, please describe appropriate cleaning and low-level disinfection of the devices between patients.

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Response 7: In response to FDA's question regarding the use of the "go, no-go" test devices, they are intended for multi-patient use. The go, no-go test accessories simply hang from the magnetic spacer and do not have direct patient contact. Prior to being used on a different patient the accessories must be cleaned with a Clorox® type disinfecting wipe. This information has been added to the "Instructions for Placement / Sizing of the Magnetic Spacers" section of the Physician Manual. Refer to the text below and Appendix 3 for the revision to the Physician Manual.

FDA review of response to #7: PARTIALLY ACCEPTED

The new content for user instructions:

> The "Go" and "No-Go" gages used in the selection of the appropriate magnetic spacers may be re-used with multiple patients. However, prior to using with another patient the accessories must be cleaned with a Clorox® type disinfecting wipe.

Clorox wipes are available for home use but may or may not be available in medical settings. Medical settings have EPA-registered hospital disinfectant wipes.

8. You provide a description of primary and secondary packaging (Response to deficiency #13a). Please include the symbol for "non-sterile" on both the primary and secondary package labels for clarity and completeness.

Response 8: As requested by the FDA, the implant's primary and secondary labels have been revised to include the symbol for "non-sterile." The primary packaging label appears as follows:

FDA review of response to #8: ACCEPTED

Labeling Deficiencies

9. Your physician labeling (Appendix 4, p. 8) includes the symbol and English text for "latex free." However, the latest Agency- accepted language is "contains no natural rubber latex." Please retain your current icon / symbol (p. 8), but change the English explanatory text to "contains no natural rubber latex." This list of symbols should also include the symbol for "Nonsterile" in reference to the implant.

Response 9: In response to the FDA's request, the phrase "latex free" has been replaced with the phrase "contains no natural rubber latex" in both the Patient and Physician Manual. Additionally, the "Nonsterile" symbol was added to the Symbols section within the Physician Manual. The updated Patient and Physician Manuals are contained in Appendices 2 and 3, respectively.

FDA review of response to #9: ACCEPTED

Patient Labeling:

10. The contraindications (p. 8) are unconventionally placed and the wording is not entirely appropriate for patients. Please revise the location and content of this section to address the following:

a. Contraindications typically appear before warnings and precautions.

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b. Please define all medical terminology and multisyllabic words (e.g., tinnitus, unilateral, asymmetrical, progressing – include the concept that both worsening and improved hearing may change the treatment plan)

c. Please address all language to the patient (i.e., second person "you," not third person, "the patient").

Response 10a: Per FDA's request, the Contraindications section was placed before the warnings and precautions within the Patient Manual. Refer to Appendix 2 for the revised version of the Patient Manual.

Response 10b: FDA's request to clearly define medical terminology within the Contraindications section of the Patient Manual has been addressed by Sophono. Additionally, Sophono added a statement to the section specifying treatment changes are dependent on improving and declining hearing. Refer to the text below and Appendix 2 for the revised version of the Patient Manual.

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer you for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- Hearing loss occurring suddenly;
- Hearing loss that grows worse rapidly;
- Pain in either ear;
- A sudden recent onset of ringing or a similar sensation in the ears, also known as tinnitus. Tinnitus may be bilateral (occurring in both ears) or unilateral (occurring in one ear);
- Unilateral or markedly asymmetrical (not equal in both ears) hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Note: While the contraindications listed above may affect the process of hearing aid fitting, it should be noted that the treatment plan for use of the Otomag Alpha 1 Sound Processor may vary with worsening or improving hearing. Your treatment plan will be determined by your primary care physician.

Deficiency 10c: As requested by the FDA, Sophono has addressed the language to the patient to ensure second person is used in all appropriate instances. In order to eliminate the potential for future questions on this subject, the entire Patient Manual reflects these changes, instead of just the Contraindications section. Refer to Appendix 2 for the revised version of the Patient Manual.

FDA review of responses to #10a-c: #10a & c are ACCEPTED. #10b is PARTIALLY ACCEPTED.

Primary care physicians are inappropriately referenced in the note after the contraindications. See new deficiency.

11. You state (section 4, p. 16) that the device lifespan is 4 years, whereas elsewhere in the application, you state that the device lifespan is 3 years. Please rectify this discrepancy.

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Response 11: The correct lifespan for the device is 4 years as stated in the patient manual. This value is based on Otomag's experience with this and similar products in the European market.

FDA review of response to #11: ACCEPTED

12. Minor changes are needed to the "Patient contacting Materials" section (p.17). Please address the following:

a. Please define the medical term "mastoid" in lay language.

b. Please replace the word "latex" with "natural rubber latex" to comply with the Agency's currently accepted terminology.

c. You do not describe the recommended cleaning / care for the optional retention clip / lanyard. Please include the missing information.

Response 12a: Per FDA's request, "mastoid" has been more clearly defined in layman's terms in the Patient Contacting Materials section within the Physician Manual and the Patient Manual. Refer to the text below and Appendices 2 and 3 for the revised versions of the Physician Manual and Patient Manual.

Portion of Headband or Softband that presses against the mastoid (bony protrusion on the skull located directly behind the ear): Fotoplast Lacquer 3 (light-curing one-component lacquer)

Response 12b: Per FDA's request, the word "latex" was replaced with "natural rubber latex" within the Physician Manual and the Patient Manual. Refer to the text below and Appendices 2 and 3 for the revised versions of the Physician Manual and Patient Manual.

The components and packaging for the Otomag Bone Conduction Hearing System contain no natural rubber latex.

Response 12c: In response to FDA's request to specify cleaning / care for the optional retention clip / lanyard, Sophono revised the Cleaning and Care section of the Patient Manual to include the retention clip / lanyard. The retention clip / lanyard does not have direct patient contact, therefore cleaning with a Clorox® disinfecting wipe is an acceptable method to ensure the accessory stays clean. Refer to the text below and Appendix 2 for the revised version of the Patient Manual.

Retention Clip / Lanyard

- The Retention Clip / Lanyard can be cleaned with a Clorox® type disinfecting wipe.

FDA review of response to #12 a-c: ACCEPTED

FDA deficiency #13:

13. You appropriately provide manufacturer contact information in Section 7, p 20. This section is entitled "Professional Support." The titling makes it unclear as to whether the information pertains to patients or to healthcare professionals. We recommend that you summarize the issues that patients should report first to

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the healthcare professional vs. those they should report directly to Sophono, Inc. If appropriate, a warranty statement along with limitations on the warranty are often included in this section.

Response 13: To address FDA's concern that the title "Professional Support" section within the Patient Manual does not provide clear indication to the patient who the section pertains to, the title of the section has been changed to "Patient Support." As a result of FDA's recommendation to support patient reporting, Sophono has revised the Patient Support section to instruct the patient to contact their primary care physician if they have any concerns or questions related to the Alpha 1 (M) system. Sophono intends for the patient to contact their primary care physician regardless of the issue type, allowing the physician to determine whether or not Sophono should be contacted. Therefore, a summary identifying the issues for patients to report to healthcare professionals and directly to Sophono was not developed. Refer to the text below and Appendix 2 for the revised version of the Patient Manual.

7 Patient Support

If you experience any device related issues, develop unexpected or excessive symptoms, or have general concerns or questions, please contact your primary care physician.

FDA review of response to #13: PARTIALLY ACCEPTED

Again the reference to primary care physician is inappropriate.

FDA deficiency #14:

14. Your 510(k) summary needs further revision for full compliance with 21 CFR 807.92 (Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92) The summary should include that the device is provided non-sterile from the manufacturer to be gravity steam sterilized by the healthcare facility. Pyrogenicity should be addressed according to your response to Deficiency #1 above.

Response 14: Per FDA's request, the 510(k) Summary has been revised to specify the device is provided non-pyrogenic. The revised text is as follows, and the revised Executive Summary can be seen in Appendix 4.

The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

FDA review of #14: ACCEPTED

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Reviewer summary of Sterility (updated in S001 and S1/A1):

This implanted titanium cased magnet is provided Nonsterile from the manufacturer to be sterilized by the user facility immediately prior to the implant surgery. An appropriately conducted validation study for gravity steam (original application) and drying time (S001) were conducted. In S1/A1 the sponsor clarifies that the pouch had an external CI and an internal BI. A CI cannot be validated because it will not turn color when exposed to only a half-cycle of sterilization. End users will place a CI inside the pouch and revised labeling specifies a compatible CI. We asked them to make the instruction more general to allow for any CI labeled for the intended cycle parameters.

In S1/A1 they advise that the implant can undergo a second full cycle steam sterilization. We ask for device functionality validation to support this instruction. In addition, we ask for a revision of the instruction to protect the implant's non-pyrogenic properties.

The original application user instructions follow ISO 17664-1: 2004 Sterilization of medical devices-Information to be provided by the manufacturer for the processing resterilizable medical devices. However additional clarifications were needed after the original, S001, and S1/A1 reviews.

Content in S001 addresses prevention of surgical site infections, sterilization of implant screws and rescue screws from a third party vendor, validated drying instructions, and removes the unvalidated reference to pre-vacuum steam sterilization for the implant.

A number of accessories for the system were previously reviewed and cleared by FDA. However, the sound processor has a new magnetic spacer that is incompletely characterized as to whether the fit test accessories are used for one or multiple patients. Cleaning and low-level disinfection of fit test components between patients was added to the physician instructions in S1/A1.

All other accessories are appropriately cleaned and / or low-level disinfected.

In S001 two reports are submitted for endotoxin testing which are internally inconsistent. The sponsor clarifies in S1/A1 that the Nelson labs study was the most recent and they meet methods and results for current standards AAMI ST72: 2002 and USP<85>.

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	Implant provided non-sterile to be sterilized using gravity steam by the user facility immediately preoperatively. 15 min at 132C / 270F in pouch Dry time = 30min	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		NA
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals*," do not include measurement of ethylene glycol residuals);		NA
2. A description of the Validation Method for the sterilization	ISO 17665-1: 2006 Sterilization of	

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cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	healthcare products- Moist Heat-Part 1Requirements for the Development, Validation, and routine control of sterilization process for medical devices Biological Indicator Overkill method Dry time validated per AAMI TIR 12: 2004 (version 2010 is identical in this content area)	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?	Yes	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	Application S001 Appendix 15 Turbidometric-Kinetic method by Nelson Labs	
5. A description of the packaging (not including package integrity test data):	-Primary = HDPE tube with a screw top lid. Lid covered with perforated shrink band for tamper-evident seal. Implant label is on this tube. -Secondary = small corrugated box containing one implant and one DFU.	

END OF REVIEW

Recommendation: TH

Suggested Deficiencies for the Sponsor:

(b)(4)

[redacted]

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(b)(4)

[redacted]

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Jim Kane's edits of S001 TH AI letter

(b)(4)

[redacted]

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Dasika, Vasant

From: Clay Anselmo [anselmoc@reglera.com]
Sent: Wednesday, January 19, 2011 6:09 AM
To: Dasika, Vasant
Cc: jim.kasic@comcast.net; jim.kasic@sophono.com
Subject: RE: Interactive review of K102199/S001
Importance: High
Follow Up Flag: Follow up
Flag Status: Purple
Attachments: Total_Response_Electronic.pdf

Hi Vasant,

Thank you for the extra hours to complete our response. Attached to this email you will find our completed response and associated attachments addressing the 14 items from your request below. Please respond and let me know that you were able to receive and open the attached file.

Thanks,
Clay

Clay Anselmo
President and CEO
Reglera LLC
(303) 832-8200 O
(303) 907-2955 C
(303) 832-6700 F

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
To: anselmoc@reglera.com [mailto:anselmoc@reglera.com]
Sent: Tue, 18 Jan 2011 15:13:04 -0700
Subject: RE: Interactive review of K102199/S001

Hi Clay-

We recommend that you please just make a statement about what the lifespan is, the basis on which you determined the lifespan, and ensure that your labeling is consistent with the determined lifespan.

Thanks,
Vasant

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Tuesday, January 18, 2011 2:37 PM
To: Dasika, Vasant
Subject: RE: Interactive review of K102199/S001

Dear Vasant,

Thank you for your help on the non-pyrogenic labeling question. We are compiling all of our responses now and hope to have the document to you by 7PM EST tonight. I do have one additional clarification. Related to

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deficiency number 11, we can find no place in our submission where we refer to 3 year lifespan of the device, only the reference you cited related to 4 years. If you could point us to this 3 year reference, it would be extremely helpful.

Sincerely,
Clay

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Monday, January 17, 2011 9:20 AM
To: anselmoc@reglera.com;Jim Kasic
Cc: jim.kasic@sophono.com;Nandkumar, Srinivas
Subject: RE: Interactive review of K102199/S001

Hi Clay- As stated in my e-mail, we may have additional questions as our review continues. In light of your request for additional time, we request that you please try your best to provide your complete responses by 7 PM Eastern time on January 18, 2011 and that I will require your responses at the very latest by 8:30 AM Eastern time on January 19, 2011. These deadlines are necessary for us to try to accommodate interactive review of your submission given our own timelines.

Regards,
Vasant

From: Clay Anselmo [mailto:anselmoc@reglera.com]
Sent: Monday, January 17, 2011 10:15 AM
To: Dasika, Vasant; Jim Kasic
Cc: jim.kasic@sophono.com; Nandkumar, Srinivas
Subject: RE: Interactive review of K102199/S001

Dear Vasant,

Thank you for allowing us to working interactively with the Agency to resolve your remaining questions. I have a quick question regarding timing for our response. Today is a holiday for Sophono (Martin Luther King Day) and their key technical staff is not available. Because of this, we would only have approximately 2 hours Tuesday morning to prepare our response. Would it be possible, in light of the number of questions and the holiday today, to allow us to have till the end of the day on Wednesday to complete our response. Your flexibility would be greatly appreciated.

Sincerely,
Clay Anselmo

From: Dasika, Vasant [mailto:Vasant.Dasika@fda.hhs.gov]
Sent: Sunday, January 16, 2011 8:41 PM
To: Jim Kasic;'anselmoc@reglera.com'
Cc: 'jim.kasic@sophono.com';Nandkumar, Srinivas
Subject: Interactive review of K102199/S001
Importance: High

Dear Jim,

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thank you for providing a copy of the requested Raicevich et al article.

With this e-mail, I have attached a list of deficiencies for interactive review. Note that the attached list is not necessarily exhaustive as our review is still on going. Please e-mail me your responses to all items by Tuesday January 18, 2011 at 12 PM Eastern time.

Please contact me by e-mail or phone if you have questions.

Kind Regards,
Vasant

Vasant K. Dasika, PhD
Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA
10903 New Hampshire Avenue
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Silver Spring, MD 20993

Phone: (301) 796-6860
Fax: (301) 847-8126

Email: Vasant.Dasika@fda.hhs.gov

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Sophono

January 18, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Room 2443

Attn: **Vasant K. Dasika, PhD**
Email: Vasant.Dasika@fda.hhs.gov

Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for Additional Information dated September 23, 2010

510(k) Applicant / Manufactured by:
Jim Kasic
President and CEO
Sophono Inc.
3022 Sterling Cr,
Boulder, CO 80301

510(k) Contact / Submission Correspondent:
Clay Anselmo
Reglera LLC
555 Zang Street
Lakewood, CO 80228 USA
Phone (Mobile): 303-907-2955
Fax: 303-832-6700
Email: **anselmoc@reglera.com**

Dear Dr. Dasika,

We received FDA's request for additional information dated January 16, 2011 in response to our 510(k) application, K102199, for the Sophono Otomag Bone Conduction Hearing System. To address the issues raised in these requests for additional information, we are providing the following information in response for your review.

The attached response reflects our response to the fourteen (14) deficiencies listed in the January 16, 2011 Additional Information Request. Please note that are response is being submitted directly to you in an electronic format. If it needs to be sent to the document mail center as well, please let me know.

If you have any questions or if further information is needed, please feel free to contact me at any time using the contact information contained above. We greatly appreciate your time and attention to this matter.

Sincerely,

Clay Anselmo
Submission Correspondent
Reglera LLC.

cc: Jim Kasic., Sophono Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Positioning the Sound Processor

Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 1. If you have thicker hair, it may be necessary to part your hair over the implant site or shorten the hair at the implant location to ensure an adequate holding force between magnets.

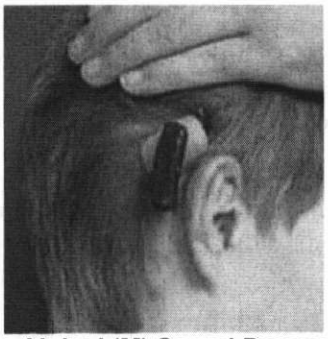

Figure 1. Positioning the Alpha I (M) Sound Processor on the Magnetic Implant

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

⚠	**Warning** • The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize a device appropriately can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Place a single steam sterilization indicator into the pouch with the implant.
- Immediately seal the autoclave pouch.

⚠	**Caution** • The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be re-sterilized by gravity steam sterilization (autoclaving) if it is not used during the implantation procedure. The following sterilization parameters have been validated for sterilization of the implant.

Limitations on Reprocessing: Magnetic implants may be resterilized if not used during the implant procedure. Implants may be stored in the sterilization pouch or the original screw-top cylinder. However, the implant must be transferred to a new sterilization pouch just prior to sterilization and implant.

Presterilization Decontamination / Cleaning / Disinfection: None Required

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cycle Type: Gravity

Sterilization Time: 15 minutes minimum

Sterilization Cycle Temperature: 132 degrees C / 270 degrees F

Drying Time: 30 minutes minimum

Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)

Storage in Sterile State: Sterilization immediately pre-implant only

Upon completion of sterilization verify that both sterilization indicator strips (interior and on exterior of package) indicate the steam cycle was completed correctly. Follow manufacturer instructions for interpretation of these indicators. If both the indicators do not show completion of the sterilization cycle, repeat the cycle.

⚠	**Warning** ▪ The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device.

Sterilization Pouch Specifications

To ensure the validated parameters are replicated appropriately, the following is to be used to individually pouch each implant prior to performing the sterilization cycle:

Manufacturer: Cardinal Health, http://www.cardinal.com, 800.964.5227

Catalog Number: 92510

Size: 5.5" x 10" Paper Self Seal Pouch

Materials: Arjowiggins 60g/m^2 Paper / CN PET 12/CPP40 Micron

Total Product Area: 0.035 m^2

Paper Area: 0.035 m^2

Ink: Medical Grade

⚠	**Caution** ▪ Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Steam Indicator Strip Specifications

Each time an implant is steam sterilized, place a single indicator strip conforming to the following specifications into the inside of the specified pouch. Follow manufacturer's instructions for interpretation of results

Manufacturer: Steris

Description: Verify® Sixcess® 270F 15 Minute Indicator - Long

Catalog Number: PCC031

Cycle Use: 270°F (132°C), 15 minute steam sterilization processes

Type: Single Use Only

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Response 6: Based on the concerns raised by the FDA, Sophono has updated its Physician Manual to include a warning that the implant is not intended to be flash steam sterilized. The updated Physician Manual is contained in Appendix 3, and the text that was added to address this deficiency is as follows:

⚠	**Warning** ▪ The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device.

Based upon FDA's further comments, a statement has been added to the Instructions for Sterilization section of the Physician Manual recommending the availability of a sterilized backup implant in the event the intended implant becomes contaminated during the implantation procedure. The revised text further instructs the Physician that the unused devices may be stored in the original container or in the sterilization pouch. However, the implant must be repackaged and resterilized just prior to surgical implantation in accordance with the instructions. The text that was added to address these concerns is included within Response 5c.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

The "Go" and "No-Go" gages used in the selection of the appropriate magnetic spacers may be re-used with multiple patients. However, prior to using with another patient the accessories must be cleaned with a Clorox® type disinfecting wipe.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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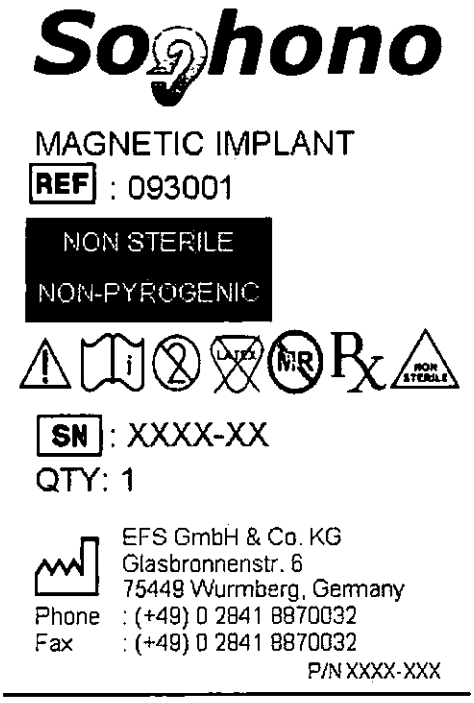
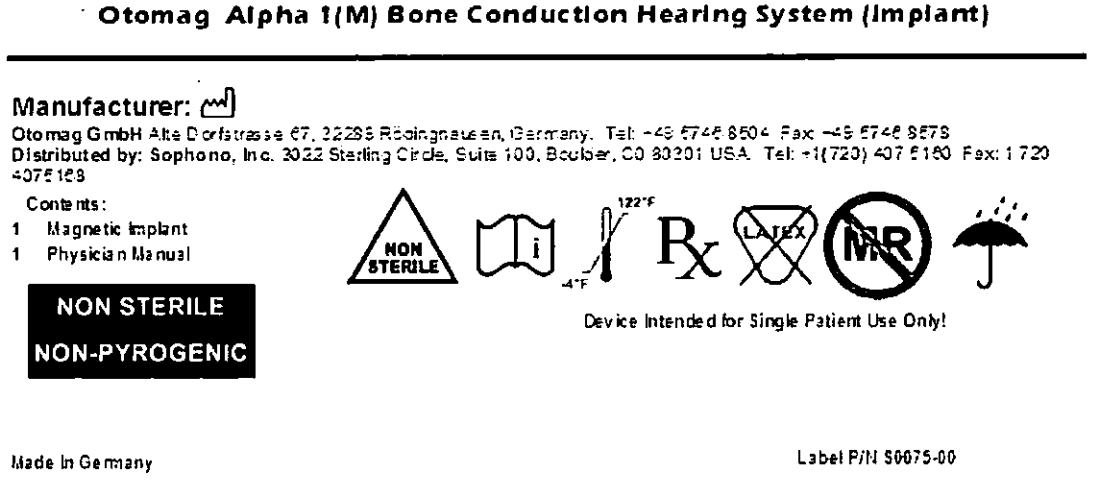
Sophono 510(k) K102199 – Request for Additional Information

Deficiency 8: You provide a description of primary and secondary packaging (Response to deficiency #13a). Please include the symbol for "non-sterile" on both the primary and secondary package labels for clarity and completeness.

Response 8: As requested by the FDA, the implant's primary and secondary labels have been revised to include the symbol for "non-sterile." The primary packaging label appears as follows:



The secondary packaging label now appears as follows:



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Sophono 510(k) K102199 – Request for Additional Information

Deficiency 9: Your physician labeling (Appendix 4, p. 8) includes the symbol and English text for "latex free." However, the latest Agency – accepted language is "contains no natural rubber latex." Please retain your current icon / symbol (p. 8), but change the English explanatory text to "contains no natural rubber latex." This list of symbols should also include the symbol for "Nonsterile" in reference to the implant.

Response 9: In response to the FDA's request, the phrase "latex free" has been replaced with the phrase "contains no natural rubber latex" in both the Patient and Physician Manual. Additionally, the "Nonsterile" symbol was added to the Symbols section within the Physician Manual. The updated Patient and Physician Manuals are contained in Appendices 2 and 3, respectively.

Deficiency 10: The contraindications (p. 8) are unconventionally placed and the wording is not entirely appropriate for patients. Please revise the location and content of this section to address the following:

a) Contraindications typically appear before warnings and precautions.

b) Please define all medical terminology and multisyllabic words (e.g., tinnitus, unilateral, asymmetrical, progressing – include the concept that both worsening and improved hearing may change the treatment plan)

c) Please address all language to the patient (i.e., second person "you," not third person, "the patient").

Response 10a: Per FDA's request, the Contraindications section was placed before the warnings and precautions within the Patient Manual. Refer to Appendix 2 for the revised version of the Patient Manual.

Response 10b: FDA's request to clearly define medical terminology within the Contraindications section of the Patient Manual has been addressed by Sophono. Additionally, Sophono added a statement to the section specifying treatment changes are dependent on improving and declining hearing. Refer to the text below and Appendix 2 for the revised version of the Patient Manual.

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer you for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- Hearing loss occurring suddenly;
- Hearing loss that grows worse rapidly;
- Pain in either ear;
- A sudden recent onset of ringing or a similar sensation in the ears, also known as tinnitus. Tinnitus may be bilateral (occurring in both ears) or unilateral (occurring in one ear);
- Unilateral or markedly asymmetrical (not equal in both ears) hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

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Note: While the contraindications listed above may affect the process of hearing aid fitting, it should be noted that the treatment plan for use of the Otomag Alpha 1 Sound Processor may vary with worsening or improving hearing. Your treatment plan will be determined by your primary care physician.

Deficiency 10c: As requested by the FDA, Sophono has addressed the language to the patient to ensure second person is used in all appropriate instances. In order to eliminate the potential for future questions on this subject, the entire Patient Manual reflects these changes, instead of just the Contraindications section. Refer to Appendix 2 for the revised version of the Patient Manual.

Deficiency 11: You state (section 4, p. 16) that the device lifespan is 4 years. (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted]

Deficiency 12: Minor changes are needed to the "Patient contacting Materials" section (p. 17). Please address the following:

a) Please define the medical term "mastoid" in lay language.

b) Please replace the word "latex" with "natural rubber latex" to comply with the Agency's currently accepted terminology.

c) You do not describe the recommended cleaning / care for the optional retention clip / lanyard. Please include the missing information.

Response 12a: Per FDA's request, "mastoid" has been more clearly defined in layman's terms in the Patient Contacting Materials section within the Physician Manual and the Patient Manual. Refer to the text below and Appendices 2 and 3 for the revised versions of the Physician Manual and Patient Manual.

Portion of Headband or Softband that presses against the mastoid (bony protrusion on the skull located directly behind the ear): Fotoplast Lacquer 3 (light-curing one-component lacquer)

Response 12b: Per FDA's request, the word "latex" was replaced with "natural rubber latex" within the Physician Manual and the Patient Manual. Refer to the text below and Appendices 2 and 3 for the revised versions of the Physician Manual and Patient Manual.

The components and packaging for the Otomag Bone Conduction Hearing System contain no natural rubber latex.

Response 12c: In response to FDA's request to specify cleaning / care for the optional retention clip / lanyard, Sophono revised the Cleaning and Care section of the Patient Manual to include the retention clip / lanyard. The retention clip / lanyard does not have direct patient contact, therefore cleaning with a Clorox® disinfecting wipe is an acceptable method to ensure the accessory stays clean. Refer to the text below and Appendix 2 for the revised version of the Patient Manual.

Retention Clip / Lanyard

- The Retention Clip / Lanyard can be cleaned with a Clorox® type disinfecting wipe.

(b)(4)

[redacted]

7 Patient Support

If you experience any device related issues, develop unexpected or excessive symptoms, or have general concerns or questions, please contact your primary care physician.

Deficiency 14: Your 510(k) summary needs further revision for full compliance with 21 CFR 807.92 (Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92). The summary should include that the device is provided non-sterile from the manufacturer to be gravity steam sterilized by the healthcare facility. Pyrogenicity should be addressed according to your response to Deficiency #4 above.

Response 14: Per FDA's request, the 510(k) Summary has been revised to specify the device is provided non-pyrogenic. The revised text is as follows, and the revised Executive Summary can be seen in Appendix 4.

The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

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Sophono 510(k) K102199 – Request for Additional Information

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Appendix 2	Updated Patient Manual
Appendix 3	Updated Physician Manual
Appendix 4	510(k) Summary
Appendix 5	Steris Steam Sterilization Indicator Strip Specification, PCC031
Appendix 6	Go/ No-Go Gauges Protocol and Final Report, DG-47
Appendix 7	Implant Magnetic Coupling Static Force Protocol and Final Report, DG-39
Appendix 8	Go / No-Go Gage Specifications, S0092

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 1 Updated Nelson Laboratories LAL GLP Test Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

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Appendix 2 Updated Patient Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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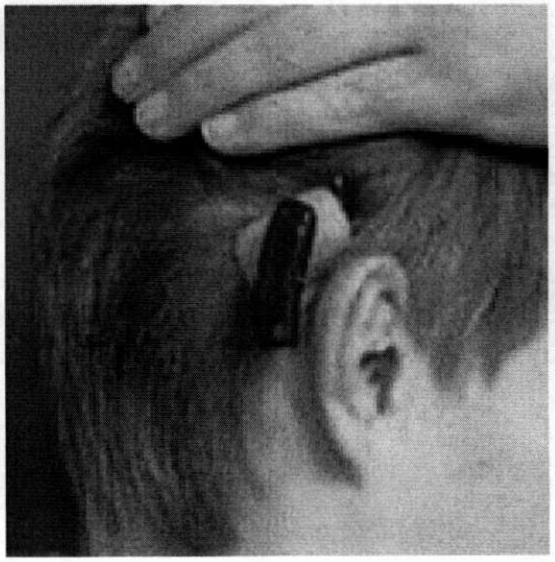
Sophono

Patient User Manual



Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Page 25 of 110

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1 About this Manual

This Patient Manual provides a description of the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. Please read this manual thoroughly before using the system.

This Patient Instruction Manual included with each Alpha I (S) & Alpha I (M) Bone Conduction Hearing System should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

⚠	**Warning** ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
⚠	**Caution** ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
📄	**Notes** ▪ Symbol indicates important general information for using the system successfully.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 Introduction

Dear Customer:

Congratulations on the purchase of your new Otomag Bone Conduction Hearing System!

The Otomag Bone Conduction Hearing System includes a family of Sound Processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag Bone Conduction Hearing System is supplied in either of two configurations. The first configuration is the Alpha 1 (S), in which the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), in which the Otomag Sound Processor is attached magnetically to a Magnetic Implant placed behind your ear. The Headband, Softband, or Magnetic Implant holds the Sound Processor against the head, and vibration is transduced through direct contact with your skin and the bone below.

The Otomag System is designed for use for patients with conductive hearing loss, patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and patients who suffer from single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software package allow for programming the Otomag System for individual patient hearing loss.

This Patient Manual will help you quickly gain confidence with your new Otomag Bone Conduction Hearing System. If you have further questions please consult your hearing healthcare provider.

General Information

A hearing device will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of a hearing device does not permit a user to attain full benefit. The use of a hearing device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading.

Note

- The components and packaging of the Otomag Bone Conduction Hearing System contain **no** natural rubber **latex**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Note ▪ The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer you for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- Hearing loss occurring suddenly;
- Hearing loss that grows worse rapidly;
- Pain in either ear;
- A sudden recent onset of ringing or a similar sensation in the ears, also known as tinnitus. Tinnitus may be bilateral (occurring in both ears) or unilateral (occurring in one ear);
- Unilateral or markedly asymmetrical (not equal in both ears) hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Note: While the contraindications listed above may affect the process of hearing aid fitting, it should be noted that the treatment plan for use of the Otomag

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Alpha 1 Sound Processor may vary with worsening or improving hearing. Your treatment plan will be determined by your primary care physician.

Warnings and Cautions Overview

The following section contains a description of all patient related Warnings and Cautions associated with the Otomag Bone Conduction Hearing System. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to patient instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warning	▪ Thoroughly read Patient Manual before using the Otomag Bone Conduction Hearing System. ▪ Rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in personal injury and damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not obtain an Magnetic Resonance Imaging (MRI) procedure while wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire. ▪ Do not attempt to recharge batteries. ▪ If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device.
Caution	▪ Read this Patient User Manual and keep it available so you can refer to it when needed. ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. .

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Caution	▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4 °F (-20 °C) or above 122 °F (+50 °C) at any time. ▪ To avoid damage to the device, do not store the Otomag System near magnets or magnetic devices. ▪ Remove the Sound Processor, Headband and Softband before x-rays of the head and neck ▪ Remove the Sound Processor, Headband, and Softband during radiation therapy ▪ Portable and mobile RF (radio frequency) communications equipment can affect the performance of the Sound Processor. ▪ Interference may occur in the area of equipment which is labeled with the following symbol: ▪ Dispose of batteries and electronic items in accordance with your local regulations. ▪ When navigating through security in airports remove the Sound Processor, Headband and Softband and have them screened through the x-ray screening process. The Sound Processor, Headband and Softband contain metal that may activate the airport security metal detectors. ▪ Do not use the Alpha 1 Sound Processor, Headband or Softband while participating in contact sports. Hard physical contact with the device or a blow to the head in the area of the Alpha 1 Sound Processor, Headband or Softband may result in damage to the device or device failure. ▪ Clean the Alpha 1 Processor, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case. ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device. ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor. ▪ Do not expose the Sound Processor to strong sunlight. ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case.

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3 Operating Instructions

Insertion of the battery

Size 675 batteries are required for your Alpha I Sound Processor.

See Figure 1 for details. Open the battery compartment (1) with a fingernail and insert the battery (2) so that the plus (+) sign on the battery and the plus (+) sign on the battery compartment are on the same side. Close the battery compartment with a finger. The Sound Processor is now switched on.

⚠	**Caution** ▪ Dispose of batteries and electronic items in accordance with your local regulations.

Switch off your Sound Processor whenever you're not using it by pivoting the battery compartment fully out. This will help preserve battery life. The Alpha 1 has a low battery indicator that generates a tone when it is time to replace the battery. Your hearing healthcare provider can adjust the volume and tone of the low battery indicator for you.

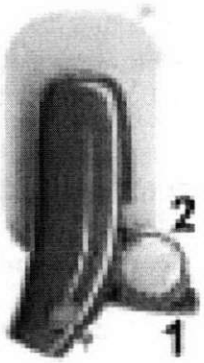

Figure 1. Alpha I Sound Processor

⚠	**Warning** ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals ▪ Do not attempt to recharge batteries. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire

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Start-up and Operation

Switch on the Alpha 1 Sound Processor by pivoting the battery compartment fully in.

Positioning the Sound Processor

Alpha 1 (S)

To place the Alpha 1 (S) Sound Processor, simply guide it into the vicinity of the magnetic pad in the Softband or Headband. The magnetic forces will bring it to its correct position. See Figure 2.

Figure 2. Positioning the Alpha I (S) Sound Processor on the Softband

⚠	**Warning** ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 3. If you have thicker hair, it may be necessary to part your hair over the implant site or shorten the hair at the implant location to ensure an adequate holding force between magnets.

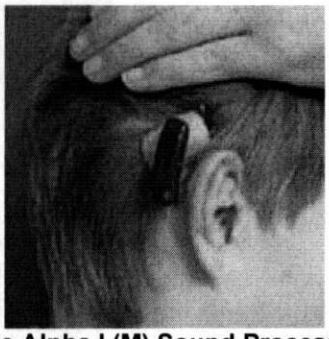

Figure 3. Positioning the Alpha I (M) Sound Processor on the Magnetic Implant

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Warning

- If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device.

Caution

- The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient.

Volume Control

The volume can be adjusted with the small wheel that is situated on the outside of the Alpha 1 Sound Processor. Using the tip of the index finger, apply slight pressure on the rotary button and simultaneously turn forward to increase volume. Turn the rotary button in the opposite direction to reduce volume.

You can switch off the Sound Processor by opening the battery access door. As soon as you take off the device, switch it off. See Figure 4 for details.

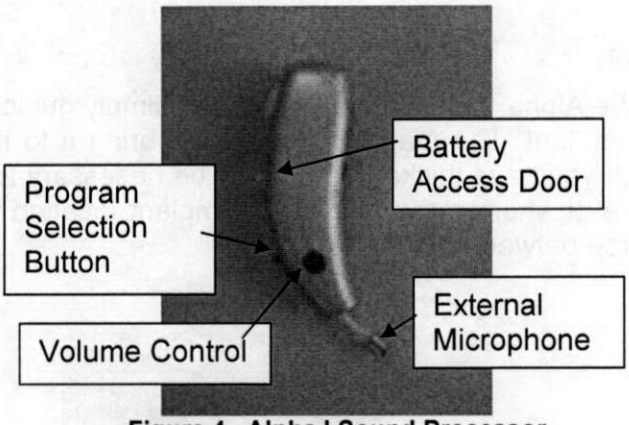

Figure 4. Alpha I Sound Processor

Program Selection Button

The Alpha 1 Sound Processors offer four program settings for different hearing situations. By pressing the small button on the Sound Processor, the programs can be activated. For each activated program you will hear a corresponding signal tone for recognition.

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- Program 1: Instrument beeps once
- Program 2: Instrument beeps twice
- Program 3: Instrument beeps three times
- Program 4: Instrument beeps four times

Your hearing healthcare provider will inform you when each of the programs should be used

Removing the Sound Processor

To remove the Alpha 1 Sound Processor, pull **ONLY** on the steel disk. See Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

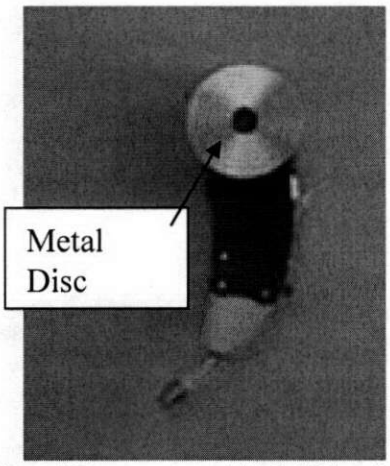

Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

	Note ▪ If you remove the Sound Processor without switching it off, it generates a vibrating tone which leads to high battery consumption. Therefore, always properly switch off the Sound Processor when you are not wearing it.

	Caution ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device.

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If Your Sound Processor Does Not Function

Check the following if the Sound Processor is not functioning properly:

- The device is properly switched on and the battery compartment is fully closed
- The battery is not dead
- The battery surface is clean.

If the device still is not functioning properly, see your hearing healthcare provider.

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4 Product Maintenance

Cleaning and Care

Sound Processor

- Have your Sound Processor checked at regular intervals as specified by your hearing professional.
- To clean your Sound Processor, wipe it with a soft cloth or a Clorox® type disinfecting wipe
- The battery compartment may be cleaned by wiping it out with a DRY cotton swab or a cotton swab that has been moistened by a Clorox® type disinfecting wipe.

	Note ▪ Remove the Sound Processor, Softband, and Headband during the application of hairspray or styling gels. If hairspray or gel comes in contact with the Sound Processor it may become sticky and difficult to clean

- If the Sound Processor becomes soaked with water:
  - Immediately open the battery door and remove the battery
  - Put the Sound Processor in a container with drying capsules such as Dri-aid kit or similar overnight. Drying kits are available from most hearing care professionals.

	Caution ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case

- The Sound Processor is provided in a plastic case which may be used to store the processor. This case may be cleaned with a Clorox® type disinfecting wipe. Make sure the case is completely dry before storing the Sound Processor in it.

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⚠	**Caution** ▪ The Sound Processor is designed to operate within the temperature ranges of 41°F (+5°C) to 104°F (+40°C). The processor should not be subject to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor ▪ Do not expose the Sound Processor to strong sunlight ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case

Softband and Headband

- The Headband can be cleaned with a Clorox® type disinfecting wipe.
- The Softband may be submerged and hand washed with a mild clothes washing detergent (with or without a small amount of color safe bleach) and air dried or may be cleaned with a Clorox® type disinfecting wipe.

Magnetic Spacer

- The Magnetic Spacer can be cleaned with a Clorox® type disinfecting wipe.

⚠	**Caution** ▪ Clean the Alpha 1 Processor, Magnetic Spacer, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

Retention Clip / Lanyard

- The Retention Clip / Lanyard can be cleaned with a Clorox® type disinfecting wipe.

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Damage and Replacement

The expected live span for the Sound Processor, Magnetic Spacer, Softband, and Headband is approximately 4 years depending on use, wear, and tear. The Sound Processor will need to be repaired or replaced when it no longer produces adequate vibrations or the sounds become highly distorted. The Softband should be replaced when it becomes damaged or the elastic begins to be stretched out and it can no longer be tightened adequately for sound transmission. The Headband should be replaced when it becomes damaged or no longer has enough spring force to press the magnetic pad against the head for adequate sound transmission. Replacement Headbands and Softbands may be purchased through your hearing healthcare provider from Sophono, Inc.

5 Accessories

If your Alpha 1 Sound Processor has a jack for an FM boot, you may plug the boot of a Phonak MLxi FM receiver into the bottom of the Sound Processor.

If you are concerned about the Alpha 1 Sound Processor falling off your head, a clip and tether are available so that the Sound Processor can be tethered to a garment you're wearing.

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6 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** • Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. • To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a Titanium case.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid (bony protrusion on the skull located directly behind the ear): Fotoplast Lacquer 3 (light-curing one-component lacquer)

The components and packaging for the Otomag Bone Conduction Hearing System contain no natural rubber latex.

The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

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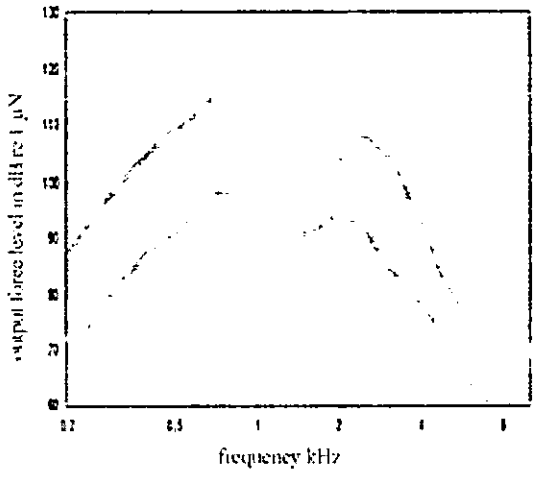
Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction Sound Processor
- Fully programmable digital hearing system
- Programs (programmable by audiologist)
- 4 channels
- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery)

Alpha 1 Sound Processor Performance Data

(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

(Measured according to DIN IEC 60118-9. Averages include all configurations of softband, headband, and magnetic spacers for a given normal force)

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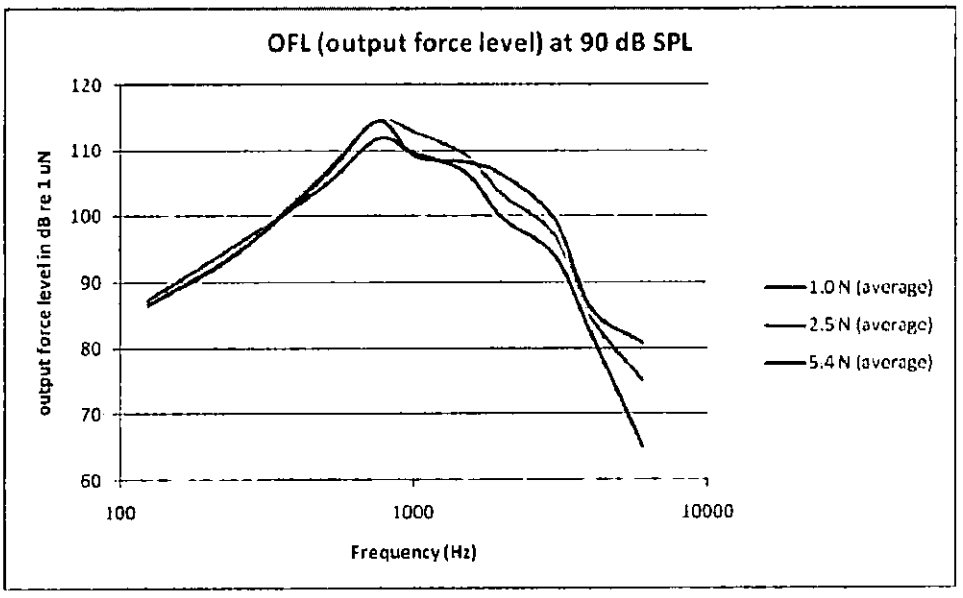

- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 μN
- Peak Output at 90 dB SPL: 115 dB re 1 μN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

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7 Patient Support

If you experience any device related issues, develop unexpected or excessive symptoms, or have general concerns or questions, please contact your primary care physician.

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Appendix 3 Updated Physician Manual

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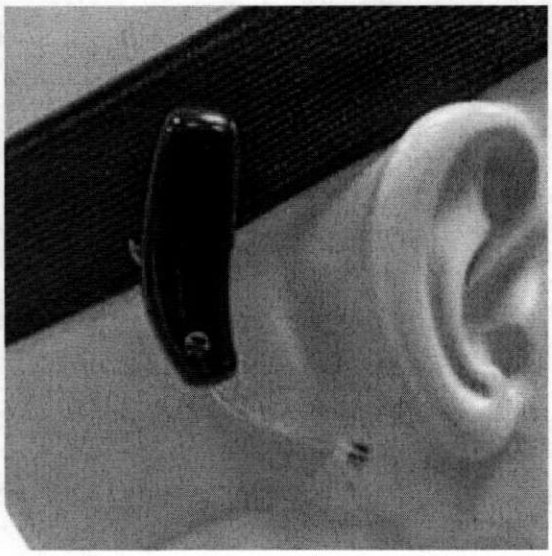
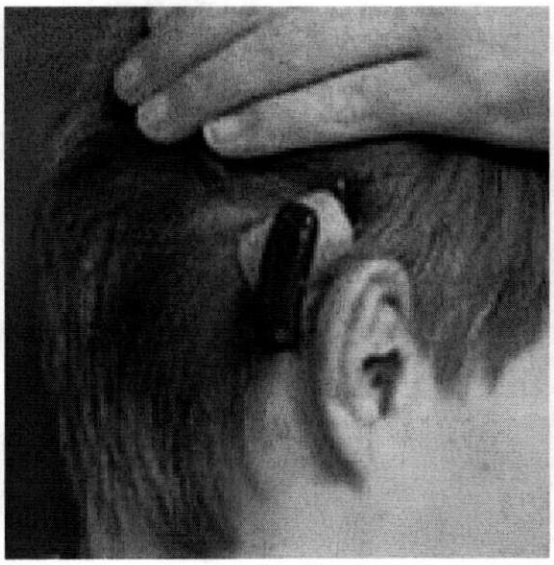
Physician Manual





Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems

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Company Information

Contact information:

Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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1 About this Manual

This Physician Manual provides a description of the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. This manual provides the information necessary for the physician to prescribe the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems to the appropriate patient population. Please read this manual thoroughly before prescribing the system.
A Patient Instruction Manual is included with each **Alpha I (S)** & **Alpha I (M)** Bone Conduction Hearing System and should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

⚠	**Warning** ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
⚠	**Caution** ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
📄	**Notes** ▪ Symbol indicates important general information for using the system successfully.

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2 Introduction

Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patient Selection Criteria

- Patients to be fitted with the Otomag Alpha 1 (S) Sound Processor and its Headband or Softband may be any age.
- Patients to be fitted with the Otomag Alpha 1 (M) Sound Processor and its Magnetic Implant should be 5 years old or older.

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- Patients and/or patient guardians must be able to understand that the Otomag System will not restore hearing to normal and will not prevent additional hearing impairment resulting from conditions such as disease, old age hearing loss, genetic hearing loss, ototoxic drugs or noise induced hearing loss.

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Warnings and Cautions Overview

The following section contains a description of all physician related Warnings and Cautions associated with the Otomag Bone Conduction Hearing Systems. Additional patient and use related Warnings and Cautions can be found in the Patient User Manual. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to physician instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warnings

Warning	▪ Thoroughly read the Physician Manual and the Patient Manual before prescribing the Otomag System. ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriately can result in serious infection. ▪ The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device. ▪ Purchased screws may be provided non-sterile and if so must be sterlized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection. ▪ Excessive, long term use of magentic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test. ▪ Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this warning may result in prolonged healing, further irritation, or infection.

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Precautions

Caution	▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual. ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws. ▪ Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches. ▪ The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or pain, numbness, or tingling occurs.

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Product Description

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag System is configured in either of two configurations. The first configuration is the Alpha 1 (S), where the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), where the Otomag Sound Processor is attached magnetically to an implanted magnet. The Headband, Softband, or Magnetic Implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Possible Adverse Effects

General

It is possible that a reaction to the materials of the Headband, Softband, or Magnetic Implant could occur. Such a circumstance may necessitate that use of the device be discontinued. Please report any adverse effects to Sophono, Inc. The address and phone number for Sophono, Inc. are listed at beginning and end of this Physician Manual. If a reaction to the Headband or Softband occurs, Sophono will supply appropriate instructions so that the device can be sent to the laboratory for analysis.

Risks that may occur during surgery:

The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, dural exposure, CSF leak, perforation of sigmoid sinus, subdural hematoma and noticeable changes in head noise.

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⚠	**Warning** ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System.

Risks that may occur after surgery:

Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma, inflammatory reaction, skin breakdown or skin necrosis.

It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant.

⚠	**Warning** ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.

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Other Symbols on Equipment and Labeling

Symbol	Description
	Consult Physician Manual
LOT	Batch Code or Lot Number
SN	Serial Number
	Keep Away From Rain / Keep Dry
	Manufacturer
MR	MR Unsafe: Device should not be worn when patient is undergoing an MRI
LATEX	Product contains no natural rubber latex
	Interference may occur in the area of equipment which is labeled with the following symbol.
122°F -4°F	Temperature Limitation: The sound processor is designed to operate within the temperature ranges of 41oF (+5oC) to 104oF (+40oC). The processor should not be subject to temperatures below -4oF (-20oC) or above 122oF (+50oC) at any time.
NON STERILE	Device provided Non-Sterile

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3 Patient Fitting Procedures

Alpha 1 (S) System: Instructions for Placement of the Softband or Headband and Alpha 1 Sound Processor

	Notes ▪ Record the product and lot or serial numbers for the Alpha 1 Sound Processor in the patient file and send the patient to a qualified audiologist for proper programming of the Alpha 1 Sound Processor.

The Otomag Softband is an elastic Softband similar to a sweat band used in sports. The Alpha 1 (S) Sound Processor magnetically adheres to the Softband via a magnetic pad sewn into the band. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by an audiologist.

- To use the Otomag Softband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Softband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Softband around the patient's head, quite loosely at first by slipping the end of the band through the slot next to the magnetic pad and attaching the mating Velcro ® loops and hooks to each other.
- Place the magnetic pad against the mastoid or other boney location.
- Tighten the Softband by adjusting the Velcro® strap until it is close-fitting enough to ensure effective sound transmission, but not tight enough to cause discomfort. The Softband is too loose if it slips off of the head, can be rotated easily around the head or no sound transmission can be heard. The Softband is too tight if the patient complains of pain or discomfort while wearing the Softband. Make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

	Warning ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

The Otomag Headband is a springy Headband, similar to that used for earphone devices. It comes in one size and is not adjustable. The Alpha 1 (S) Sounds Processor magnetically adheres to the Headband via a magnetic pad fitted to the Headband. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by the audiologist.

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- To use the Otomag Headband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Headband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Headband on the patient's head and place the magnetic pad against the mastoid or other boney location.

The choice of a Headband or Softband is a matter of patient preference.

Alpha 1 (M) System: Compatible Screws

Notes

- The Alpha 1 (M) implant requires 5 screws for implantation that are **NOT** included with the implant.

Screws

The Alpha 1 (M) implant requires 5 screws to be used to affix the implant to the skull. These screws are NOT included as part of the Alpha 1 (M) implant system and must be obtained separately.

The implant bracket holes are sized to accept Stryker/Leibinger 1.7 mm diameter Craniomaxillofacial titanium Self Tapping Screws, (Gold) and 1.7 mm diameter Self Drilling Screws (Silver) in 4 mm lengths and 1.9 mm Emergency Screws (Purple) in 3 mm lengths.

Craniomaxillofacial Titanium Screws	*1.7 mm dia. x 4.0 mm Self Tapping*	*1.7 mm dia. x 4.0 mm Self Drilling*	*1.9 mm dia. x 3.0 mm Emergency*
Stryker/Leibinger Part Numbers	*50-17004*	*50-17904*	*50-19004*

While all screw sizes / types specified above have been validated for this application, the Stryker/Leibinger 1.7mm x 4 mm self drilling screws, part number 50-17904 is considered optimal.

Other commercially available craniomaxillofacial titanium screws may be used as long as the screw shaft diameter is less than 2.0 mm and the screw head size is greater than 2.45 mm. Screw must be 4 mm in length (3mm for emergency screws).

The screws must be sterile prior to implantation. If the screws are not purchased sterile, refer to the screw manufacturer's instructions for sterilization.

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⚠	**Warning** ▪ Purchased screws may be provided non-sterile and if so must be sterlized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection.

⚠	**Caution** ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws.

If the initial attempt to place a screw does not work and the screw hole becomes "stripped" emergency "rescue" screws can be threaded into the stripped hole. The largest size screw that can be used is 1.9 mm in diameter.

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Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

⚠	**Warning** ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize a device appropriately can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Place a single steam sterilization indicator into the pouch with the implant.
- Immediately seal the autoclave pouch.

⚠	**Caution** ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be re-sterilized by gravity steam sterilization (autoclaving) if it is not used during the implantation procedure. The following sterilization parameters have been validated for sterilization of the implant.

Limitations on Reprocessing: Magnetic implants may be resterilized if not used during the implant procedure. Implants may be stored in the sterilization pouch or the original screw-top cylinder. However, the implant must be transferred to a new sterilization pouch just prior to sterilization and implant.

Presterilization Decontamination / Cleaning / Disinfection: None Required

Cycle Type: Gravity

Sterilization Time: 15 minutes minimum

Sterilization Cycle Temperature: 132 degrees C / 270 degrees F

Drying Time: 30 minutes minimum

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Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)

Storage in Sterile State: Final sterilization immediately pre-implant only

Upon completion of sterilization verify that both sterilization indicator strips (interior and on exterior of package) indicate the steam cycle was completed correctly. Follow manufacturer instructions for interpretation of these indicators. If both the indicators do not show completion of the sterilization cycle, repeat the cycle.

⚠	**Warning** ▪ The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device.

Sterilization Pouch Specifications

To ensure the validated parameters are replicated appropriately, the following is to be used to individually pouch each implant prior to performing the sterilization cycle:

Manufacturer: Cardinal Health, http://www.cardinal.com, 800.964.5227

Catalog Number: 92510

Size: 5.5" x 10" Paper Self Seal Pouch

Materials: Arjowiggins 60g/m^2 Paper / CN PET 12/CPP40 Micron

Total Product Area: 0.035 m^2

Paper Area: 0.035 m^2

Ink: Medical Grade

⚠	**Caution** ▪ Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches.

Internal Steam Indicator Strip Specifications

Each time an implant is steam sterilized, place a single indicator strip conforming to the following specifications into the inside of the specified pouch. Follow manufacturer's instructions for interpretation of results

Manufacturer: Steris

Description: Verify® Sixcess® 270F 15 Minute Indicator - Long

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Catalog Number: PCC031

Cycle Use: 270°F (132°C), 15 minute steam sterilization processes

Type: Single Use Only

Pre-Surgical Training Requirements

Before attempting to implant the Otomag Implant, surgeons are required to complete training provided by Sophono, Inc. During the training they will receive guidance regarding the procedure, a thorough understanding of the device and surgical procedure and other important information. Contact Sophono Customer Services at the contact number listed in Section 6 of this manual to arrange training.

Surgical Risks

The implantation of the Otomag Implant requires a surgical procedure involving the removal of tissue and bone. As with any surgical procedure involving a general anesthetic, certain risks exist. Those risks include the risk of infection from poor hygiene or non-sterile technique, irritation of tissues during the implantation procedure, unintended cuts and abrasions, and irritation of tissues due to unintended exposure to implant materials. The implant is made of materials considered to be hypo-allergenic but in the case of unintended damage to the device, a patient could come in contact with substances that could generate an adverse reaction.

Surgical Site Preparation:

The hair should be clipped and the scalp shaved at the incision site immediately before surgery. With the incision site skin free of gross contamination, apply antiseptic (such as iodophors, alcohol-containing products, or chlorhxidine gluconate) in the area of the proposed incision to an area large enough to allow for the extension of the incision or creation of a new incision or drain sites (if necessary).

Pre-Surgical Antibiotic Prophylaxis:

Antibiotic prophylaxis should be considered if the surgeon determines that this surgical procedure may be associated with a considerable risk of infection or if a post operative infection would cause a serious hazard to the patient's recovery or well being.

Surgical Implantation Steps

Step 1 - Making The Incision

The proper position for the implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant will be placed. The incision must be large enough to allow placement of the implant. See Figure 1.

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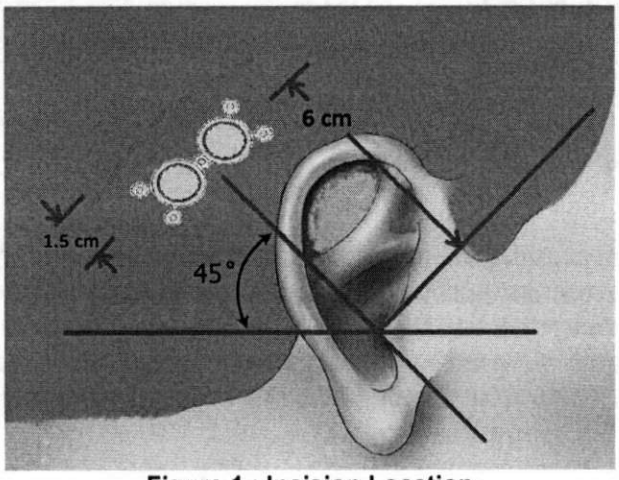

Figure 1 : Incision Location

Step 2 - Create a bone bed (optional)

The implant is approximately 2.6 mm thick and optimal tissue thickness over the implant is 4 mm to 5 mm.

To create a bone bed, mark the position of the implant magnets on the bone and drill the bone bed to a depth of approximately 3 mm. The implant magnets have a diameter of 10 mm.

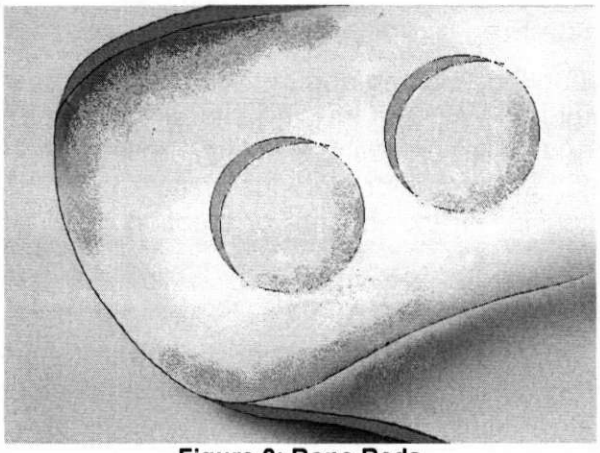

Figure 2: Bone Beds

Step 3 - Implant Placement

After creation of the bone bed, install the magnetic implant using the specified screws such that the implant is oriented with the "This Side Up" label facing out. In addition, be sure to place the implant so that the small fiduciary mark is located in the most anterior and superior location. Place one screw in each of the bracket holes to securely attach the implant to the skull. The surface of the implant should be nearly flush with the surface of the mastoid.

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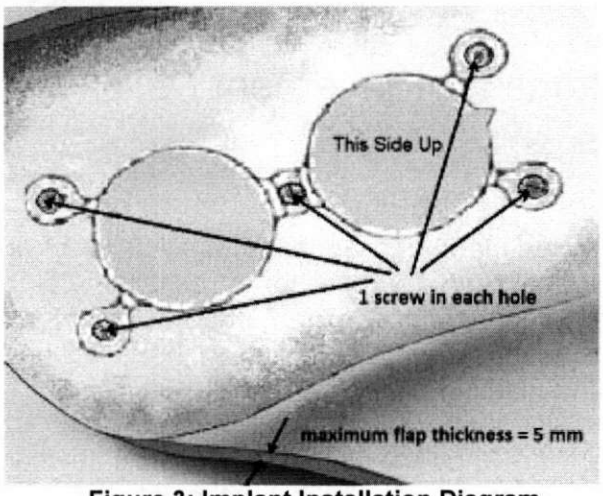

Figure 3: Implant Installation Diagram

Step 4 - Tissue Thinning and Closing the Incision

If the tissue flap is thicker than 6 mm, thin down a 10 mm wide strip of tissue to 5 mm directly over the implant magnets. Suture the incision closed.

Implant Surgical Removal Steps

Step 1 - Making The Incision

The implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant has been placed. The incision must be large enough to allow removal of the implant. See Figure 1 above.

Step 2 - Implant Removal

Remove each of the 5 screws holding the magnetic implant in place. It may be necessary to excise bone or tissue growth occurring over the face of the implant. Once the screws are removed the implant can be lifted carefully from the bone or bone beds. Suture incision closed.

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Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system and patient comfort. The Alpha 1 (M) configuration is supplied with five strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid.

The spacers are labeled with "dots" to indicate magnetic strength. Magnetic strength increases based on the number of dots present on the spacer. One dot is the lowest strength and five dots is the highest strength.

Several magnetic spacer strengths may be applicable to an individual patient. To determine the appropriate magnetic spacer for a patient use the "Go" and "No-Go" gages as follows.

The "Go" and "No-Go" gages used in the selection of the appropriate magnetic spacers may be re-used with multiple patients. However, prior to using with another patient the accessories must be cleaned with a Clorox® type disinfecting wipe.

Using the "Go" gage to determine the weakest appropriate magnetic spacer

1. *Starting with the one dot magnetic spacer, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the magnetic spacer poles align with the implant poles and the strongest magnetic attraction is achieved.*
2. *Ask the patient to sit upright with their head in a typical vertical position. Attach the "Go" gage clip to the patient's clothing.*
3. *Hang the "Go" gage disk from the magnetic spacer.*
4. *If the magnetic spacer detaches from the side of the patient's head, then the spacer is too weak and the process should be repeated with increasing magnetic spacer strengths until the magnetic spacer remains attached to the side of the head while attached to the "Go" gage disk.*
5. *The lowest dot number magnetic spacer that passes the "Go" test indicates the weakest magnetic spacer strength that should be recommended to the patient.*

Using the "No -Go" gage to determine the strongest applicable magnetic spacer

1. *Starting with the lowest dot number magnetic spacer that passes the "Go" test, place the magnetic spacer over the implant. Magnetic attraction will*

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pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the poles align with the implant poles and the strongest magnetic attraction is achieved.

2. *Again, ask the patient to sit upright with their head in a typical vertical position. Attach the "No-Go" gage clip to the patients clothing.*
3. *Hang the "No-Go" gage disk from the magnetic spacer.*
4. *The magnetic spacer **should detach** from the head from the weight of the disk. If the magnetic spacer detaches from the head then the magnetic spacer is one of the appropriate spacers for the patient.*
5. *Repeat this process, increasing magnetic spacer strength one dot at a time until the magnetic spacer **does not detach** from head.*
6. *The highest number magnetic spacer that **detaches** from the head using the "No-Go" test indicates the highest magnetic spacer strength that **should be used** by the patient on a regular basis.*
7. *Any magnetic spacer that remains attached during the "No-Go" test is too strong and should not be recommended for patients long term use.*
8. *If all magnetic spacers used in the "No-Go" test detach when the "No-Go" disc is attached, then all of the spacers tested in the "No-Go" test may be appropriate for the particular patient.*

Several spacer magnet strengths may be applicable for an individual patient. The patient should be prescribed the lowest dot magnet strength that is both comfortable, functions correctly and fits with their age and lifestyle.

⚠	**Warning** ▪ Excessive, long term use of magentic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test.

⚠	**Caution** ▪ The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or if pain, numbness, or tingling occurs.

Placement of the Alpha 1 (M) Audio Processor

Approximately 4 weeks after the incision site has healed and all signs of inflammation are gone, the patient may be fit with the Alpha 1 (M) Audio Processor.

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⚠	**Warning** • Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this warning may result in prolonged healing, further irritation, or infection.

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4 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a biocompatible titanium case. Only the titanium case of the implant is in contact with patient tissue.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid (bony protrusion on the skull located directly behind the ear): Fotoplast Lacquer 3 (light-curing one-component lacquer)

The components and packaging for the Otomag Bone Conduction Hearing System contain no natural rubber latex.

The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

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Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction sound processor
- Fully programmable digital hearing system
- programs (programmable by audiologist)
- 4 channels
- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery

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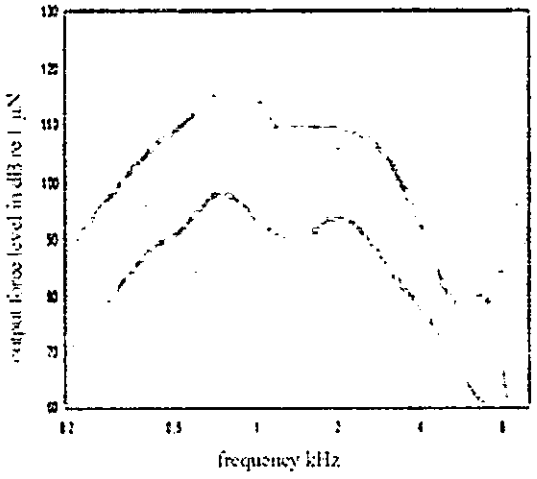
Alpha 1 Sound Processor Performance Data

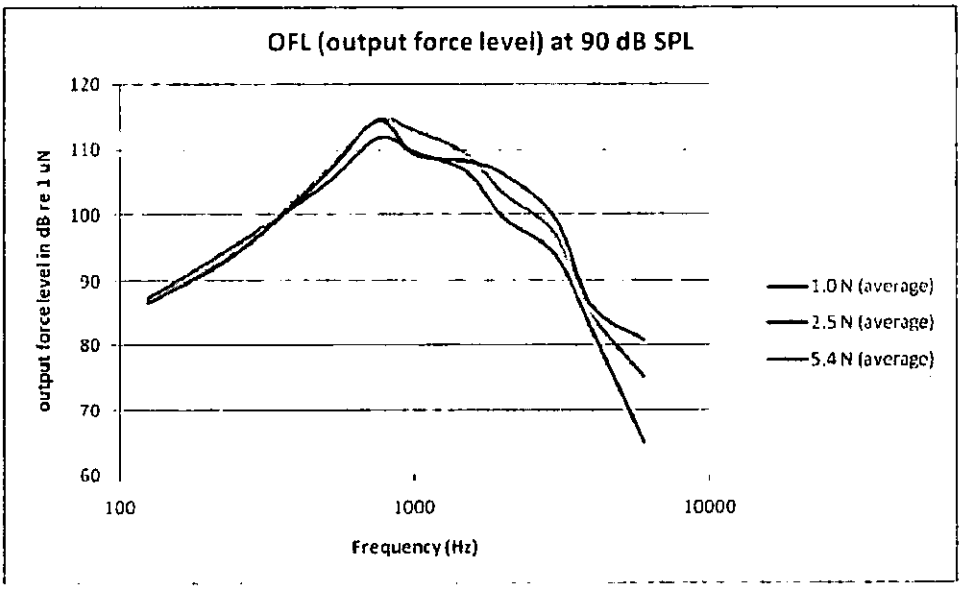
(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

(Measured according to DIN IEC 60118-9. Averages include all configurations of softband, headband, and magnetic spacers for a given normal force)



Questions? Contact FDA/CDRH/OCE/DIDPA/CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 μN
- Peak Output at 90 dB SPL: 115 dB re 1 μN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 Storage and Handling

Storage

⚠	**Caution** • To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -20 C (-4 F) or above +50 C (122 F) at any time. • To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Handling

⚠	**Caution** • Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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6 Professional Support

For more information or to report concerns, device malfunctions, adverse events, or patient complaints, please contact:

Sophono, Inc.

903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663
postmaster@sophono.com

Manufactured for: Sophono, Inc. 903 Brooklawn Dr., Boulder, Colorado 80303 USA +1 (303) 564-1663

Printed in U.S.A.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Appendix 4 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 07: 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary: Otomag Bone Conduction Hearing System

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

Submitter: Sophono, Inc.

Establishment Registration Number: Not Yet Assigned

Contact Information:

Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
Ph: 303-546-1663
Fax: 720-222-2432
Contact: Jim Kasic
Email: jkasic@comcast.net

Date Prepared: July 27, 2010

Name of Device: Otomag Bone Conduction Hearing System

Common Name: Bone Conduction Hearing System

Classification Name: Hearing Aid

Device Classification:

- Classification: II
- Classification Panel: Ear, Nose and Throat
- Regulation Number: 874.3300
- Product Code: LXB

Predicate Device:

Otomag Bone Conduction Hearing System, Unmodified Version – K100193

Xomed Audiant Bone Conductor - K855059 / K861971

Device Description:

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Technological Characteristics:

The technological characteristics of the version of the Otomag Bone Conduction Hearing System are equivalent to those of the predicate device. Items that are identical between the modified version and the predicate are:

- Overall Device Performance
- Fundamental Technology (bone conduction)
- Software

Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Through non-clinical performance testing and evaluation, the identified technological differences do not raise new questions of safety and effectiveness.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;

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- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Performance Standards:

The design of the Otomag Bone Conduction Hearing System conforms to the following voluntary standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
- AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI/ANSI ST8:2008, Hospital steam sterilizers
- AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products – Requirements for products labeled "STERILE"
- AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization
- AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications

Non-Clinical Performance Testing:

The Otomag Bone Conduction Hearing System has been subjected to extensive safety, performance testing, and verification / validation. Testing of the Otomag Bone Conduction Hearing System included various device performance tests and software validation tests designed to ensure that the device meet all of its functional specifications and is fit for its intended use. Tests have also been performed to ensure the device complies with industry and safety standards. The testing

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information presented in this submission demonstrates the device's performance is substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Conclusion:

Based on the non-clinical performance testing, the modified version of the Otomag Bone Conduction Hearing System is as safe and effective and considered to be substantially equivalent to the predicate Otomag device cleared in K100193 and the Audiant cleared K855059 and K861971 and that the differences between the three devices:

- Do not raise any new issues of safety and effectiveness
- Do not amount to a change in the "fundamental scientific technology" of the device with regard to the Otomag predicate K100193
- Do not present any adverse health effect or safety risks to patients when used as intended.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 5 Steris Steam Sterilization Indicator Strip

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Technical Data

(b)(4) Technical Data

(b)(4) Technical Data

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(b)(4) Technical Data

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(b)(4) Technical Data

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Appendix 6 Go/ No-Go Gauges Protocol and Final Report, DG-47

(b)(4) Protocol Test Reports

(b)(4) Protocol Test Reports

(b)(4) Protocol Test Reports

(b)(4) Protocol Test Reports

(b)(4) Protocol Test Reports

(b)(4) Protocol Test Reports

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Appendix 7 Implant Magnetic Coupling Static Force Protocol / Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Protocol Test Reports

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(b)(4) Protocol Test Reports

(b)(4) Protocol Test Reports

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Appendix 8 Go / No-Go Gage Specifications, S0092

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Vasant Dasika

Subject: 510(k) Number K102199

To: The Record

Please list CTS decision code _____

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) ENTB (Branch Code) 9/23/10 (Date)

Final Review:

(Division Director) (Date)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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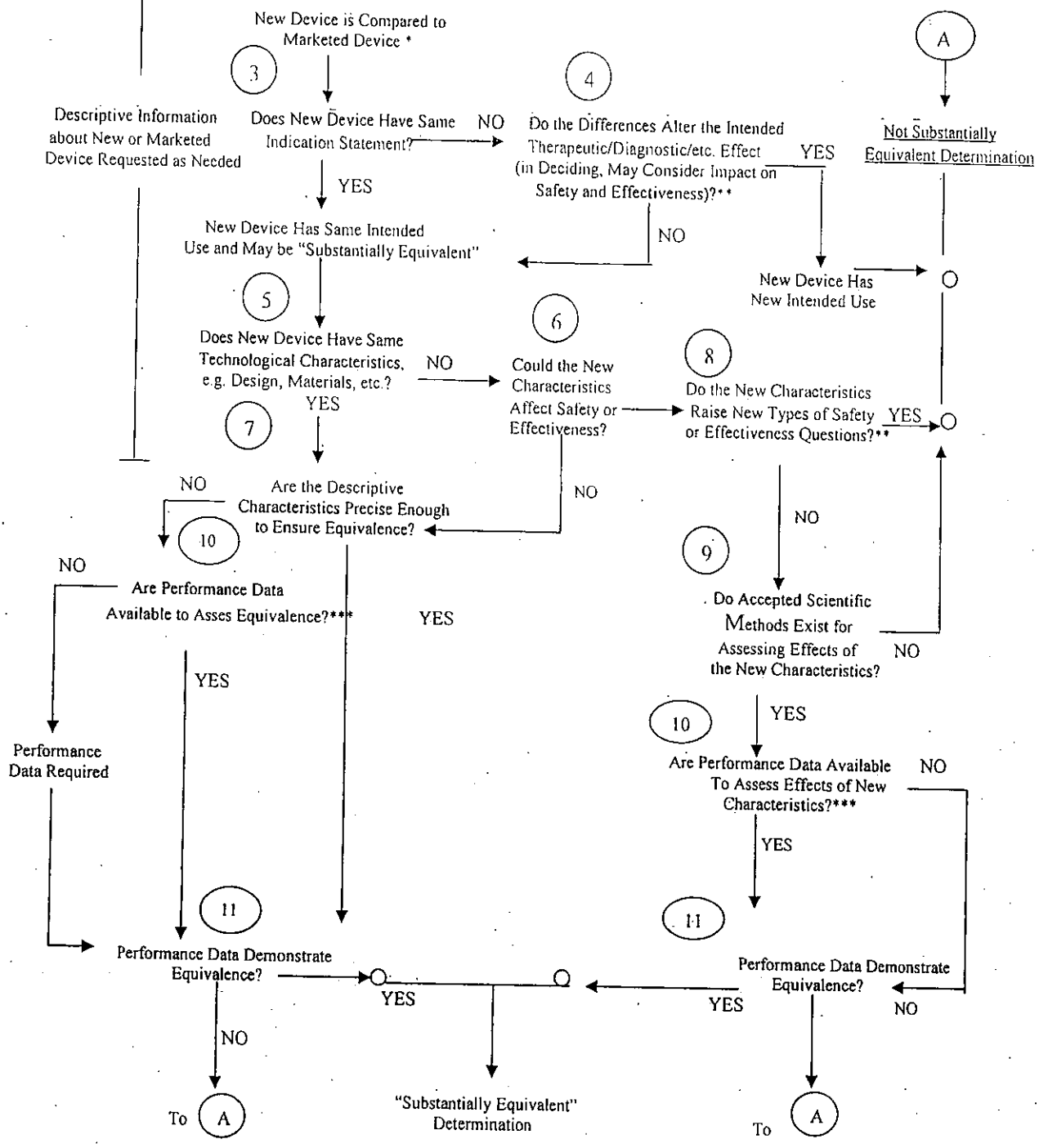
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K102199

Date: September 23, 2010
To: The Record
From: Vasant K. Dasika, Ph.D.

Office: ODE
Division: DONED

510(k) Holder: Sophono, Inc.
Device Name: Otomag Bone Conduction Hearing System
Contact: Clay Anselmo, President and CEO, Reglera LLC
Phone: 303-223-4303
Fax:
Email: anselmoc@reglera.com

Recommendation: Telephone Hold

Major deficiencies

(b)(4)

[redacted]

Review Team

Vasant Dasika, Ph.D.	Lead Reviewer & Electrical Engineering
Angie Khan, M.D.	Clinical
Sue Rudy	Sterility
Shu-Chen Peng, Ph.D.	Audiology
Daniel Clupper, Ph.D.	Materials Science & Mechanical Engineering
Vasant Malshet, Ph.D.	Biocompatibility

I. Purpose and Submission Summary

The 510(k) holder would like to introduce a modified Otomag Bone Conduction Hearing System into interstate commerce.

The modification "adds a new configuration into the Otomag Bone Conduction Hearing System family.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The new configuration (Alpha 1(M)) uses an implantable magnet as a fixation system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193 – Otomag Bone Conduction Hearing System – May 18, 2010."

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X	X	
Are "cleaning" instructions included for the end user?	X		

The following device description is excerpted from the review memos of Drs. Clupper and Khan:

Description of the Osseointegrated Alpha 1 (M) Configuration (p. 13-4; 41 of 192)
In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Osseointegrated Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 1 below shows the details of the configuration; Figure 2 shows the magnetic spacer in isolation; Figure 3 shows the sound processor attached to the spacer.

For the Alpha 1(M) configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

To ensure that appropriate pressure is applied between the sound processor and the patient's skin / bone, various strengths of magnetic spacers are available (4 sizes – 2mm, 4mm, 6mm, and 8mm).

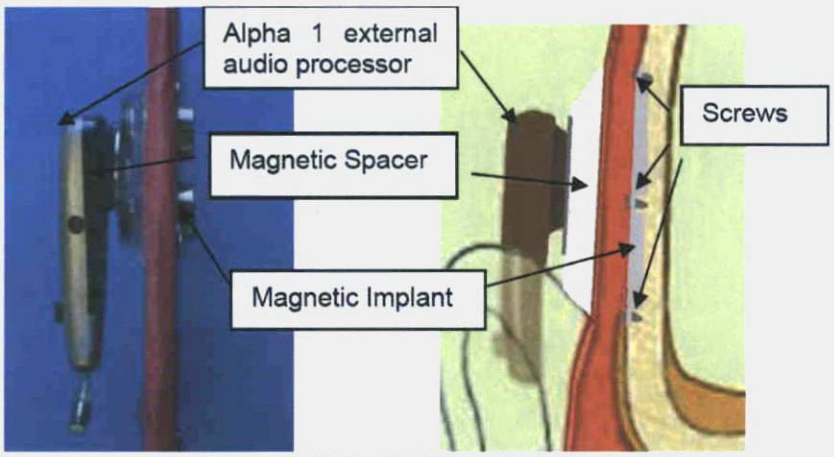

Figure 1. Alpha 1(M) configuration.

Figure 2. Magnetic spacer in Alpha 1(M) configuration.

Figure 3. Sound processor with metal disc attached to magnetic spacer.

The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical implant site.

Osseointegrated Magnetic Implant (p. 13-7; 44 of 192)
The implant consists of two (b)(4) magnets hermetically sealed in a titanium housing as shown in Figure 4. The implant is manufactured for Otomag by Eberle, EFS GmBH. Validation documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in Appendix C to the overall submission. Each implant is welded, cleaned, and 100% leak tested by the manufacturer using formally validated processes.

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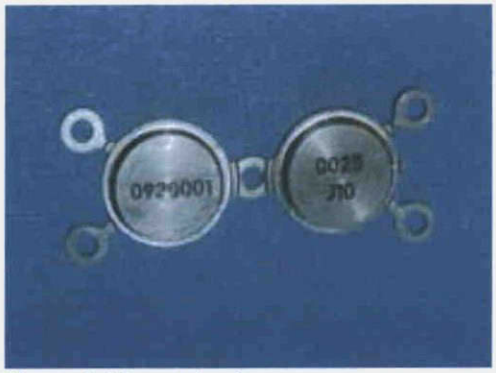

Figure 4. Magnet implant.

Please refer to the review memos of Drs. Clupper and Khan for additional details about device description. Please refer to Ms. Rudy's memo for a table of device components.

IV. Indications for Use

The sponsor provides the following indications for use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

V. Predicate Device Comparison

The sponsor claims one predicate device K100193, the Otomag bone conduction hearing aid system in the Alpha 1 (S) (headband or softband) configuration. The sponsor also claims that the Xomed Audiant Bone Conductor cleared in K855059 and K861971 employs the same coupling technology for the attachment of the sound processor but does not cite the Xomed device as a predicate.

The following table (Table 3 in K102199) provided by the sponsor compares the subject device with the cleared Alpha 1 (S) Bone Conduction Hearing
System:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	Identical
Class	Class II	Class II	Identical
Product Code	LXB	LXB	Identical
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	Identical
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical
Power Supply	Zinc-air battery	Zinc-air battery	Identical
Sound Processing	Digital	Digital	Identical
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical
Frequency Processing Range	125 – 8kHz	125 – 8kHz	Identical
Max Gain (60dB SPL)	38 dB	38 dB	Identical
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	29 dB	Identical
Material of sound processor coupling	Stainless Steel Disc	Stainless Steel Disc	Identical
Accessories/Options	Direct audio input via FM jack	Direct audio input via FM jack	Identical
Patient Contact Materials for Biocompatibility Purposes	Fotoplast-Lac	Fotoplast-Lac Titanium Grade 4 and 5 (Magnetic Implant)	See discussion below

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Sterilization	No sterile components	Steam sterilization of surgical implant	See discussion below
Manufacturer	Otomag GmBH	Otomag GmBH	Identical
Peak Output at 90 dB SPL	115 dB	115 dB	Identical
Frequency range per ANSI S3.22-2009	280-5000 Hz	280-5000 Hz	Identical
Total harmonic distortion per ANSI S3.22-2009	<3%	<3%	Identical
Equivalent input noise:	17 dB SPL	17 dB SPL	Identical
Battery current drain	0.95 mA	0.95 mA	Identical
Processor:	16 Band, 4 Channel WDRC	16 Band, 4 Channel WDRC	Identical
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical
Compression Attack Time (minimum)	0.25 ms	0.25 ms	Identical
Compression Release Time (maximum)	8192 ms	8192 ms	Identical
Patient Volume Control Wheel	38 dB range	38 dB range	Identical
Power Supply	1.3 V, #675 Zinc Air Battery	1.3 V, #675 Zinc Air Battery	Identical
Force Application Methods	Headband or Softband	Headband or Softband (Alpha 1(S) Version) Osseointegrated Magnetic Implant (Alpha 1(M) Version)	Substantially Equivalent – See discussion below

The sponsor claims four major differences between the subject and predicate devices:

1. **Indications for use:** The new Alpha 1(M) configuration is indicated for patients age 5 and older whereas the cleared (S) configuration is indicated for all ages.

2. **New patient contact materials:** The Magnetic Implant in the Alpha 1(M) configuration contains new patient contacting materials: Titanium Grades 4 and 5.

3. **Sterilization:** The Magnetic Implant is provided clean but not sterile and requires sterilization via gravity or prevacuum steam sterilization at the healthcare facility prior to implantation.

4. **Method for coupling sound processor to patient:** The Alpha 1(M) configuration utilizes a magnetic field to apply the necessary force to the patient's mastoid to conduct sound. The force generated by the magnetic field is adjustable through 4 different strength magnetic spacers provided with the product. In contrast, the cleared Alpha 1(S) device uses either elastic material (in the softband version) or spring tension (in the headband version), to couple the sound processor to the patient's head. The predicate therefore uses no implanted components.

The sponsor claims that the above differences do not negatively impact safety or effectiveness and do not raise any new safety or effectiveness questions.

(b)(4)

[redacted]

VI. Labeling

The sponsor lists 4 labeling materials that have been revised for the Alpha 1(M) configuration:

1. Physician's Manual
2. Patient User Manual
3. Magnetic Implant Package Label
4. Revised Primary Device Labels

This information was reviewed by Drs. Khan and Ms. Rudy. Please refer to the review memos of these reviewers for details, including several deficiencies relating to labeling.

VII. Sterilization/Shelf Life/Reuse

This information was reviewed by Ms. Rudy.

Please see Ms. Rudy's review memo for details, including a deficiency relating to the greater risk of infection compared to the predicate, in addition to several deficiencies relating to sterilization.

VIII. Biocompatibility

This information was reviewed by Dr. Malshet. Dr. Malshet has determined that the information is acceptable. Please see Dr. Malshet's review memo for details.

IX. Software

Comment (Lead Reviewer): *Changes in this submission relate only to the method of physically coupling the sound processor to the patient, and not in the sound-processor firmware or the clinical programming software. I therefore concur with the sponsor's assessment that, "All software documents provided in the original 510(k) submission (K100193) continue to be applicable to the modified version of this device." Please refer to the lead review memo for K100193 for review of the device software.*

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Comment (lead reviewer): *The following deficiency is identified which relates to electrical engineering and bench performance testing:*

(b)(4)

[redacted]

678

(b)(4)

[redacted]

XI. Performance Testing – Bench

(b)(4)

[redacted]

XII. Performance Testing – Animal

No animal performance-testing data were provided.

Comment (Lead Reviewer): *This is acceptable provided that the sponsor demonstrate substantial equivalence through bench performance testing and possibly, clinical performance testing.*

XIII. Performance Testing – Clinical

No clinical performance-testing data were provided.

Dr. Peng raises a deficiency relating to the lack of clinical performance testing. Please see Dr. Peng's review memo for details.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?		X	If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

The indication statement is the same as the indication for the predicate except for the addition that the (subject) Alpha 1(M) configuration which requires a surgically placed implant, is intended for ages 5 and older only.

2. Explain why there is or is not a new effect or safety or effectiveness issue:

The change made in the new indication statement does not raise any new safety of effectiveness issues because the age range has been appropriately specified per the review of the clinical reviewers.

3. Describe the new technological characteristics:

New technological characteristics include magnetic coupling of the sound processor to the patient's skull via a magnetic implant and (externally worn) magnetic spacer. The predicate instead uses a headband or softband to couple the sound processor to that patient's skull and there is no implant.

4. Explain how new characteristics could or could not affect safety or effectiveness:

The implanted component in the subject device poses several safety risks, including those relating to sterility and infection. The effectiveness of the new spacer system has also not been established.

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

Hearing-aid bone-conduction devices are not new. Therefore the general set of safety and effectiveness questions remains constant across various types of devices.

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

At a minimum, additional bench performance data are needed to demonstrate substantial equivalence to the predicate. Clinical performance data may also be needed.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" (http://www.fda.gov/cdrh/modact/guidance/1195.html) and "A Suggested Approach to Resolving Least Burdensome Issues" (http://www.fda.gov/cdrh/modact/leastburdensome.html).

See attached e-mailed for final deficiencies conveyed to sponsor.

XVI. Contact History

August 9, 2010: Lead Reviewer requested e-copy of submission from sponsor. Sponsor provided a download link to the submission the same day.

September 15, 2010: Lead Reviewer requested device sample from sponsor. Sponsor indicated on same day that this was possible and had some clarification questions: purpose, use, and whether sample will be returned. Lead reviewer responded on September 16, 2010. Sample received on September 22, 2010.

September 22, 2010: Lead Reviewer e-mailed sponsor question to clarify magnetic spacers provided in the sample. Sponsor provided requested clarification the next day.

September 23, 2010: Lead Reviewer e-mailed sponsor that additional information is needed to continue review of K102199 and informed the sponsor that the submission will be on hold until the information is provided.

XVII. Recommendation

Telephone Hold (TH).

Reviewer — Date 9/23/10

Branch Chief — Date 9/23/10

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Dasika, Vasant

From: Dasika, Vasant
t: Thursday, September 23, 2010 12:28 PM
To: 'jim.kasic@sophono.com'; 'anselmoc@reglera.com'
Cc: Nandkumar, Srinivas
Subject: K102199: Additional information needed

Importance: High

Attachments: K102199 additional information needed.pdf

Dear Mr. Kasic,

K102199
ional informat

We have conducted a preliminary review of the above referenced submission. Based on our review, additional information is needed. Please see the attached letter for details. Please also be advised that your submission will be placed on hold today and will remain on hold until the requested information is provided.

When you do respond with the requested additional information, please provide this information per the instructions in the letter (i.e., submit it to the address stated in the letter). At the same time, please also provide directly to me a complete e-copy of your response. This will greatly facilitate the review process.

We look forward to receiving and reviewing your supplement.

Please contact me if you have any questions.

Kind Regards,
Vasant

Vasant K. Dasika, PhD
Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA
10903 New Hampshire Avenue
WO66, Room 2443
Silver Spring, MD 20993

Phone: (301) 796-6860
Fax: (301) 847-8126

Email: Vasant.Dasika@fda.hhs.gov

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based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Re: K102199
Trade Name: Sophono Otomag Bone Conduction Hearing System
Dated: August 3, 2010
Received: August 4, 2010

Dear Mr. Kasic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, please provide the following additional information:

Predicate device

1. You seek clearance for the Alpha 1(M) configuration of your Otomag Bone Conduction Hearing System. This configuration uses magnetic attraction between a magnetic implant and an externally worn magnetic spacer to couple the sound processor to the patient. You list the cleared Alpha 1(S) configuration of your Otomag system as the single predicate. However, the Alpha 1(S) configuration uses neither an implant nor magnetic attraction for coupling the sound processor to the patient. You state, "The approach of using a magnetic implant to attach the sound processor has been previously employed by another family of bone conduction hearing devices. The Xomed Audiant Bone Conductor cleared in K855059 and K861971 employs this same technology for the attachment of the sound processor" (page 58 of 192). However, you do not cite this device as a predicate, nor compare it to your subject device. Given these insufficiencies, please address the following:

(b)(4)

[redacted]

Clinical and Bench performance data

(b)(4)

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Labeling, Clinical, and Sterility

(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Vasant K. Dasika, Ph.D. at (301) 796-6860. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Dasika, Vasant

From: Clupper, Daniel C
Sent: Thursday, September 23, 2010 1:42 AM
To: Dasika, Vasant
Subject: RE: K102199 Sophono deficiencies

Hi Vasant,

Yes, I think the labeling should somehow address this. I'm not sure if we have control over the marketing materials. Here are some possible deficiencies:

(b)(4)

[redacted]

Thanks,
Dan

From: Dasika, Vasant
Sent: Wednesday, September 22, 2010 6:01 PM
To: Clupper, Daniel C
Subject: RE: K102199 Sophono deficiencies

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Thanks!!
Vasant

From: Dasika, Vasant
Sent: Wednesday, September 22, 2010 4:00 PM
To: Clupper, Daniel C
Subject: K102199 Sophono deficiencies

Hi Dan,

The latest set of other deficiencies are on p-drive:

<file:\\P:\DONED\510 (k)\E N T B\K102199 Sophono Otomag BC System-magnetic configuration>

The following summarizes what I believe we just talked about. Please add or correct anything for the below that may be missing or inaccurate.

(b)(4)

[redacted]

Thanks!
Vasant

Vasant K. Dasika, PhD
Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA
10903 New Hampshire Avenue
WO66, Room 2443
Silver Spring, MD 20993

Phone: (301) 796-6860
Fax: (301) 847-8126

Email: Vasant.Dasika@fda.hhs.gov

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Dasika, Vasant

From: Clupper, Daniel C
Sent: Thursday, September 23, 2010 1:42 AM
To: Dasika, Vasant
Subject: RE: K102199 Sophono deficiencies

Hi Vasant,

(b)(4)

[redacted]

Thanks,
Dan

From: Dasika, Vasant
Sent: Wednesday, September 22, 2010 6:01 PM
To: Clupper, Daniel C
Subject: RE: K102199 Sophono deficiencies

Hi Dan- Sorry to keep piling Sophono issues on you, but I was thinking more about a few more related to the potential

(b)(4)

[redacted]

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(b)(4)

[redacted]

Thanks!!
Vasant

From: Dasika, Vasant
Sent: Wednesday, September 22, 2010 4:00 PM
To: Clupper, Daniel C
Subject: K102199 Sophono deficiencies

Hi Dan,

The latest set of other deficiencies are on p-drive:

<file:\\P:\DONED\510 (k)\E N T B\K102199 Sophono Otomag BC System-magnetic configuration>

(b)(4)

[redacted]

Thanks!
Vasant

Vasant K. Dasika, PhD
Biomedical Engineering Scientific Reviewer
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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
510(k) AUDIOLOGY REVIEW MEMO

From: Shu-Chen Peng, Ph.D. CCC-A
ENTB/DONED/ODE

To: Vasant Dasika, Ph.D., ENTB

CC: Nandu Nandkumar, Ph.D., ENTB

Subject: **K102199**: Otomag Bone Conduction Hearing System
Sophono

Date: September 16, 2010

Per your request, I have completed the review on this submission, K102199, regarding the Otomag Bone Conduction Hearing System, from the perspective of clinical audiology. My review of this submission reveals one question for the sponsor to address. This question is listed under the section entitled "**CONCLUSION & RECOMMENDATION**". Given this outstanding question along with the other possible outstanding questions identified by other reviewers, I suggest that this submission be placed on hold. Please refer to the remainder of this review memo for details, and indicate to me if any questions arise.

BACKGROUND

This 510(k) is being submitted to add the Osseointegrated Alpha 1 (M) configuration to the existing product family for the Otomag Bone Conduction Hearing System (re: k100193). Reportedly, The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Osseointegrated Alpha 1 (M).

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. In the Otomag Osseointegrated Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted Osseointegrated magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. The pressure applied by the magnetic attraction between the implant and the sound processor is equivalent to that in the Alpha 1 (S) configuration.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INDICATIONS FOR USE

Reportedly, the Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Reviewer's Comment: The indication for use (IFU) of the subject device is identical to its predicate (Otomag Bone Conduction Hearing System, Unmodified Version – K100193). The sponsor simply add the additional Osseointegrated Magnetic Implant version of the product to the overall statement including an age limitation for use of the Osseointegrated Magnetic Implant configuration (Osseointegrated Alpha 1(M)) to patients 5 years of age or older. Although there is no particular concern from the perspective of clinical audiology, it is anticipated that the sponsor provide proper performance data to support safety and effectiveness with this osseointegrated magnetic implant configuration added to the system.

DEVICE DESCRIPTION

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Osseointegrated Alpha 1 (M) configuration to the existing product family. In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an osseointegrated implanted magnet assembly. This configuration of the system is based on osseointegration of the implant through which living tissue integrates with the titanium implant causing the implant to be integrated into the bone. The magnetic field holds the sound processor agains the head and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Technological Characteristics: The technological characteristics of the Osseointegrated version of the Otomag Bone Conduction Hearing System are equivalent to those of the predicate device (non-Osseointegrated version). Items that are identical between the Osseointegrated version and the predicate are:

- Overall Device Performance
- Fundamental Technology (bone conduction)
- Software

Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Through non-clinical performance testing and evaluation, the identified technological differences do not raise new questions of safety and effectiveness.

Reviewer's Comment: The sponsor indicates that some aspects of the technological characteristics of the subject device (Otomag Alpha 1 (M)) are different from its predicate device. This information should be reviewed from the perspectives of biocompability and software/electrical engineering. The sponsor does not provide clinical performance data. They will be asked to justify why they believe that given these differences, clinical performance data are not needed.

COMPARISON TO PREDICATE DEVICES

The sponsor claims that the Otomag Bone Conduction Hearing System is substantially equivalent in material, design and function to the Otomag Bone Conduction Hearing System, Unmodified Version cleared under K100193.

Reportedly, the sponsor indicates that the changes to the device that are the subject of this 510(k) relate to the addition of another device configuration to the product family. The additional configuration, called Osseointegrated Alpha 1(M) includes a Magnetic Implant that is placed in bone beds behind and above the patient's ear to provide for attachment of the sound processor

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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without the use of the headband or softband. This change impacts detailed engineering specifications, labeling and patient contact materials, but does not alter the overall performance of the device. Due to the specificity of the Indications for Use statement for the prior version of the device, minor wording changes are also required.

The sponsor provides the following table summarizes and compares data on the Otomag Bone Conduction Hearing System cleared in K100193 (predicate device) to the Osseointegrated Alpha 1 (M) device that is the subject of this 510(k) submission.

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Osseointegrated Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	Identical
Class	Class II	Class II	Identical
Product Code	LXB	LXB	Identical
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz) • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz) The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic implant (patients 5 years of age and up) for the following patients and indications • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz) • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	Identical

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Osseointegrated Bone Conduction Hearing System	Comparison
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical
Power Supply	Zinc-air battery	Zinc-air battery	Identical
Sound Processing	Digital	Digital	Identical
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical
Frequency Processing Range	125 – 8kHz	125 – 8kHz	Identical
Max Gain (60dB SPL)	38 dB	38 dB	Identical
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	29 dB	Identical
Material of sound processor coupling	Stainless Steel Disc	Stainless Steel Disc	Identical
Accessories/Options	Direct audio input via FM jack	Direct audio input via FM jack	Identical
Patient Contact Materials for Biocompatibility Purposes	Fotoplast-Lac	Fotoplast-Lac Titanium Grades 4 and 5 (Magnetic Implant)	See discussion below
Sterilization	No sterile components	Steam sterilization of surgical implant	See discussion below
Manufacturer	Otomag GmbH	Otomag GmbH	Identical
Peak Output at 90 dB SPL	115 dB	115 dB	Identical

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Osseointegrated Bone Conduction Hearing System	Comparison
Frequency range per ANSI S3.22-2009	280-5000 Hz	280-5000 Hz	Identical
Total harmonic distortion per ANSI S3.22-2009	<3%	<3%	Identical
Equivalent input noise.	17 dB SPL	17 dB SPL	Identical
Battery current drain	0.95 mA	0.95 mA	Identical
Processor:	16 Band, 4 Channel WDRC	16 Band, 4 Channel WDRC	Identical
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical
Compression Attack Time (minimum)	0.25 ms	0.25 ms	Identical
Compression Release Time (maximum)	8192 ms	8192 ms	Identical
Patient Volume Control Wheel	38 dB range	38 dB range	Identical
Power Supply	1.3 V, #675 Zinc Air Battery	1.3 V, #675 Zinc Air Battery	Identical
Force Application Methods	Headband or Softband	Headband or Softband (Alpha 1(S) Version) Osseointegrated Magnetic Implant (Alpha 1(M) Version)	Substantially Equivalent – See discussion below

The sponsor provides a discussion on the differences between the subject and predicate devices, as follows:

The differences in specifications identified in the comparison table above between the predicate Otomag Bone Conduction Hearing device and the Otomag Osseointegrated device as reflected in the above SE table are the following. A detailed discussion of each device change is contained in Section 13 – Device Description / Description of Changes.

Indications for Use: The changes in the Indications For Use statement simply add the additional Osseointegrated Magnetic Implant version of the product to the overall statement including an age limitation for use of the Osseointegrated Magnetic Implant configuration (Osseointegrated Alpha 1(M)) to patients 5 years of age or older. These changes do not impart a new intended use for the product and do not raise new questions of safety and effectiveness.

Patient Contact Materials: The Magnetic Implant (includes attachment screws) constitute new patient contacting materials. The implant is made of (b)(4) [redacted] (b) This material is a biocompatible metal alloy not containing toxic substances. The addition of new patient contact materials that are biocompatible does not raise new questions of safety and effectiveness.

Sterilization: The Magnetic Implant is provided clean but not sterile and intended to be sterilized via gravity or prevacuum steam sterlization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The addition of an appropriately specified and validated sterilization cycle does not raise new questions of safety and effectiveness.

Force Application Method: The new Osseointegrated Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 4

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different strength magnetic spacers provided with the product. Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device.

The approach of using a magnetic implant to attach the sound processor has been previously employed by another family of bone conduction hearing devices. The Xomed Audiant Bone Conductor cleared in K855059 and K861971 employs this same technology for the attachment of the sound processor.

The sponsor concludes that the Otomag Osseointegrated Bone Conduction Hearing System is substantially equivalent to the Oticon Medical Ponto Pro Sound Processor and the Cochlear Baha BP100 Sound Processor.

(b)(4)

[redacted]

PERFORMANCE TESTING

As a result of the application of risk analysis and the differences identified in the substantial equivalency comparison table, the following verification and validation activities were completed to ensure that the differences between the non-osseointegrated predicate device and the Osseointegrated version of the Otomag Bone Conduction Hearing System do not raise new questions of safety and effectiveness.

Risk Areas identified as a result of risk analysis included: Material Biocompatibility, Implant Anchoring, Force Application to patient skin / mastoid, Sealing of Magnetic Implant. The following section outlines the categories of Verification and Validation testing that were conducted and rationale for those areas where additional testing was unnecessary as a result of the scope of changes.

Implant Anchoring: Implant Anchoring using titanium bone screws (Liebinger 4mm facial plating screws) were validated for this use in validation protocol (b)(4) contained in Appendix C to this overall submission.

Force Application: Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and

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headband versions of the device. This validation is documented in validation protocol DG-35 contained in Appendix C to this overall submission.

Sealing of Magnetic Implant: The two halves of the titanium casing are welded together, cleaned and 100% leak tested. Each of these processes has been appropriately validated by the manufacturer (Eberle, EFS GmBH).

Sound Processor: The sound processor itself was not modified and therefore additional performance testing of this part of the device was not necessary.

Vibration Transmission: The method, mechanics, and materials used to transmit vibration from the sound processor to the patient are unchanged in the Osseointegrated Alpha 1(M) configuration. The metal disc and magnetic spacers used in the Osseointegrated Alpha 1(M) configuration are identical in material and vibration application method to the Fotoplast encased magnets used in Alpha 1(S) configuration of the device (headband and softband versions). As a result, no additional performance testing related to these characteristics was required for the Osseointegrated Alpha 1(M) configuration.

Sterilization Validation including Sterile Packaging: The sterilization process specified in the Physician's Manual was validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The validation was performed by Nelson Laboratories and the protocol and final report documenting this validation is contained in Appendix D to this overall submission. In addition, the Physician's Manual contains the information required by ISO 17664-1:2004: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.

Biocompatibility Testing: In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible.

Software: No changes were made to either the embedded software in the sound processor or the fitting software associated with the device; therefore no software testing is associated with this modification to the device.

Electrical Safety Testing: The changes made to the modified version of the device have no effect/impact on electrical safety, and therefore no additional electrical safety testing was required.

EMC Testing: The changes made to the modified version of the device have no effect/impact on EMC performance, and therefore no additional EMC testing was required.

Animal / Clinical Testing: Animal and Clinical studies were not deemed necessary to validate the changes in the Osseointegrated Alpha 1(M) version of the device.

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The results of analyses, evaluation, and testing of the Otomag Bone Conduction Hearing System demonstrate that the Osseointegrated device is substantially equivalent to the prior cleared version of the device both in Intended Use and technological characteristics. The changes to the device do not raise new questions of safety and effectiveness and have been appropriately validated through the application of Otomag's and Sophono's design control programs.

The sponsor concludes that based on the non-clinical performance testing, the Osseointegrated version of the Otomag Bone Conduction Hearing System is as safe and effective and considered to be substantially equivalent to the previously 510(k) cleared non-Osseointegrated version of the device (K100193).

(b)(4)

[redacted]

LABELING INFORMATION

The sponsor's proposed labeling is provided on pages 59 – 104 of 192. The sponsor provides updates to labeling in conjunction with the addition of the osseointegrated Alpha 1(M) configuration of the Otomag Bone Conduction Hearing System. Reportedly, as a part of these updates the original manuals have been reorganized and reformatted to better and more clearly present the original information. No substantive changes to the original labeling pertaining to the Alpha 1(S) configuration have been made. Additional sections have been added to both the Physician's Manual and the Patient User Manual to appropriately address the osseointegrated Alpha 1(M) configuration. The changes are summarized as follows:

- Addition of new Warnings and Cautions related to the Alpha 1(M) Configuration
- Addition of sterilization instructions and cycle parameters relating to pre-implant sterilization of the Magnetic Implant
- Addition of surgical implantation and explantation instructions and diagrams have been added addressing the placement and removal of the Magnetic Implant
- Addition of instruction for attaching the Sound Processor to the Magnetic Implant

In addition to the revised Patient User Manual and Physician's Manual, the label for the Magnetic Implant is included in this section. The primary device label has been modified to clearly indication which device configuration is included in the packaging, Alpha 1(S) or osseointegrated Alpha 1(M). Please refer to the submission for details.

(b)(4)

[redacted]

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CONCLUSION & RECOMMENDATION

I have completed the audiology review on this submission, K102199 regarding the Otomag Bone Conduction Hearing System. My review reveals one question, as follows:

(b)(4)

[redacted]

Given this outstanding question, I recommend that this submission be placed on hold until proper response is provided. Please feel free to indicate to me if you have any questions about this review memo.

Shu-Chen Peng

Reviewed by Shu-Chen Peng, Ph.D. CCC-A
Scientific Reviewer in Audiology

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510 (k) REVIEW (K102199)

Date: 09-07-10

To: Vasant Dasika, PhD
Engineering Reviewer, ENTB/DONED/ODE

From: Anjum Khan, M.D., MPH
Medical Officer, ENTB/DONED/ODE

A. Khan 9.14.10.

Cc: Srinivas Nandkumar, M.D., Ph.D.
Branch Chief, ENTB/DONED/ODE

Subject: Modification to Otomag Bone Conduction Hearing System

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Purpose:

Sophono Inc. submits a Traditional 510(k) for modifications made to a previously cleared device. The modification described adds a new configuration into the Otomag Bone Conduction Hearing System family. The new configuration (Alpha 1(M)) uses an implantable magnet as a fixation system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193 – Otomag Bone Conduction Hearing System – May 18, 2010.

Classification: Class II

Product Code: LXB

Indications for Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

• Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

• Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

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• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Predicate Device:

Otomag Bone Conduction Hearing System, Unmodified Version (K100193)

(b)(4)

[redacted]

Device Description / Description of Changes (Section 13, Page 38/192):

General Introduction (1.1)

The new osseointegrated configuration (Alpha 1(M)) uses an implantable magnet encased in titanium as a retention system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193.
Per sponsor the addition of the Alpha 1(M) configuration of the product requires no change in intended use of the device, but does require the following:

a) Minor wording changes to the Indications for Use statement.
b) New configuration introduces new material, performance and design specifications to the product
c) New configuration requires revisions to product labeling.

* No changes to software or to the sound processor are being made as a part of introducing this additional configuration.

Device Introduction (Section 2):

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and the osseointegrated Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the

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head and vibration is transduced through direct contact with the patient's skin and the bone below.

In the modified **Otomag Alpha 1 (M)**, the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. Vibration is not primarily transmitted through the magnetic implant.

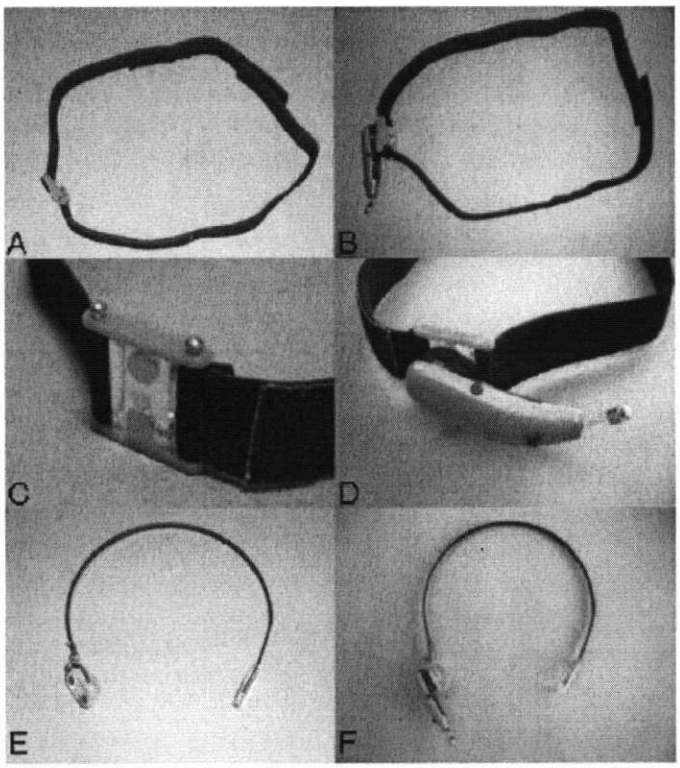

Figure 1: Alpha 1(S) Configuration / Headband, Softband, and Sound Processor

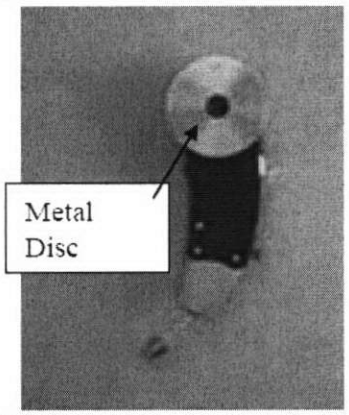

Figure 2: Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment to Headband / Softband

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Description of the Osseointegrated Alpha 1 (M) Configuration (Addition to Product Family), Section 5.3, Page 41 of 192:

In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Osseointegrated Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 3 below shows the details of the configuration

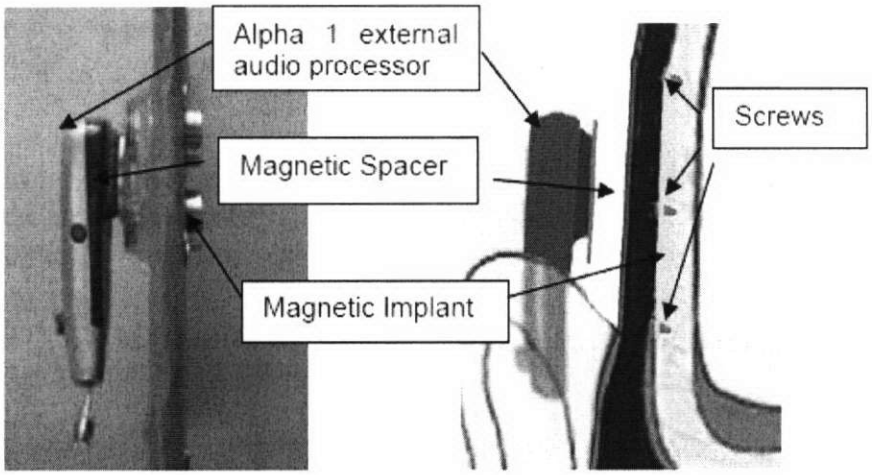

Figure 3: Alpha 1 (M) Magnetic Implant System

For this configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

To ensure that appropriate pressure is applied between the sound processor and the patient's skin / bone, various strengths of magnetic spacers are available (b)(4) [redacted]
(b)(4) [redacted]

The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical implant site.

Reviewer's Comments: In the new configuration of Alpha 1(M) Magnetic Implant
(b)(4) [redacted]

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Description of the Otomag Alpha 1 Sound Processor (Section 5.4, Page 41 of 192):

A key component of the Otomag System is the Alpha 1 Sound Processor, which is similar to a behind the ear air conduction hearing with a traditional bone conduction vibrator. The Alpha 1 Sound Processor utilizes proprietary software. The Alpha 1 Sound Processor is available for left or right sides with or without an external microphone, and with or without an FM jack.

The Alpha 1 Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone (Figure 4) within a plastic housing. The microphone opening is situated in the bottom of the housing and the vibrator in the upper part of the housing. The volume control with integrated switch and the battery compartment are accessible to the patient on the housing. The programming socket is situated beneath a cover. The programming socket is used for initial programming of the hearing device, as well as when adjustments are needed. No part of the sound processor has the user contact.

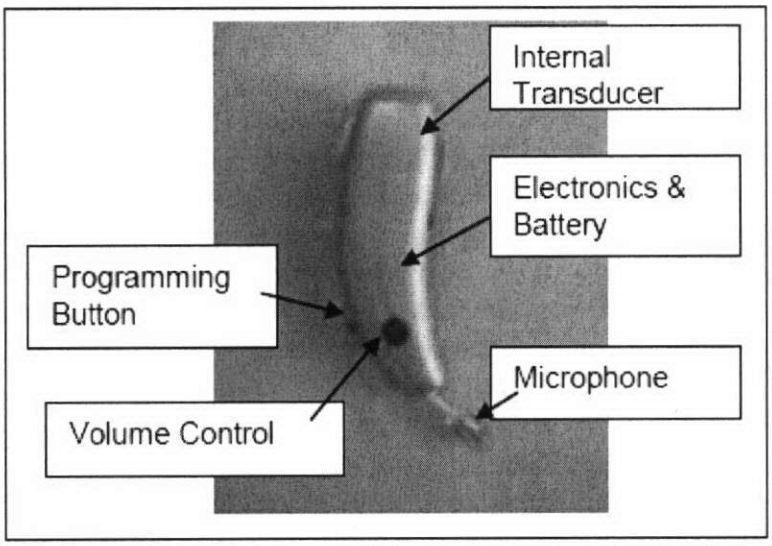

Figure 4: Alpha 1 Sound Processor

Sound Processor Circuit Description (Section 5.4.3., Page 42 of 192):

(b)(4)

[redacted]

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(b)(4) [redacted]

Gravity 2 Software Description (Section 5.4.4., Page 42 of 192):

(b)(4) [redacted]

Osseointegrated Magnetic Implant (Section 5.5, Page 44 of 192):

The implant consists of two (b)(4) [redacted]) magnets hermetically sealed in titanium housing as shown in Figure 5. The implant is manufactured for Otomag by (b)(4) [redacted]. Validation documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in Appendix C to the overall submission. Biocompatibility information, including material specifications for the implant can be found in Appendix B to the overall submission. Each implant is welded, cleaned, and (b)(4) [redacted] (b)(4) [redacted].

The magnetic implant is placed in 3 mm deep bone beds as shown in Figure 6 and Figure 7. The implant is secured using 4 mm titanium facial plating screws.

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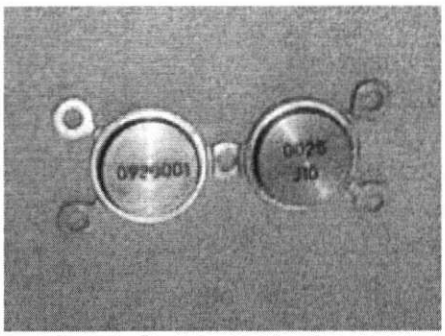

Figure 5: Magnetic Implant

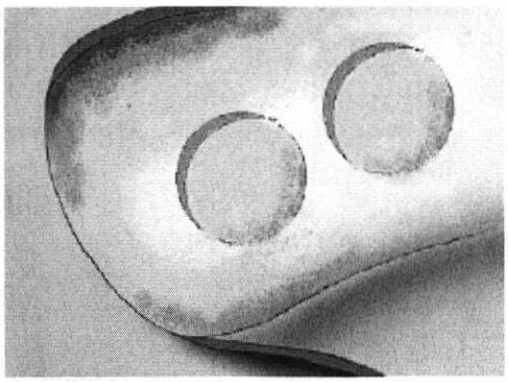

Figure 6: Bone Beds

Reviewer's Comments: The implant consists of two magnets with 5 titanium anchoring screws, with one screw between the two magnets. Sponsor has not described the advantages of this design and its contact to the spacer as well as the processor.

The magnetic implant is supplied to the physician clean but non-sterile, in sealed packaging to prevent contamination. The device is intended to be steam sterilized at the healthcare facility prior to implantation.

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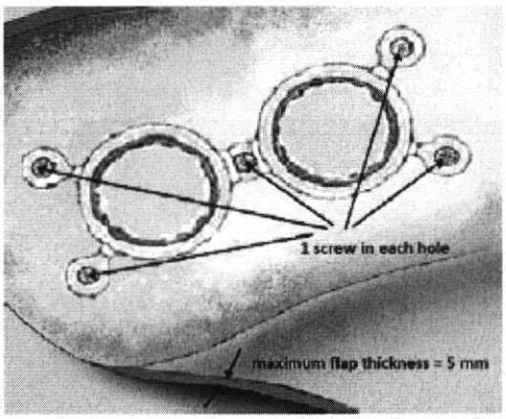

Figure 7: Implant Secured into Bone Beds

Magnetic Spacer (Section 5.6, Page 45 of 192):

The spacer consists of a nickel plated neodymium iron boron magnet encapsulated in 100% Fotoplast S IO, (b)(4) [redacted] (b)(4) [redacted] Both plastic materials are those commonly used for the production of custom ear molds. Complete material specifications can be found in Appendix B to the overall submission. Four magnetic strengths of the spacer are available to accommodate for variations in skin thicknesses and holding requirements to obtain approximately (b)(4) [redacted] of holding force.

(b)(4) [redacted]

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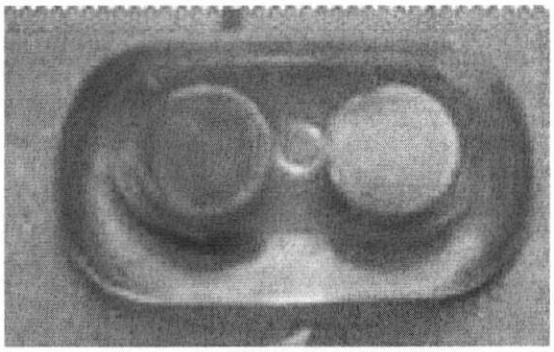

Figure 8: Magnetic Spacer

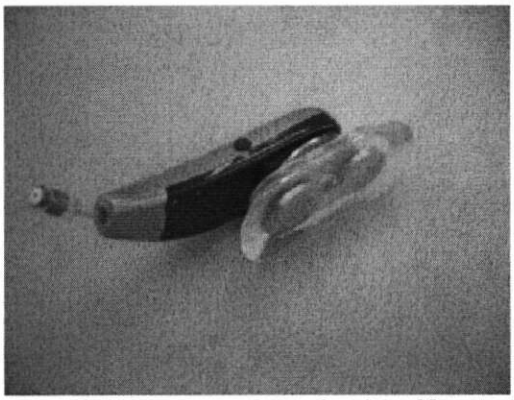

Figure 9: Sound Processor Attached to Magnetic Spacer

Patient-Contacting Components and Materials (Section 6, Page 45 of 192):

The components of the Otomag System that are patient contacting are the Fotoplast components on the headband / softband, the Fotoplast Magnetic Spacer, and the titanium magnetic implant. All materials used in the Alpha 1 device are materials commonly used in medical devices in the same applications (external tissue contact, implant). Biocompatibility information for these materials is contained in Section 17 and Appendix B of the overall submission. Each Magnetic Implant is cleaned to remove any manufacturing process contaminants.

Fotoplast-Lac and Fotoplast S IO (Section 6.2, Page 46 of 192):

The Fotoplast S IO is the material that directly encapsulates the magnets in the softband and headband. The Fotoplast-Lacquer 3 is (b)(4) [redacted] (b)(4) [redacted] This Fotoplast-Lacque[redacted] material is in direct skin contact with healthy skin behind the ear, at the site of bone conduction. Both materials have been found biocompatible for their intended use. These materials are commonly used to fabricate hearing aid ear molds and thus have years of use in the ear canal without biocompatibility problems.

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Titanium (Section 6.3, Page 46 of 192):

The titanium material (Appendix C) used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible and is used in many medical implant applications.

The bone screws used to anchor the magnetic implant are also titanium. These screws are manufactured by Stryker Leibinger and are a legally marketed device which was cleared under K970912 for use as self threading bone screw.

Kit Configurations (Section 7):

The Otomag System will be available in two kit configurations (e.g., Alpha 1 (S) with appropriate means of attachment, Alpha 1 (M) with appropriate magnetic spacers) or the components may be ordered separately. Each kit or component will be labeled appropriately and will include the Patient User Manual and / or the Physician Instructions for Use as appropriate.

Each Alpha 1 Sound Processor will be available in right or left sided versions, with either an internal or external microphone, and with or without an FM jack. Alpha 1 Sound Processor configurations are show in Table 3.

Table 3		
Sound Processor Configurations		
Right sided	Internal Microphone	With FM Jack
	External Microphone	
Left sided	Internal Microphone	
	External Microphone	
Right sided	Internal Microphone	Without FM Jack
	External Microphone	
Left sided	Internal Microphone	
	External Microphone	

An example of a component that is likely to be sold separately is an Alpha 1 (S) Sound Processor. Because it will not be known if the patient prefers a softband or headband, the Alpha 1 (S) will likely be shipped separately from the softband or headband.

Sophono, Inc. will also distribute to qualified hearing healthcare providers the Otomag Gravity 2 Fitting Software

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9. Description of Changes

9.1. The following section contains a summarized description of the changes to the device that include Indications for Use, additional hardware, and labeling. It should be noted that the changes described below do not constitute a change in intended use of the device, or the fundamental scientific principles of the device.

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C1	Indications for Use	Minor wording change in the Indications for Use statement to add the term "...or magnetic implant" to the end of the first paragraph. The new paragraph now reads: "The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband, Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:..." In addition, the following paragraph was removed because it was redundant with the first paragraph: "The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband."	None: Changes in Indications for Use statement are minor and do not result in a new Intended Use for the device. Specific impacts of design changes associated with this Indications for Use change are analyzed in each additional line item in this table.	None

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C2	Force Application Method	Addition of the magnetic spacer in 4 strengths, to be used in conjunction with the magnetic implant, to mimic the pressure applied by the softband or headband. Spacers are chosen by the fitting physician, based on tissue thickness, to ensure an application force of between approximately 2.5 and 5.4 N. Material of the magnetic spacer is identical to the skin contact materials present in the headband and the softband (Fotoplast Lacquer 3). Part of the function of the magnetic spacer is identical to the prior version of the device which utilized a magnetic field to hold the sound processor to the headband or softband. In addition to holding the Sound Processor, the magnetic spacer additionally holds the Sound Processor assembly (Sound Processor and magnetic spacer) to the patient's skin through the creation of an attractive magnetic field.	None: • Patient Contact materials for this component are identical to the prior version of the device • The switch from pressure application via the headband or softband to an attractive magnetic field does not impact risk assessment as long as forces are equivalent	Otomag Softband, Headband, and Magnetic Implant Static Force Verification / Validation Protocol, DG-35: Validation showed magnetic attachment mechanism via magnetic implant is equivalent to headband / softband versions of the device.

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C3	Force Application Method / Patient Contact Materials	Addition of the magnetic implant, to be used in conjunction with the magnetic spacer, to mimic the pressure applied by the softband or headband. Patient contact material of the magnetic implant is Titanium. Magnets are hermetically sealed within the titanium case. The magnet is of similar design and the same construction methods as is used in currently available cochlear implants. Screws used to anchor the implant in the bone beds are included with the device and are 4 mm titanium bone screws manufactured by Stryker Leibinger and cleared under K970912.	The addition of the implanted magnet raises the following new risks not present in the prior version of the device • Biocompatibility related the implant As discussed immediately above, the switch from pressure application via the headband or softband to an attractive magnetic field does not impact risk assessment as long as forces are equivalent	• See Appendix B for Biocompatibility information for the magnetic implant • Otomag Softband, Headband, and Magnetic Implant Static Force Verification / Validation Protocol, DG-35. Validation showed magnetic attachment mechanism via magnetic implant is equivalent to headband / softband versions of the device. • Otomag Magnetic Implant Screw Retention Force Validation Protocol, DG-36: Showed the retention force of the 5 retention screws far exceeds the forces applied to the implant during operation.

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Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C4	Labeling	Primary Device Labeling has been modified to include clear identification of which configuration of the device is included (Alpha 1(S) or Osseointegrated Alpha 1(M)) Physician's Manual has been revised to include implant and explant instructions, magnetic spacer fitting instructions, and additional Warnings / Cautions related to the magnetic implant. Users Manual has been revised to include additional user instructions for placement of the Sound Processor with the magnetic implant, and additional Warnings / Cautions related to the magnetic implant A label has been developed for the magnetic implant packaging to correctly identify this portion of the device.	None: Additional instructions are intended to ensure safe, effective use of the device. New Warnings and Cautions are included as a result of detailed risk analysis. The labeling changes themselves only serve to lower overall risk associated with the device	None

3. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

3.1. The following table summarizes and compares data on the Otomag Bone Conduction Hearing System cleared in K100193 (predicate device) to the osseointegrated device that is the subject of this 510(k) submission.

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	Identical
Class	Class II	Class II	Identical
Product Code	LXB	LXB	Identical
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz) The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2 and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2 and 4 kHz, or less than 15 dB at individual frequencies • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Otomag Bone Conduction Hearing System	Comparison
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	Identical
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical
Power Supply	Zinc-air battery	Zinc-air battery	Identical
Sound Processing	Digital	Digital	Identical
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical

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Frequency Processing Range	125 – 8kHz	125 – 8kHz	Identical
Max Gain (60dB SPL)	38 dB	38 dB	Identical
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	29 dB	Identical
Material of sound processor coupling	Stainless Steel Disc	Stainless Steel Disc	Identical
Accessories/Options	Direct audio input via FM jack	Direct audio input via FM jack	Identical
Patient Contact Materials for Biocompatibility Purposes	Fotoplast-Lac	Fotoplast-Lac Titanium Grade 4 and 5 (Magnetic Implant)	See discussion below
Specification / Characteristic	**Original Otomag Bone Conduction Hearing System K100193 (predicate device)**	**Otomag Bone Conduction Hearing System**	**Comparison**
Sterilization	No sterile components	Steam sterilization of surgical implant	See discussion below
Manufacturer	Otomag GmBH	Otomag GmBH	Identical
Peak Output at 90 dB SPL	115 dB	115 dB	Identical
Frequency range per ANSI S3.22-2009	280-5000 Hz	280-5000 Hz	Identical
Total harmonic distortion per ANSI S3.22-2009	<3%	<3%	Identical
Equivalent input noise:	17 dB SPL	17 dB SPL	Identical
Battery current drain	0.95 mA	0.95 mA	Identical
Processor:	16 Band, 4 Channel WDRC	16 Band, 4 Channel WDRC	Identical
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical
Compression Attack Time (minimum)	0.25 ms	0.25 ms	Identical
Compression Release Time (maximum)	8192 ms	8192 ms	Identical
Patient Volume Control Wheel	38 dB range	38 dB range	Identical
Power Supply	1.3 V, #675 Zinc Air Battery	1.3 V, #675 Zinc Air Battery	Identical
Force Application Methods	Headband or Softband	Headband or Softband (Alpha 1(S) Version) Osseointegrated Magnetic Implant (Alpha 1(M) Version)	Substantially Equivalent – See discussion below

Discussion of Differences (Section 4, Page 57 of 192):

Indications for Use:

Per sponsor the changes in the Indications for Use statement simply add the additional Magnetic Implant version of the product to the overall statement including an age limitation for use of the Osseointegrated Magnetic Implant configuration (Alpha 1(M)) to patients 5 years of age or older. These changes do not impart a new intended use for the product and do not raise new questions of safety and effectiveness.

Patient Contact Materials:

The Magnetic Implant contains new patient contacting materials.
The implant is made of Titanium Grades 4 and 5. The titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not

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contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible. Per sponsor the addition of new patient contact materials that are biocompatible does not raise new questions of safety and effectiveness.

Sterilization:

The Magnetic Implant is provided clean but not sterile and intended to be sterilized via gravity or pre-vacuum steam sterilization at the healthcare facility immediately prior to implantation. Per sponsor, the addition of an appropriately specified and validated sterilization cycle does not raise new questions of safety and effectiveness.

Force Application Method:

The new osseointegrated Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 4 different strength magnetic spacers provided with the product. Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device.

The approach of using a magnetic implant to attach the sound processor has been previously employed by another family of bone conduction hearing devices. The Xomed Audiant Bone Conductor cleared in K855059 and K861971 employs this same technology for the attachment of the sound processor.

Labeling (Section 15, Page 59):

Additional sections have been added to both the Physician's Manual and the Patient User Manual to appropriately address the osseointegrated Alpha 1(M) configuration. The changes are summarized as follows:

1.1.1. Addition of new Warnings and Cautions related to the Alpha 1(M) Configuration
1.1.2. Addition of sterilization instructions and cycle parameters relating to pre-implant sterilization of the Magnetic Implant
1.1.3. Addition of surgical implantation and explantation instructions and diagrams have been added addressing the placement and removal of the Magnetic Implant
1.1.4. Addition of instruction for attaching the Sound Processor to the Magnetic Implant
1.2. In addition to the revised Patient User Manual and Physician's Manual, the label for the Magnetic Implant is included in this section.
1.3. The primary device label has been modified to clearly indication which device configuration is included in the packaging, Alpha 1(S) or osseointegrated Alpha 1(M)

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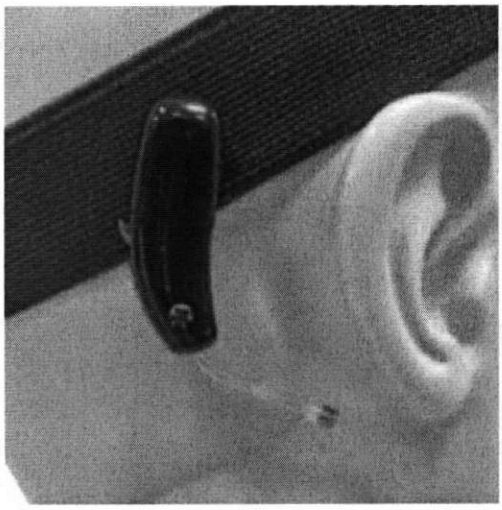

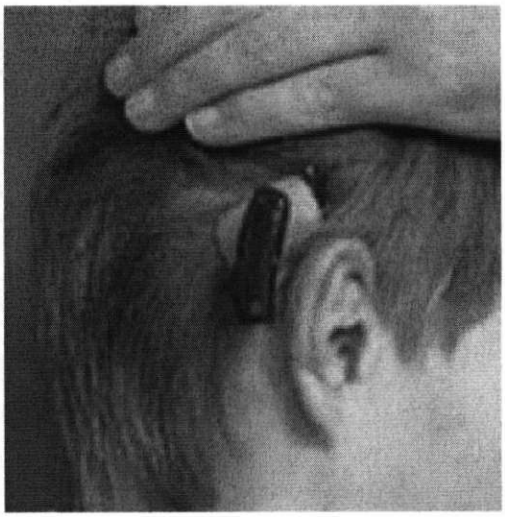

Alpha I (S) & Osseointegrated Alpha I (M) Bone Conduction Hearing Systems

Warnings

Warning

- Thoroughly read the Physician Manual and the Patient Manual before prescribing the Otomag System.
- To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria
- A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure.
- When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.
- Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.
- Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System.
- The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection.

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Precautions

Caution	• The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient. • Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. • To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. • To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. • Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual.

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Possible Adverse Effects

General

It is possible that a reaction to the materials of the Headband, Softband, or Magnetic Implant could occur. Such a circumstance may necessitate that use of the device be discontinued. If a reaction to the Headband or Softband occurs, Sophono will supply appropriate instructions so that the device can be sent to the laboratory for analysis.

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Risks that may occur during surgery:

The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, post-cholesteatoma, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, disturbance of taste or balance and noticeable changes in head noise.

Reviewer's Comments: Under the section of Risks that may occur during surgery, sponsor states that "These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, post-cholesteatoma, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, disturbance of taste or balance and noticeable changes in head noise." However, sponsor needs to clarify how they expect the risk of "post cholesteatoma" and "Disturbance of taste and balance" to occur in the procedure they are planning with the implantation of the magnets without transgressing the middle ear.
In addition, sponsor's list of risks that may occur during surgery does not include some critical risks of dural exposure, CSF leak, perforation of sigmoid sinus, and subdural hematoma. Sponsor should be asked to include those.

⚠	Warning • To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria. • Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System.

Risks that may occur after surgery:

Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma and inflammatory reaction. It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant.

Reviewer's Comments: Sponsor does not include the possibility of risks of implant extrusion and skin necrosis.

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Warning

- A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure.
- When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.
- Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.

Pre-Surgical Training Requirements

Before attempting to implant the Otomag Implant, surgeons are required to complete training provided by Sophono, Inc. During the training they will receive guidance regarding the procedure, a thorough understanding of the device and surgical procedure and other important information.

Surgical Risks

The implantation of the Otomag Implant requires a surgical procedure involving the removal of tissue and bone. As with any surgical procedure involving a general anesthetic, certain risks exist. Those risks include the risk of infection from poor hygiene or non-sterile technique, irritation of tissues during the implantation procedure, unintended cuts and abrasions, and irritation of tissues due to unintended exposure to implant materials. The implant is made of materials considered to be hypo-allergenic but in the case of unintended damage to the device, a patient could come in contact with substances that could generate an adverse reaction.

Surgical Implantation Steps

Step 1 - Making The Incision

The proper position for the implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant will be placed. The incision must be large enough to allow placement of the implant. See Figure 1.

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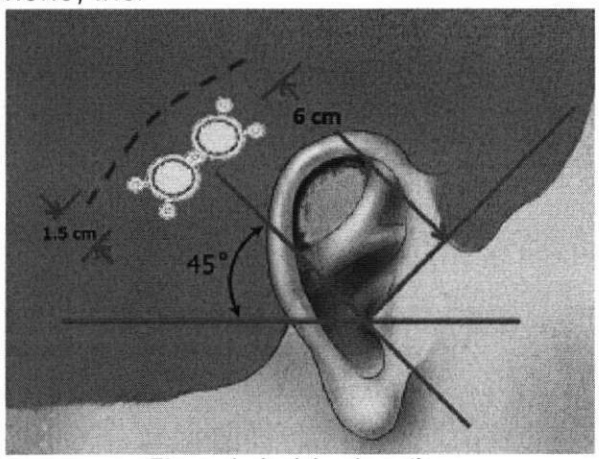

Figure 1 : Incision Location

Step 2 - Create a bone bed (optional)

The implant is approximately 2.6 mm thick and optimal tissue thickness over the implant is 4mm to 5 mm. Bone beds are recommended for the implant if the tissue thickness over the implant is less than 3 mm. To create a bone bed, mark the position of the implant magnets on the bone and drill the bone bed to a depth of approximately 3 mm. The implant magnets have a diameter of 10 mm.

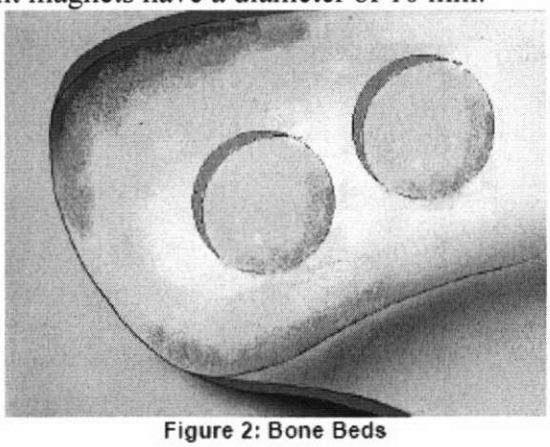

Figure 2: Bone Beds

Step 3 - Implant Placement

Place the implant with the magnets in the bone beds (if created) or with the magnets face up such that the bracket legs are flush to the skull. Place one screw in each of the bracket holes to securely attach the implant to the skull.

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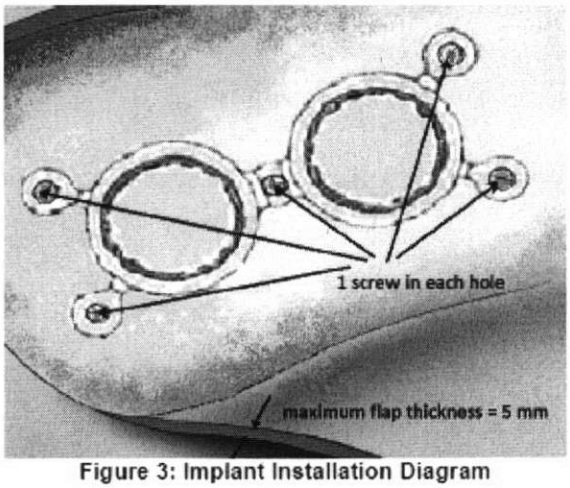

Figure 3: Implant Installation Diagram

Step 4 - Tissue Thinning and Closing the Incision
If the tissue flap is thicker than 6 mm, thin down a 10 mm wide strip of tissue to 5 mm directly over the implant magnets. Suture the incision closed.

Implant Surgical Removal Steps

Step 1 - Making the Incision

The implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant has been placed. The incision must be large enough to allow removal of the implant. See Figure 1 above.

Step 2 - Implant Removal

Remove each of the 5 screws holding the magnetic implant in place. It may be necessary to excise bone or tissue growth occurring over the face of the implant. Once the screws are removed the implant can be lifted carefully from the bone or bone beds. Suture incision closed.

<u>Instructions for Placement / Sizing of the Magnetic Spacers</u>

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system. The Alpha 1 (M) configuration is supplied with three strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid. Choose a magnetic spacer to achieve appropriate sound transmission without being uncomfortable to the patient. The spacers are labeled XX, YY, ZZ to indicate increasing magnetic strength. The patient should be

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instructed to select a lower strength spacer if the pressure on the skin is uncomfortable of if numbness occurs.

Section 22: Performance Testing-Clinical Data

Not applicable: Clinical data is not included as part of this submission.

Reviewers Comments: Because of the new configuration, it is advisable that clinical performance data be provided. However, I defer to Dr. Peng regarding this issue.

Conclusion/ Recommendations:

Substantial Equivalence for Otomag Alpha 1 (M) Sound Processor with the Otomag Osseointegrated Magnetic Implant cannot be determined until the following issues are resolved:

Deficiency #1:

(b)(4)

[redacted]

Deficiency #2:

(b)(4)

[redacted]

Deficiency #3:

(b)(4)

[redacted]

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(b)(4)

[redacted]

(b)(4)

[redacted]

Deficiency #4:

(b)(4)

[redacted]

Comments for the Team Lead:

1. The implant consists of two magnets with 5 titanium anchoring screws, with one screw between the two magnets. Sponsor has not described the advantages of this design and its contact to the spacer as well as the processor. Please try to identify the advantages of such a design.

2. No Clinical performance data has been submitted for review. Because of the new configuration, I think it is advisable that clinical performance data be provided. However, I defer to Dr. Peng's opinion regarding this issue.

Anjum Khan, M.D., MPH
Medical Officer, ENTB/DONED/ODE

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
ODE / DONED / ENTB
WO66 Rm 2574
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

TO: **Vasant Dasika, PhD – team leader**

FROM: Susan Rudy, MSN, CRNP, CORLN, OCN®
Nurse Consultant and Family Nurse Practitioner, ENTB

S. Rudy CRNP 9/14/2010

DATE: 9/14/2010

RE: **K102199 Sophono Otomag Bone Conduction System Alpha 1(M)**
Sterility review for Traditional 510(k)

RECOMMENDATION: Additional Information is needed (TH)

Purpose / History:

The sponsor submits a traditional 510(k) for a modification to an existing cleared device. The modification is to the cleared indications for use statement, introduces new design specifications, new materials and revisions to product labeling. They claim that the scientific technology is unchanged for the device.

Regulatory:

Product Code LXB
Regulation: 21 CFR 874.3300
Class II
Sophono is a small business in Boulder, CO.

Indications for Use (PDF p.13)

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

• Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

• Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15

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dB at individual frequencies.
• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

The device is by prescription only.

Device Description

The model Alpha1(S) was cleared in K100193 using a softband or a headband for the magnetic fixation of the sound processor. The Sponsor now applies for the model Alpha 1(M) using an implantable osseointegrated magnet assembly as the fixation system for the sound processor.

The implant is 2.6mm thick and 10mm diameter/

Summary of System Components

Device component	Materials	Spaulding Classification	Reprocessing instructions	Notes
Magnetic implant	Sumarium cobalt sealed in titanium casing	Critical	No cleaning Steam sterilize with gravity or prevacuum cycle in a pouch.	No pre-vacuum validation. No drying validation. Incomplete description of packaging
Titanium bone fixation screws	Third party component.	Critical	No instruction for sterilizing.	Incomplete description of compatible screws
Magnetic spacer in 3 sizes XX, YY, or ZZ (shown with sound processor)	Not described.	?Noncritical – patient contacting? Although may contact non-intact skin	Clean with Clorox type disinfectant wipe	Spacer is incompletely characterized
Sound Processor (Previously reviewed by the			Wipe with a soft cloth or Clean with Clorox type	

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Device component	Materials	Spaulding Classification	Reprocessing instructions	Notes
same team with a disk)			disinfectant wipe Clean battery compartment with dry Q-tip or Q-tip moistened with Clorox type disinfectant wipe. Use dry aid kit for excessive moisture exposure.	
Storage case (Previously reviewed by the same team)			Clean with a clorox type disinfectant wipe	
Head band (previously reviewed by the same team			Clean with a clorox type disinfectant wipe	
Soft band (previously reviewed by the same team)			Submerge and hand wash using mild clothes washing detergent with or without a small amount of color safe bleach, and air dry or clean with a Clorox type disinfectant wipe.	

Reviewer comment:

(b)(4)

[redacted]

Device Operation

The headband, softband, or magnetic implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The implant is placed in a surgical procedure under a general anesthetic.

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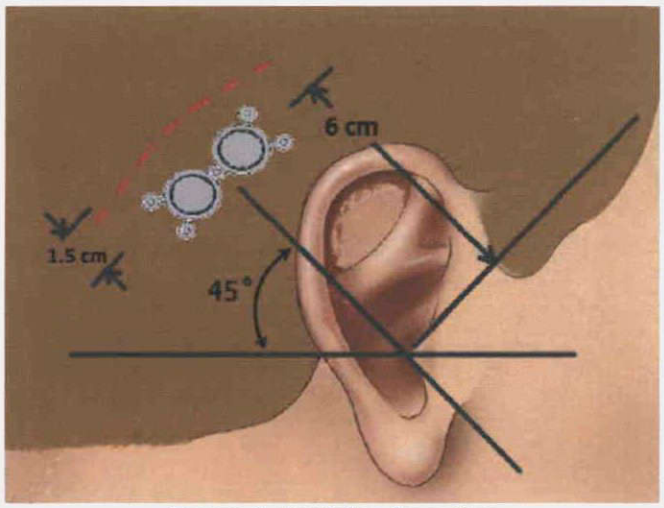

Figure 1 : Incision Location

Optional bone beds are created in the skull in which the magnets sit.

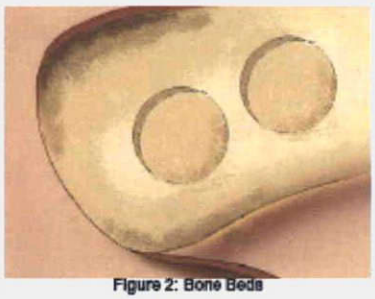

Figure 2: Bone Beds

The implants then sit in the bone beds and are attached to the skull using titanium screws.

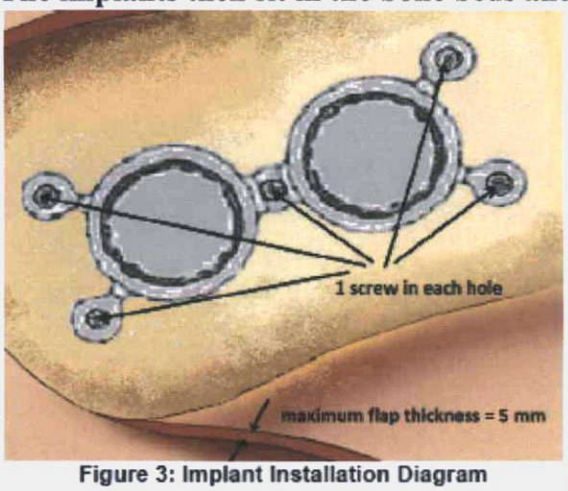

Figure 3: Implant Installation Diagram

Liebinger 4mm facial plating screws (titanium bone screws) for implant anchoring were validated.

Directions for explanting the magnets are also given, which are basically the reverse of implanting.

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Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system. The Alpha 1 (M) configuration is supplied with three strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid. Choose a magnetic spacer to achieve appropriate sound transmission without being uncomfortable to the patient. The spacers are labeled XX, YY, ZZ to indicate increasing magnetic strength. The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable of if numbness occurs.

Reviewer comment: This implant appears to be surgically placed in a hair bearing area. The Sponsor should recommend a method of hair removal that will minimize the chance of surgical site infection, or should at least refer readers to the published guideline on the subject. Since there have been a number of published studies since the guideline, I would prefer to see a literature-based response. See deficiency.

b. Preoperative hair removal

Preoperative shaving of the surgical site the night before an operation is associated with a significantly higher SSI risk than either the use of depilatory agents or no hair removal.[16,100,166-169] In one study, SSI rates were 5.6% in patients who had hair removed by razor shave compared to a 0.6% rate among those who had hair removed by depilatory or who had no hair removed.[166] The increased SSI risk associated with shaving has been attributed to microscopic cuts in the skin that later serve as foci for bacterial multiplication. Shaving immediately before the operation compared to shaving within 24 hours preoperatively was associated with decreased SSI rates (3.1% vs 7.1%); if shaving was performed >24 hours prior to operation, the SSI rate exceeded 20%.[166] Clipping hair immediately before an operation also has been associated with a lower risk of SSI than shaving or clipping the night before an operation (SSI rates immediately before = 1.8% vs night before = 4.0%).[170-173] Although the use of depilatories has been associated with a lower SSI risk than shaving or clipping,[166,167] depilatories sometimes produce hypersensitivity reactions.[166] Other studies showed that preoperative hair removal by any means was associated with increased SSI rates and suggested that no hair be removed.[100,174,175]

Reference:

Mangram, A. J., Horan, T. C., Pearson, M. L., Silver, L. C., Jarvis, W. R., & HICPAC. (1999). Guideline for Prevention of Surgical Site Infection, 1999. Atlanta, GA: USDHHS / PHS / CDC / NCID / HIP. P. 15. Available from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf

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Nature and Duration of Patient Contact

The implant is placed in a surgical procedure under a general anesthetic. It is Spaulding classification "Critical" requiring sterilization prior to implantation.

This would normally be a " Class 1 / clean" wound primarily closed.
It does violate a hair-bearing area.

It is a permanent contact device (> 30 days) per ISO 10993-1.

Reviewer comment:
1) The Sponsor does not detail the expected lifespan of the implant in the mastoid bone.
2) The Sponsor should address the recommendation for hair removal preoperatively to minimize the postoperative risk for infection.
3) The Sponsor should address whether prophylactic antibiotics are advised. Per Fairbanks, 2007, p. 66-68, "surgery for prosthetic device implantation" may or may not be an indication.

INFECTION PROPHYLAXIS IN SURGERY.
For CLEAN SKIN-ONLY INCISIONS IN HEALTHY PATIENTS, risk is low, sterile technique is sufficient, and antimicrobial prophylaxis is generally unnecessary.1
Microbiology: *Staph. aureus* (including meth-resistant strains: MRSA•), *Staph. epidermidis*
Drug choices (if circumstances deem necessity):
Primary:
IV: cefazolin (Ancef, Kefzol)
1 Gm before anesthesia induction
OR
Oral: cephalexin (Keflex)
500 mg 1 h pre-op
• If MRSA suspected or prevalent: TMP/SMX oral, Vancomycin or Tygecycline IV (p. 49).
Alternative:
IV: clindamycin (Cleocin)
600-900 mg (slow drip) before anesthesia
OR
Oral: clindamycin (Cleocin)
150-300 mg 1 h pre-op

Per Mangram et al, 1999

AMP is sometimes indicated for operations that entail incisions through normal tissue and in which no viscus is entered and no inflammation or infection is encountered. Two well-recognized AMP indications for such clean operations are: (1) when any intravascular prosthetic material or a prosthetic joint will be inserted, and (2) for any operation in which an incisional or organ/space SSI would pose catastrophic risk. Examples are all cardiac operations, including cardiac pacemaker placement,[290] vascular operations involving prosthetic arterial graft placement at any site or the revascularization of the lower extremity, and most neurosurgical operations (Table 4). Some have advocated use of AMP during all operations on the breast.[80,242,]

See deficiency for clarification of measures to prevent surgical site infections with the subject device implant surgery.

Materials

Patient contacting materials include Fotoplast-Lac and Titanium Grades 4 and 5 implant. The device is latex free.

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Standards PDF p 115 (Appendix A)

Standard # Cited & Date	Title	FDA Recognized	Declaration of Conformance	Notes
ISO 17665-1:2006 with Updated 510(k) sterility review guidance K90-1	Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices	Yes	Yes – without deviations, adaptations or exclusions	Nelson Labs
ISO 17664-1:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	No	Yes- – without deviations, adaptations or exclusions	
ISO 15223-1:2007	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Yes	Yes-– without deviations, adaptations or exclusions	
AAMI TIR 12: 2004				Cited by Nelson labs
USP 32 <1211>	Sterilization and sterility assurance of compendial articles			Cited by Nelson labs
AAMI ST79: 2006 with A1:2008 & Z3: 2009				Cited by Nelson labs
AAMI ST8: 2008	Hospital Steam Sterilizers			Cited by Nelson labs
AAMI ST67: 2003 (R2008)	Sterilization of healthcare products – requirements for products labeled "STERILE"			Cited by Nelson labs
EN556-2: 2003	Sterilizatin of medical devices. Requirements for medical devices to be desiginated "STERILE."			Cited by Nelson labs

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	Requirements for aseptically processed medical devices			
AAMI ST77: 2006	Containment devices for reusable medical device sterilization.			Cited by Nelson labs
FDA / ODE 1996	Labeling reusable medical devices guidance			Cited by Nelson labs

Predicate Devices:

K100193 Otomag Bone Conduction Hearing System – Models Alpha 1(S) and Alpha 1(M).

The Xomed Audiant Bone Conductor (K855059 and K861971) use the same technology.

Sterilization and Shelf-Life: (Section 16; PDF p. 105)

Whereas the Alpha 1(S) configuration had no sterile components, the Alpha 1(M) has a surgical implant that is sterilized by the user facility prior to surgery.

Section 16: Sterilization and Shelf Life

1. Sterilization

1.1. The Osseointegrated Magnetic Implant is provided clean but not sterile and is intended to be sterilized via gravity or prevacuum steam sterilization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices.

1.2. Attachment 1 to Section 15 – Labeling contains a copy of the revised Physician's Manual which contains details regarding pre-implant sterilization. Refer to pages 11 and 12 of this manual for details.

1.3. Appendix D to the overall submission contains validation protocols and reports for the specified sterilization cycle.

2. Shelf-Life

2.1. Not Applicable. The Osseointegrated Magnetic Implant is not supplied sterile and the materials of the implant case (titanium grades 4 and 5) are not expected to suffer performance degradation over the life of the overall product.

Reviewer comments: The sponsor should more fully characterize the packaging of the implant to aid our understanding of the appropriateness of their instruction not to clean the implant prior to sterilization. See deficiency.

Implant Steam Sterilization Validation appears in Attachment D (b)(4) [redacted]

(b)(4) [redacted]

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Reviewer summary:

(b)(4)

[redacted]

Figure 1: Inoculation site on device

(b)(4)

[redacted]

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TABLE 1. Results for the Gravity Half Cycles

(b)(4)

[redacted]

Proposed Labelling (Attachment 1 to Section 15, pp 11-12)

Physician's Manual (starts PDF p. 60)

Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

Warning

□ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Immediately seal the autoclave pouch.
- Drying of the device is not required.

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☐ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be sterilized a single time by prevacuum or gravity steam sterilization (autoclaving). The following sterilization parameters have been validated for sterilization of the implant.

Limitations on Reprocessing: Single Sterilization Only
Presterilization Decontamination / Cleaning / Disinfection: None Required
Cycle Type: Prevacuum or Gravity
Sterilization Time: 15 minutes minimum
Sterilization Cycle Temperature: 132 degrees C / 270 degrees F
Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)
Storage in Sterile State: Not Allowed – Sterilization immediately pre-implant only

Reviewer comments:
1) Prevacuum has not been validated, and has very different (shorter) cycle parameters, thus must be validated.
2) The materials and dimensions of the pouch should be specified, not just the manufacturer.
3) The Sponsor should provide assurance that the manufacturing process removes all inorganic and organic residue.
4) Drying time must be validated and specified for the end user.
5) The packaging for the implant should be fully described.
See multiple deficiencies.

Package labels PDF p. 99

Sophono

MAGNETIC IMPLANT
REF: 093001

NON STERILE

SN: XXXX-XX
QTY: 1

EFS GmbH & Co. KG
Glasbronnenstr. 6
75449 Wurmberg, Germany
Phone : (+49) 0 2841 8870032
Fax : (+49) 0 2841 8870032
P/N XXXX-XXX

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Otomag Alpha 1(S) Bone Conduction Hearing System

Manufacturer:
Otomag GmbH Alte Dorfstrasse 67, 32289 Rödinghausen, Germany. Tel: +49 5746 8504 Fax: +49 5746 8578
Distributed by: Sophono, Inc. 903 Brooklawn Drive, Boulder, CO 80303, USA. Tel: +1 303 564 1663 Fax: +1 720 222 2432

Contents:
1 Alpha 1 (S) Bone Conduction Hearing System
1 Physician Manual
1 Patient Manual

Device Intended for Single Patient Use Only!

PN xxxxxxx SN xxxxxxx LOT xxxxxxx

Made in Germany Label P/N 3000-03

Reviewer comment:
I believe we currently require that the English text be displayed with each international symbol.

Patient User Manual (starts PDF p. 82)

Below from p. 10 of manual

Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 3.

Figure 3. Positioning the Alpha I (M) Sound Processor on the osseointegrated Magnetic Implant

Patient User manual section 4, p. 13 (PDF p.94) Product maintenance cleaning and care.

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4 Product Maintenance

Cleaning and Care

Sound Processor

- Have your Sound Processor checked at regular intervals as specified by your hearing professional.
- To clean your Sound Processor, wipe it with a soft cloth or a Clorox® type disinfecting wipe
- The battery compartment may be cleaned by wiping it out with a DRY cotton swab or a cotton swab that has been moistened by a Clorox® type disinfecting wipe.

	Note • Remove the Sound Processor, Softband, and Headband during the application of hairspray or styling gels. If hairspray or gel comes in contact with the Sound Processor it may become sticky and difficult to clean

- If the Sound Processor becomes soaked with water:
  - Immediately open the battery door and remove the battery
  - Put the Sound Processor in a container with drying capsules such as Dri-aid kit or similar overnight. Drying kits are available from most hearing care professionals.

⚠	**Caution** • The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. • To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case

- The Sound Processor is provided in a plastic case which may be used to store the processor. This case may be cleaned with a Clorox® type disinfecting wipe. Make sure the case is completely dry before storing the Sound Processor in it.

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⚠	**Caution** • The Sound Processor is designed to operate within the temperature ranges of 41°F (+5°C) to 104°F (+40°C). The processor should not be subject to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. • Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor • Do not expose the Sound Processor to strong sunlight • Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case

Softband and Headband

- The Headband can be cleaned with a Clorox® type disinfecting wipe.
- The Softband may be submerged and hand washed with a mild clothes washing detergent (with or without a small amount of color safe bleach) and air dried or may be cleaned with a Clorox® type disinfecting wipe.

Magnetic Spacer

- The Magnetic Spacer can be cleaned with a Clorox® type disinfecting wipe.

⚠	**Caution** • Clean the Alpha 1 Processor, Magnetic Spacer, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. • To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

Reviewer comment: These instructions are adequate. The Sponsor should provide more information about the magnetic spacer however, and its materials and patient contact. *See deficiency*.

Pyrogenicity

The sponsor does not mention bacterial endotoxins. Technically this should be mentioned as a necessary item for a complete sterility review of a 510(k) per the K90-1 sterility review guidance. AAMI ST72: 2002 has a blanket statement that implants should be nonpyrogenic. However, from earlier research and conversation with DAGID expert reviewers, many bone implants are not, including orthopedic joints, facial plating systems, dental implants and mastoid implants. There have been no reported issues with pyrogenic reactions from these implanted devices. I will query the sponsor, but his is not likely to be a major deficiency. The sponsor will be easily able to justify the lack of pyrogen testing.

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Reviewer summary of Sterility:

This implanted titanium cased magnet is provided Nonsterile from the manufacturer to be sterilized by the user facility immediately prior to the implant surgery.
The original application bears a sterilization validation study that requires clarification and is incomplete.
The original application user instructions need clarification.
The Sponsor does not address standard measures for preventing surgical site infections.
A number of accessories for the system were previously reviewed and cleared by FDA. However, the sound processor has a new magnetic spacer that is incompletely characterized. All other accessories are appropriately cleaned and / or low-level disinfected.

1. Sterilant:	**YES**	**NO**
a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	Implant provided non-sterile to be sterilized using gravity or prevacuum steam by the user facility preoperatively.	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		NA
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals*," do not include measurement of ethylene glycol residuals);		NA
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),	ISO 17665-1: 2006 Biological Indicator Overkill method	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?	Not stated	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	Not described.	

END OF REVIEW

Recommendation: Additional information is needed (TH)

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Suggested Sterility / Re-use Deficiencies for the Sponsor:

1. You do not address several issues that impact on the potential for surgical site infections postoperatively. Please address the following:

   a. Your magnets appear to be implanted in a hair-bearing area. Surgeries in hair-bearing areas are at risk for surgical site infections (Mangram et al., 1999). Your Surgeon's manual does not address the removal of hair from the surgical area preoperatively. Please address this concern.

   b. You do not advise any skin preparation (topical antimicrobials) prior to making the skin incision. Please address this concern and revise your Surgeon's instructions if indicated.

   c. You do not advise any antibiotic prophylaxis for implanted patients. Please discuss whether antibiotic prophylaxis is recommended with your implants and revise the Surgeon's instructions if indicated.

References:

Fairbanks, D. N. F. (2007). Pocket Guide to Antimicrobial Therapy in Otolaryngology-Head and Neck Surgery (13th Ed.) Alexandria, VA: The American Academy of Otolaryngology-Head and Neck Surgery Foundation. Available from **http://www.entnet.org/EducationAndResearch/upload/AAO-PGS-9-4-2.pdf**

Mangram, A. J., Horan, T. C., Pearson, M. L., Silver, L. C., Jarvis, W. R., & HICPAC. (1999). Guideline for Prevention of Surgical Site Infection, 1999. Atlanta, GA: USDHHS / PHS / CDC / NCID / HIP. Available from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf

(b)(4)

[redacted]

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(b)(4)

[redacted]

5. You do not recommend (Surgeon's instruction manual, p. 12) or validate (Attachment D) a drying time for your implanted magnets. Please address the following:

   a. In your Surgeon's manual (p.11), in the section where you describe the preparation of the implant for sterilization, you state "Drying of the device is not required." This statement is illogically placed and not relevant to the preparation for sterilization, since none of your recommended preparation steps involve making the implant wet. Please delete this statement.

   b. (b)(4) [redacted]

   c. As communicated in "*Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance*" (available at http://www.fda.gov/cdrh/ode/198.pdf), manufacturers are responsible for including at least one validated, technically feasible sterilization

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(b)(4)

[redacted]

Notes for Team Leader / Other reviewers to consider:

- For the engineering reviewers – any bench / functionality testing should be performed on sterilized and aged devices.

(b)(4)

[redacted]

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(b)(4)

[redacted]

- Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices.

(b)(4)

[redacted]

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REVIEW OF TOXICOLOGY DATA

Date : September 7, 2010
From: : Vasant G. Malshet, Ph.D., DABT **Division/Branch:** DONED/ENTB
To : Vasant Dasika, Ph.D. **Division/Branch:** DONED/ENTB
Trade Name: Otomag Bone conducting Hearing System
510(k)# : K102199
Applicant : Sophono Inc

Checklist: Biocompatibility Evaluation of Medical Devices

Indications for Use: The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Brief Device Description: The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Osseointegrated Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an osseointegrated implanted magnet assembly. This configuration of the system is based on osseointegration of the implant through which living tissue integrates with the titanium implant causing the implant to be integrated into the bone. The magnetic field holds the sound

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processor agains the head and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Component Materials:

Introduction

1.1. The only new patient contacting materials present in the Osseointegrated Alpha 1(M) addition to the Otomag Bone Conduction Hearing System are related to the Magnetic Implant and its retention hardware (bone screws).

A available route through the flow chart conservatively assumes that the implant is not exactly the same as a legally marketed device and follows the path that asks if the material "is a polymer" (no), "is the material a metal, metal allow, or ceramic" (yes), "does it contain toxic substances" (no). This path through the flow chart also indicates that biocompatibility requirements have been met for the material of the implant case. The materials specifications for the titanium materials used in the case are contained in Appendix B to the overall submission.

The titanium material used in the magnetic implant is well established as biocompatible and is used in implantable medical devices in similar applications such as cochlear implants and extensively as a material for orthopedic implants.

The bone screws used to anchor the magnetic implant are also titanium. These screws are manufactured by Stryker Leibinger and are a legally marketed device which was cleared under K970912 for use as self threading bone screw.

Type of Tissue Contact: (check one)

____ Surface device: skin
____ Surface device: mucosal membrane
__x__ Surface device: breached or compromised surfaces
____ External communicating device: blood path, indirect
____ External communicating device: tissue/bone/dentin
____ External communicating device: circulating blood
____ Implant device: tissue/bone
____ Implant device: blood

Duration of Contact: (check one)

____ < 24 hours
____ > 24 hours, but less than 30 days
__x__ > 30 days

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____ potential for repeat exposure (If so, please explain)

Biocompatibility Testing Submitted: (See Table 2.)

Summary of Biocompatibility Data Submitted: (See Table 3.)

Table 2. Biocompatibility Testing Submitted

Biocompatibility Test	Recommended (will plan to add links to tests)	Provided	Need to provide
Cytotoxicity	x		
Sensitization	x		
Irritation or intracutaneous reactivity	x		
Acute systemic toxicity and material mediated pyrogenicity			
Sub-chronic toxicity			
Genotoxicity*			
Gene mutations in bacteria			
Gene mutations in mammalian cells			
Clastogenicity in mammalian cells			
Implantation			
Hemocompatibility			
Hemolysis			
Complement activation			
Thrombogenicity			
Chronic toxicity			
Carcinogenicity			
Reproductive/developmental			
Biodegradation			

*Per ISO 10993-3 genotoxicity testing should be performed using methods outlined in option 1.

L929 MEM ELUTION TEST - ISO

No biological reactivity (Grade 0) was observed (b)(4) [redacted]
(b)(4) [redacted]

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(b)(4) [redacted] The test article (b)(4) [redacted] considered non-cytotoxic and meets the requirements of the Elution Test, ISO 10993.

KLIGMAN MAXIMIZATION TEST – MODIFIED

(b)(4) [redacted]

INTRACUTANEOUS INJECTION TEST-ISO

The test article, (b)(4) [redacted] was evaluated for its potential to produce irritation after intracutaneous injection in New Zealand white rabbits. The test article sites did not show a significantly greater biological reaction than the sites injected with the control article. Based on the criteria of the protocol, the test article is considered a negligible irritant.

Conclusions: The submission contains biocompatibility information to show that the patient contacting material is biocompatible during the intended use of this device.

Vasant G. Malshet, Ph. D., DABT
Expert Toxicologist

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K102199 – Materials Science and Engineering Review

To: Vasant Dasika, Ph.D.
Team Leader, DONED/ENTB

From: Daniel C. Clupper, Ph.D.
Biomedical Engineer, DONED/ENTB

Date: September 14, 2010

Device: Otomag Bone Conduction Hearing System
Model Alpha 1 (S) and Alpha 1 (M)
(Sophono Inc.)

Regulatory Background
Regulation Number: 21 CFR 874.3300
Product Code: LXB

Indications for Use
The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Device Introduction (p. 13-1; 38 of 194)
The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and the osseointegrated Alpha 1 (M).

This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

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In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. Vibration is not primarily transmitted through the magnetic implant.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Description of the Osseointegrated Alpha 1 (M) Configuration (p. 13-4; 41 of 192)
In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Osseointegrated Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 1 below shows the details of the configuration.

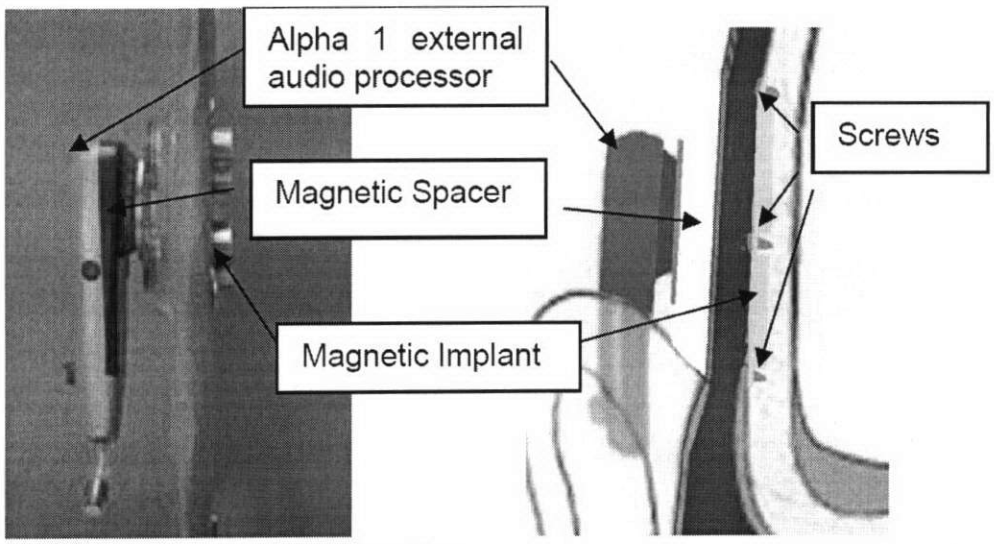

Figure 1. Alpha 1(M) configuration.

For this configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

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To ensure that appropriate pressure is applied between the sound processor and the patient's skin / bone, various strengths of magnetic spacers are available (4 sizes – 2mm, 4mm, 6mm, and 8mm).

The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical implant site.

Osseointegrated Magnetic Implant (p. 13-7; 44 of 192)
The implant consists of two (b)(4) 5 magnets hermetically sealed in a titanium housing as shown in Figures 2 and 3. The implant is manufactured for (b)(4) [redacted] (b)(4) [redacted] Validation documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in Appendix C to the overall submission. (b)(4) [redacted] (b)(4) [redacted]

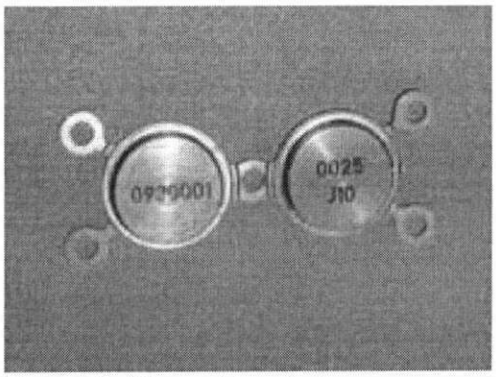

Figure 2. Magnet implant.

(b)(4) [redacted]

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The magnetic implant is placed in 3 mm deep bone beds as shown in Figure 4. The implant is secured using 4 mm titanium facial plating screws. The device is intended to be steam sterilized at the healthcare facility prior to implantation.

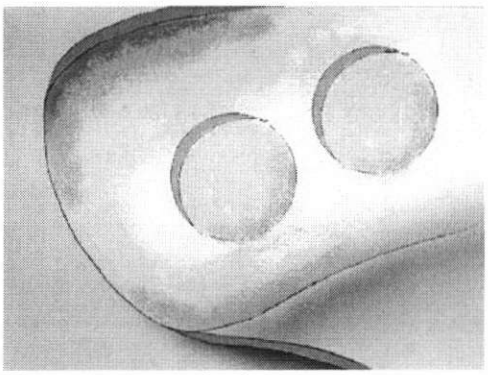

Figure 4. Bone bed.

Reviewer Comments:

(b)(4)

[redacted]

Magnetic Spacer (p. 13-8; 45 of 192)

The spacer consists of a (b)(4) [redacted] magnet encapsulated in

(b)(4)

[redacted]

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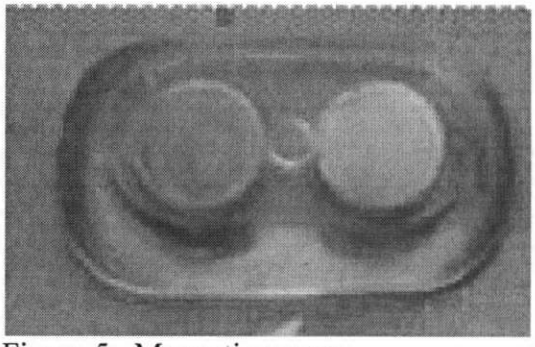

Figure 5. Magnetic spacer.

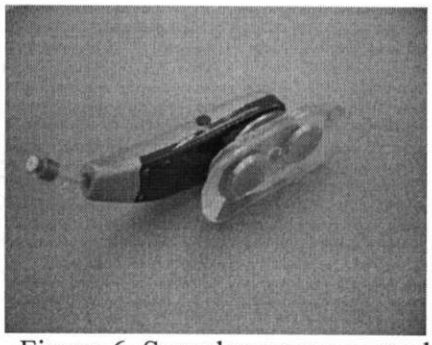

Figure 6. Sound processor attached to magnetic spacer.

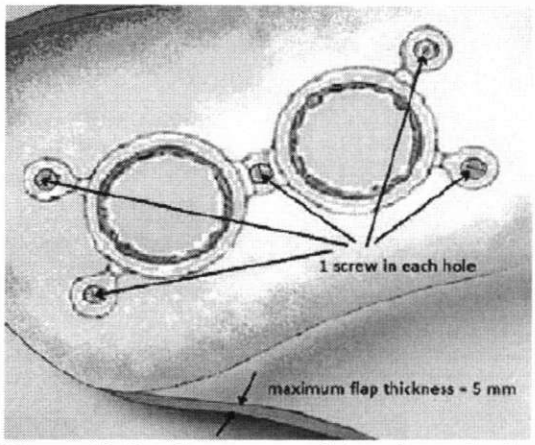

Figure 7. Implant secured into bone bed.

Patient-Contacting Components and Materials (p. 13-8; 45 of 192)
The components of the Otomag System that are patient contacting are the Fotoplast components on the headband / softband, the Fotoplast Magnetic Spacer, and the titanium magnetic implant. Biocompatibility information for these materials is contained in Section 17 and Appendix B of the overall submission. Each Magnetic Implant is cleaned to remove any manufacturing process contaminants.

Fotoplast-Lac and Fotoplast S IO

(b)(4) [redacted]

(b)(4) [redacted] at the site of bone conduction. Both materials have been found biocompatible for their intended use. These materials are commonly used to fabricate hearing aid ear molds and thus have years of use in the ear canal without biocompatibility problems.

(b)(4) [redacted]

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Titanium
The implant consists of a samarium cobalt magnet sealed in a biocompatible titanium case. Only the titanium case of the implant is in contact with patient tissue.

The bone screws used to anchor the magnetic implant are also titanium. These screws are manufactured by Stryker Leibinger and are a legally marketed device which was cleared under K970912 for use as self threading bone screw.

(b)(4) [redacted]

Force Application Method (p. 14-6; 58 of 194)
The new Osseointegrated Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 4 different strength magnetic spacers provided with the product. (b)(4) [redacted]
(b)(4) [redacted]

The approach of using a magnetic implant to attach the sound processor has been previously employed by another family of bone conduction hearing devices. The Xomed Audiant Bone Conductor cleared in K855059 (Fig. 8) and K861971 employ this same technology for the attachment of the sound processor.

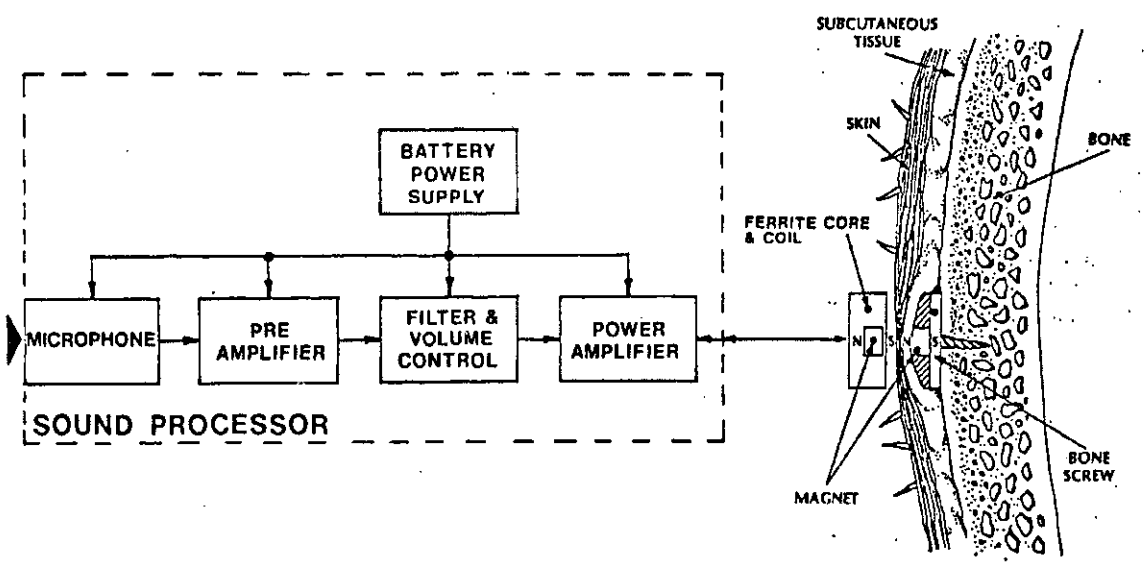

Figure 8. Xomed device (K855059).

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K855059 Materials
The implant portion of the K855059 Audiant Bone Conductor system is composed of:

1. Titanium Alloy Ti-6Al-4V (cup and screw portion of the Audiant Bone Conductor implant).

2. Cobalt Samarium Magnet - This portion of the implant, which is affixed to the Titanium Alloy cup, is coated with Parylene-C film to isolate it from body fluids and further potted in silicone elastomer.

3. The Parylene-C coated magnet and the interior of the titanium alloy cup are potted in PE1055 silicone elastomer.

The magnet specifications are shown below:

II. VENDOR REQUIREMENTS:

** VENDOR MUST MEET ALL REQUIREMENTS LISTED **

A. Physical:

1. Material:

a. Disk - Sintered rare earth/cobalt alloys

b. Coating - Parylene-C coating to meet MIL-STD-46058C

2. Visual: Section III

B. Mechanical

Typical Room Temperature Properties:

1. Coercive Force (Hc), Oersteds: 8200.

2. Intrinsic Coercive Force (Hci), Oersteds: 1500+.

3. Residual Induction (Br), Gauss: 8700

4. Maximum Energy Product (BH): 18.

5. Curie Temperature = 700°.

Coating: Magnets shall be uniformly coated on all surfaces, except the "North Pole", with 76 micron of Parylene-C.

Magnets shall be polarized through the .110" dimension.

Performance Testing Summary (p. 13-4; 41 of 192 and Sec. 20)
Sealing of Magnetic Implant

(b)(4)

[redacted]

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Force Application
Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device. This validation is documented in validation protocol [redacted] (Appendix C).

Implant Anchoring
Implant Anchoring using titanium bone screws (Liebinger 4mm facial plating screws) were validated for this use in validation protocol [redacted] (Appendix C).

(b)(4) **- Otomag Magnetic Implant Static Force Verification / Validation Protocol**
The purpose of this protocol is to measure the force that the Otomag magnetic implant exerts on the Alpha 1 audio processor against the side of the head over the available range of magnetic spacers and the expected range of skin thicknesses. The intention is to show that for all skin thicknesses, a magnetic spacer is available to generate a holding force within the range provided by the headband and softband versions of the device.

The Otomag softband and headbands were approved in 510(k) K100193 for use with the Alpha 1 Audio Processor for the treatment of conductive, mixed and single sided deafness.

In the case of the implant magnet, the plastic pad is held in the same radial direction by the implant magnet as it is with the headband or the softband. The audio processor is held to the plastic pad by magnetic force.

Current standards specify that a headband should hold a bone vibrator in position with a static force of (b)(4) ANSI S3.6, 2004) for audiometric measurements and (b)(4) (b)(4) IEC60118.9, 1985) for calibration of a hearing aid bone vibrator on an artificial mastoid. Raicevich et. al., measured the force exerted by bone vibrator on the head for 11 subjects, the measured mean force exerted by a headband fitted with an (b)(4) (b)(4) [redacted].

While these standards are intended for specific purposes, the information in these standards can be used to establish a force range that allows for meaningful audiometric measurements and relativistic comparison of the device using artificial mastoids. The force specification range used in this protocol was derived based on these standards and the intent of this protocol is to show that the magnetic implant of the Alpha 1(M) version of the Otomag Bone Conduction Hearing System is capable of generating application forces within this range to support the device.

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Results Table – (Green shade denotes meeting specification range)

(b)(4)

[redacted]

The acceptance criteria was met where the population average for at least one combination of magnetic implant and magnetic spacer attraction force is within the range set by the standards quoted above (b)(4) [redacted] for each tissue thickness.

Reviewer Comments: According to the sponsor, current standards specify that a headband should hold a bone vibrator in position with a static force of (b)(4) [redacted] (ANSI S3.6, 2004). I defer to the audiologist and/or team leader regarding the applicability of the (b)(4) [redacted] values referenced above which are used to support the data shown in the "Results Table" above.

(b)(4) [redacted] **- Otomag Magnetic Implant Screw Retention Force Validation Protocol**

(b)(4)

[redacted]

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(b)(4)

[redacted]

Conclusions

The following deficiencies are recommended:

(b)(4)

[redacted]

Daniel C. Clupper, Ph.D.
Biomedical Engineer
DONED/ENTB

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Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm	X		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm		X	
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm	X		
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm			X

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Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm	X		
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm		X	
Proposed Labeling	Device Advice " Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm		X	
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm		X	
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm	X		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm			X

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			X
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm		X	
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf		X	
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**	X		
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm			X

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Internal Administrative Form

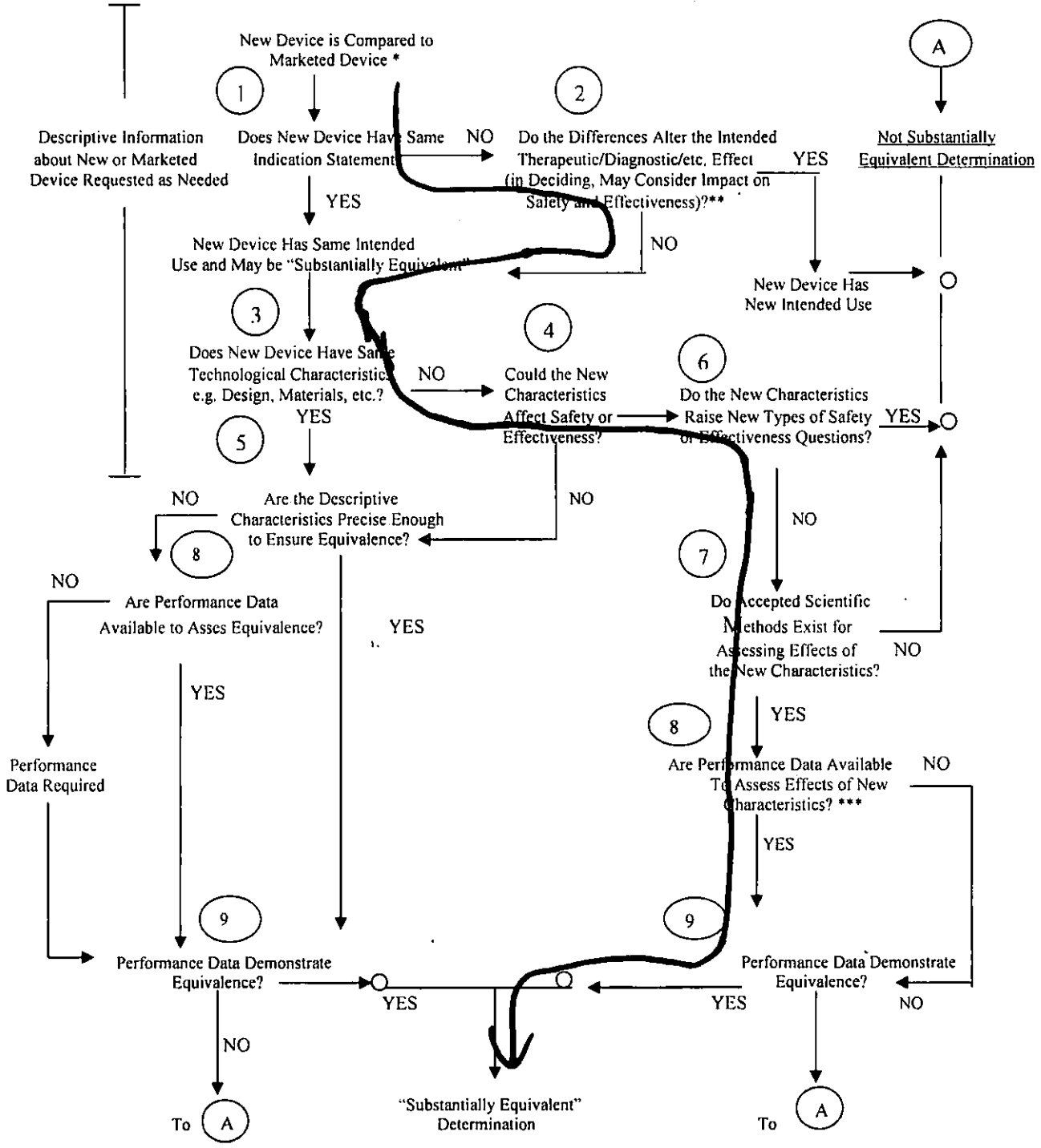
	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		
3. Is the product a device?	X	
4. Is the device exempt from 510(k) by regulation or policy?		X
5. Is the device subject to review by CDRH?	X	
6. Does the tradename imply a new intended use or new indication? If yes, please see the 510(k) Staff		X
7. Are you aware that this device has been the subject of a previous NSE decision?	X	
8. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		X
9. Are you aware of the submitter being the subject of an integrity investigation?		X
10. If, yes, consult the ODE Integrity Officer.		
11. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

765.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Sophono

K102199 | S2

December 20, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Room 2443

FDA CDRH DMC

DEC 21 2010

Received

Attn: **Vasant K. Dasika, PhD**
Email: Vasant.Dasika@fda.hhs.gov

Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA

K-23

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for Additional Information dated September 23, 2010

510(k) Applicant / Manufactured by:
Jim Kasic
President and CEO
Sophono Inc.
3022 Sterling Cr,
Boulder, CO 80301

510(k) Contact / Submission Correspondent:
Clay Anselmo
Reglera LLC
555 Zang Street
Lakewood, CO 80228 USA
Phone (Mobile): 303-907-2955
Fax: 303-832-6700
Email: **anselmoc@reglera.com**

Dear Dr. Dasika,

We received FDA's request for additional information dated September 23, 2009 in response to our 510(k) application, K102199, for the Sophono Otomag Bone Conduction Hearing System. To address the issues raised in these requests for additional information, we are providing the following information in response for your review.

The attached response reflects our response to the twenty (20) deficiencies listed in the September 23, 2010 Additional Information Request. Please note that we are including two hard copies of our complete response and one electronic copy provided on CD.

If you have any questions or if further information is needed, please feel free to contact me at any time using the contact information contained above. We greatly appreciate your time and attention to this matter.

Sincerely,

Clay Anselmo,
Submission Correspondent
Reglera LLC.

cc: Jim Kasic., Sophono Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

December 20, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Room 2443

Attn: **Vasant K. Dasika, PhD**
Email: Vasant.Dasika@fda.hhs.gov

Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for Additional Information dated September 23, 2010

510(k) Applicant / Manufactured by:
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cc: Jim Kasic., Sophono Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 1: (b)(4) [redacted]

Response 1: Per the FDA request, Sophono has updated its substantially equivalency section of the 510(k) to include the Audiant Bone Conductor (ABC) cleared in K855059 and K861971 as a predicated device to address FDA's concerns regarding the magnetic attachment technology employed by the Alpha 1(M) configuration of the device. This revised section of the 510(k) now contains a complete comparison of the ABC device to the Alpha 1(M) device. As is now shown in the comparison table contained in the SE section, the ABC device has the same intended use as the Alpha 1(M) device, and similar technological characteristics. Specifically, the ABC device employs the same magnetic attachment technology as the Alpha 1(M) device.

Deficiency 2: (b)(4) [redacted]

Response 2:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

Deficiency 3: [redacted]

Response 3: [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

Deficiency 4:

Response 4:

Deficiency 5:

Response 5:

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 6: (b)(4)

Response 6:

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 7:

(b)(4)

[redacted]

Response 7:

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

Deficiency 8:

Response 8:

[redacted]

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

Deficiency 9:

Response 9:

[redacted]

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

(b)(4)

[redacted]

Deficiency 10: Under the section of Risks that may occur during surgery (Page 68 of 192), you state that "These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, post-cholesteatoma, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, disturbance of taste or balance and noticeable changes in head noise." Please address the following concerns regarding these risks.

a) Although most of your described risks are understandable, please clarify how you expect the risk of "post cholesteatoma" and "Disturbance of taste and balance" to occur in the procedure you propose for the implantation of the magnetic implant, without transgressing the middle ear or in the vicinity of the mastoid area.

b) Your list of risks that may occur during surgery does not include some critical risks of dural exposure, CSF leak, perforation of sigmoid sinus, and subdural hematoma. Please include these potential risks to your list of risks during surgical procedure.

Response 10a: Sophono agrees with FDA's comments regarding "post cholesteatoma" and "disturbance of taste and balance". The Alpha 1(M) magnetic implant does not transgress the middle ear nor the vicinity of the mastoid area, the risks of "post cholesteatoma" and "disturbance of taste and balance" are not likely in this application and have been removed from this labeling. Refer to the text below and Appendix 4 for the revised version of the Physician Manual.

Response 10b: Per FDA's request, the risks of dural exposure, CSF leak, perforation of sigmoid sinus and subdural hematoma have been added to the Physician Manual. Refer to the text below and Appendix 4 for the revised version of the Physician Manual.

Risks that may occur during surgery:

The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, dural exposure, CSF leak, perforation of sigmoid sinus, subdural hematoma and noticeable changes in head noise.

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 11: In the Section of Risks that may occur after surgery (Page 68 of 192), you describe that "Potential risks related to the implant following surgery include infection, reparative granuloma and inflammatory reaction. It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant." This list does not include the risk of skin breakdown or skin necrosis. Please add this risk to the list.

Response 11: Per FDA's request, the risks of skin breakdown or skin necrosis have been added to the Physician Manual. Refer to the text below and Appendix 4 for the revised version of the Physician Manual.

Risks that may occur after surgery:

Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma, inflammatory reaction, skin breakdown or skin necrosis.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 12: You do not address several issues that impact on the potential for surgical site infections postoperatively. Please address the following:

a) Your magnets appear to be implanted in a hair-bearing area. Surgeries in hair-bearing areas are at risk for surgical site infections (Mangram et al., 1999). Your Surgeon's manual does not address the removal of hair from the surgical area preoperatively. Please address this concern.

b) You do not advise any skin preparation (topical antimicrobials) prior to making the skin incision. Please address this concern and revise your Surgeon's instructions if indicated.

c) You do not advise any antibiotic prophylaxis for implanted patients. Please discuss whether antibiotic prophylaxis is recommended with your implants and revise the Surgeon's instructions if indicated.

References:

Fairbanks, D. N. F. (2007). Pocket Guide to Antimicrobial Therapy in Otolaryngology-Head and Neck Surgery (13th Ed.) Alexandria, VA: The American Academy of Otolaryngology-Head and Neck Surgery Foundation. Available from http://www.entnet.org/EducationAndResearch/upload/AAO-PGS-9-4-2.pdf

Mangram, A. J., Horan, T. C., Pearson, M. L., Silver, L. C., Jarvis, W. R., & HICPAC. (1999). Guideline for Prevention of Surgical Site Infection, 1999. Atlanta, GA: USDHHS / PHS / CDC / NCID / HIP. Available from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf

Response 12: As requested by FDA in Parts a and b of this deficiency, the Physician Manual has been updated to address the removal of hair from the surgical area preoperatively as well as skin preparation (topical antimicrobials) prior to making the skin incision. The following section has been added to the Physician Manual.

Surgical Site Preparation:

The hair should be clipped and the scalp shaved at the incision site immediately before surgery. With the incision site skin free of gross contamination, apply antiseptic (such as iodophors, alcohol-containing products, or chlorhxidine gluconate) in the area of the proposed incision to an area large enough to allow for the extension of the incision or creation of a new incision or drain sites (if necessary).

Although under typical circumstances antibiotic prophylaxis would not be necessary, per the FDA's request in Part (c) of this deficiency, the Physician Manual has been updated to address antibiotic prophylaxis. The following section has been added to the physician manual.

Pre-Surgical Antibiotic Prophylaxis:

Antibiotic prophylaxis should be considered if the surgeon determines that this surgical procedure may be associated with a considerable risk of infection or if a post operative infection would cause a serious hazard to the patient's recovery or well being.

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 13: Your implant is steam sterilized by the end user facility immediately prior to surgical implantation. You advise that the user facility does not need to clean the implant and you describe a no-touch technique for transferring the implant from your package to the user facility's sterilization pouch. Your Surgeon's instruction manual (p. 11) mentions a container with a screw cap coming from the manufacturer. Please address the following:

a) Please fully describe your primary, secondary and tertiary packaging for the implant as applicable to complete the record and to assist our evaluation of your user instructions.

b) Please provide assurance that your manufacturing process removes both inorganic and organic residues prior to packaging. This information can be briefly summarized in one or two paragraphs.

c) Please state whether your manufacturing process renders the implant to have less than 0.5 EU / ml or < 20 endotoxin units / device per AAMI ST72: 2002 *Bacterial endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing* or USP <85> *Bacterial Endotoxins Test*. Please address the case of bilateral implants.

d) You describe the recommended sterilization pouch for the end user facility by manufacturer and part number. Please expand this description (Surgeon's manual p. 12) to include the materials and size of the pouch to better assure that the validated conditions are replicable by the end user facility.

Response 13a: Per the FDA's request in Part (a) of this deficiency, the following paragraphs briefly describe the primary, and secondary packaging for the implant. There is currently no tiertiary packaging. In addition, the device description has been updated to contain this information. The revised device description is included in Appendix 3 and the packaging specifications can be found in Appendix 9 of this response.

Primary Packaging

The primary packaging for the Alpha 1 (M) Sound Processor Implantable Device is a high density polyethylene (HDPE) tube (P/N S0072) with a screw top lid supplied by the Implant Vendor (Eberle EFS). The lid is covered with a perforated shrink band to provide a tamper- evident seal. This package is opened by the clinician at the time the implant is transferred into the sterilization pouch described in the labeling. The implant label is placed on the primary package. This label contains key symbols, the words "Non-Sterile", the serial number of the implant, quantity, and manufacturer information.

Secondary Packaging

The secondary packaging consists of a small corrugated box (8"x6"x1.5", P/N S0043) into which the primary packaging is inserted along with a copy of the Physician's Manual. The box is sealed with packaging tape and the shipping contents label is applied to the outside of the box. The exterior label on this package appears as follows:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Otomag Alpha 1(M) Bone Conduction Hearing System (Implant)

Manufacturer:
Otomag GmbH Alte Dorfstrasse 67, 32289 Rödinghausen, Germany. Tel: +49 5746 8504 Fax: +49 5746 8578
Distributed by: Sophono, Inc. 3022 Sterling Circle, Suite 100, Boulder, C0 80301 USA. Tel: +1(720) 407 5160 Fax: 1 720 4075168

Contents:
1 **Magnetic Implant**
1 **Physician Manual**

Device Intended for Single Patient Use Only!

Made In Germany

Label P/N S0075-00

Response 13b: (b)(4) [redacted]

Response 13c:

Response 13d: Per the FDA's request in Part (d) of this deficiency, the Physician Manual has been updated to contain additional sterilization pouch information to ensure the validated conditions are replicatable by the end user. The updated Physician Manual is contained in Appendix 4, and the text that was added to address this deficiency is as follows:

Sterilization Pouch Information

To ensure the validated parameters are replicated appropriately, the following is to be used to individually pouch each implant prior to performing the sterilization cycle:

Manufacturer: Cardinal Health, http://www.cardinal.com, 800.964.5227

Sophono 510(k) K102199 – Request for Additional Information

Catalog Number:	92510
Size:	5.5” x 10” Paper Self Seal Pouch
Materials:	Arjowiggins 60g/m^2 Paper / CN PET 12/CPP40 Micron
Total Product Area:	0.035 m^2
Paper Area:	0.035 m^2
Ink:	Medical Grade

⚠	**Caution** ▪ Refer to the original manufacturer’s instructions for use for specific directions on how to appropriately use these sterilization pouches.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 14: You advise that titanium screws must be used to fix your implant to the patient's mastoid bone. Please address the following:

a) Please clarify if you supply the titanium screws or if you recommend the use of screws available from another vendor. If the latter, please detail in your Surgeons' instruction manual the material, length, width and any other important features of the screws that should be used. In addition, you should advise users of the exact screws that have been validated as compatible and optimal, by manufacturer, device name, and part number. Your instructions should make it clear that the screws must be sterile and should either provide sterilization instructions or should refer to the original manufacturer's instructions for sterilization, unless the screws are provided sterile from the manufacturer.

b) Most bone screw / implant systems involve "rescue screws." Please advise users what they should do if the initial attempt to place a screw doesn't work, and what the maximum screw size is that can be used with your device.

Response 14: To address FDA's concern, the information regarding the screws to be used to attach the implant has been supplemented to:

- Fully specify the screws to be used including manufacturer, description, and part number
- Specify that the screws must be sterile and that the physician must follow the manufacturer's instructions related to use and sterilization (if purchased non-sterile)
- Specify an emergency "Rescue" screw to be used in the event of problems with placement of the original screw. This includes information on the maximum screw size that can be used with the implant.

The following additions have been made to the Physician Manual. Please refer to Appendix 4 for a copy of the revised manual. Appendix 14 contains validation protocols and reports related to the screw sizes specified in the revised Physician Manual.

Alpha 1 (M) System: Compatible Screws

	Notes ▪ The Alpha 1 (M) implant requires 5 screws for implantation that are **NOT** included with the implant.

Screws

The Alpha 1 (M) implant requires 5 screws to be used to affix the implant to the skull. These screws are NOT included as part of the Alpha 1 (M) implant system and must be obtained separately.

The implant bracket holes are sized to accept Stryker/Leibinger 1.7 mm diameter Craniomaxillofacial titanium Self Tapping Screws, (Gold) and 1.7 mm diameter Self Drilling Screws (Silver) in 4 mm lengths and 1.9 mm Emergency Screws (Purple) in 3 mm lengths.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Craniomaxillofacial Titanium Screws	***1.7 mm dia. x 4.0 mm Self Tapping***	***1.7 mm dia. x 4.0 mm Self Drilling***	***1.9 mm dia. x 3.0 mm Emergency***
Stryker/Leibinger Part Numbers	*50-17004*	*50-17904*	*50-19003*

While all screw sizes / types specified above have been validated for this application, the Stryker/Leibinger 1.7mm x 4 mm self drilling screws, part number 50-17904 is considered optimal.

Other commercially available craniomaxillofacial titanium screws may be used as long as the screw shaft diameter is less than 2.0 mm and the screw head size is greater than 2.45 mm. Screw must be 4 mm in length (3mm for emergency screws).

The screws must be sterile prior to implantation. If the screws are not purchased sterile, refer to the screw manufacturer's instructions for sterilization.

	Warning ▪ Purchased screws may be provided non-sterile and if so must be sterlized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection.

	Caution ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws.

If the initial attempt to place a screw does not work and the screw hole becomes "stripped" emergency "rescue" screws can be threaded into the stripped hole. The largest size screw that can be used is 1.9 mm in diameter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 15: You advise users (Surgeon's manual, p. 11) that they must follow your sterilization instructions precisely. Please address the following:

a) You state (Surgeon's manual, p. 12) that either pre-vacuum or gravity steam sterilization can be utilized for an exposure time of 15 minutes minimum at 132 degrees C. While this time and temperature are common hospital gravity steam sterilizer parameters, they are uncommon (and unvalidated per your Nelson Labs report) parameters for prevacuum steam sterilization (per AAMI ST79: 2006 and A1: 2008 and A2: 2009 consolidated text, Tables 4 & 5 *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*). Please remove your recommendation for pre-vacuum steam sterilization, or perform and document a pre-vacuum steam sterilization validation for your implant.

b) Your gravity steam sterilization validation study report does not state the chamber size utilized for the study. Please provide assurance that a hospital-sized sterilization chamber was used, and that neither an industrial-sized, nor a table-top sized chamber were used.

Response 15a: Per the FDA's request in Part (a) of this deficiency, the Physician Manual has been updated to remove the recommendation for pre-vacuum steam sterilization. The updated Physician Manual is contained in Appendix 4, and the text that was added to address this deficiency now reads as follows:

- *Limitations on Reprocessing: Single Sterilization Only*
- *Presterilization Decontamination / Cleaning / Disinfection: None Required*
- *Cycle Type: Gravity*
- *Sterilization Time: 15 minutes minimum*
- *Sterilization Cycle Temperature: 132 degrees C / 270 degrees F*
- *Drying Time: 30 minutes minimum*
- *Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)*
- *Storage in Sterile State: Not Allowed – Sterilization immediately pre-implant only*

Response 15b: In response to FDA's request for additional information in Part b. of this deficiency, the sterilization chamber used for the validation study report has been clarified via an amended Steam Sterilization Validation Report contained in Appendix 16. The chamber that was used in the original study was and FDA cleared, hospital sterilization chamber with the following specifications. Our used of the device in the study was consistent with the cleared intended use of the device:

Manufacturer: Steris (Amsco)

Model Number: SV-120

Size: Size 16" x 16" x 26"

510K Number: K030789

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 16: You do not recommend (Surgeon's instruction manual, p. 12) or validate (Attachment D) a drying time for your implanted magnets. Please address the following:

a) In your Surgeon's manual (p.11), in the section where you describe the preparation of the implant for sterilization, you state "Drying of the device is not required." This statement seems to be illogically placed and not relevant to the preparation for sterilization, since none of your recommended preparation steps involve making the implant wet. Please justify or delete this statement.

b) Your Nelson Labs sterilization validation protocol (Attachment D) includes a plan and method for validating drying associated with steam sterilization. However, the sterilization validation study report contains no validation of drying, and therefore it appears that a drying validation was not conducted. We believe that a drying validation study is necessary. Please explain the discrepancy between your protocol and validation study report and justify the lack of a drying validation study. Alternatively, please submit the missing drying validation study.

As communicated in "*Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance*" (available at http://www.fda.gov/cdrh/ode/198.pdf), manufacturers are responsible for including at least one validated, technically feasible sterilization method in their product labeling. Each sterilization instruction should include all critical cycle parameters. We regard drying as a critical cycle parameter, because wet instrument pouches exposed to environmental air and surfaces can become contaminated by microbes on strike through (i.e., wicking). Even though your implant is to be sterilized immediately before the surgery, we believe it must go through the drying part of the steam cycle in order to maintain sterility during preoperative handling.

Response 16a: Per the FDA's request in Part (a) of this deficiency, the Physician Manual has been updated to remove the statement "Drying of the device is not required". Refer to the Response to 15(a) above and Appendix 4 to this response for the revised version of the Physician Manual.

Response 16b: Per the FDA's request in Part (b) of this deficiency, a drying validation study was completed and the results of the study are contained in Appendix 17. The study validated a minimum drying time of 30 minutes to achieve the <3% residual moisture (from AAMI TIR 12, 2004). The sterilization cycle in the Physician Manual has been revised to contain the specifications for drying time as shown in the response to Deficiency 15(a) above.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 17: (b)(4)

[redacted]

Response 17:

[redacted]

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 18: Your sterility validation contractor, Nelson Labs, cites a number of standards and guidance documents that guide their methods. You submit declarations of conformance for just two of these. You should submit a declaration of conformance form (FDA form 3654) for each standard or guidance cited by Nelson labs.

Response 18: Per the FDA's request in this deficiency, the submission has been updated to include declarations of conformance for the standards cited in the Steam Sterilization Validation Report and copies of our revised Declaration of Conformity and additional Forms 3654 are included in Appendix 10. We now additionally claim limited or full compliance with the following additional standards:

- AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI/ANSI ST8:2008, Hospital steam sterilizers
- AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products – Requirements for products labeled "STERILE"
- AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization
- AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (Added from Response 20)
- ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (Added from Response 20)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 19: (b)(4) [redacted]

Response 19: [redacted]

Sophono 510(k) K102199 – Request for Additional Information

Deficiency 20 (b)(4) [redacted]

Response 20: [redacted]

Sophono 510(k) K102199 – Request for Additional Information

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Section 14: Substantial Equivalence Discussion

1. INTRODUCTION

1.1. Section 14 of this Traditional 510(k) identifies the predicate device and provides a detailed comparison between the modified device that forms the subject of this Traditional 510(k) and the predicate devices in order to demonstrate the substantial equivalence of the modified device to the predicates.

2. PREDICATE DEVICE(S)

2.1. The predicate devices for the modified version of the Otomag Bone Conduction Hearing System Alpha 1 (M) are the unmodified version of the Otomag device (Alpha 1 (S) / K100193) and the Audiant Bone Conductor (K855059 and K861971). The device changes presented in this 510(k) are substantially equivalent to the predicate devices in terms of:

- 2.1.1. Intended Use
- 2.1.2. Fundamental Technological Characteristics
  - 2.1.2.1. Device Performance
  - 2.1.2.2. Operating Principles
- 2.1.3. Target User and Patient Populations
- 2.1.4. Use Environment

2.2. The changes to the device that are the subject of this 510(k) relate to the addition of another device configuration to the product family. The additional configuration, called Alpha 1(M), includes a Magnetic Implant that is placed in bone beds behind and above the patient's ear to provide for attachment of the sound processor without the use of the headband or softband. This change impacts detailed engineering specifications and patient contact materials, but does not alter the overall performance of the device. Due to the specificity of the Indications for Use statement for the prior version of the device, minor wording changes are also required.

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

3. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

3.1. The following table summarizes and compares data on the Otomag Bone Conduction Hearing System cleared in K100193 (primary predicate device) and the Audiant Bone Conductor cleared in K855059 / K861971 (secondary predicate device) to the modified Alpha 1 (M) version of the device that is the subject of this 510(k) submission.

3.2. Section 4 following the comparison table discusses each difference between the unmodified version of the Otomag device (primary predicate) and the modified version (new device). The Audiant Bone Conductor device is included as a predicate device, as requested by the FDA, to show that the magnetic attachment method employed by the Alpha 1 (M) version of the Otomag Bone Conduction Hearing device to attach the sound processor has been employed safely and effectively by other bone conduction hearing devices. The Audiant device has the same intended use and utilizes similar technological characteristics as shown in the table below, and is therefore an appropriate secondary predicate device for this submission. Other technological differences between the modified Otomag device and the Audiant device are not relevant to it use in addressing the magnetic attachment method employed by the Alpha 1(M) configuration, and relate to the electromagnetic approach used by the Audiant device to vibrate the implanted magnet. This technology is not employed by the Alpha 1(M) version of the Otomag device.

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	874.3300	Identical to both predicates
Class	Class II	Class II	Class II	Identical to both predicates
Product Code	LXB	LXB	LXB	Identical to both predicates
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	The Audiant Bone Conductor is a device for Conductive Hearing Loss not correctable by conventional reconstructive surgery	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical to Alpha 1(S) Substantially Equivalent to ABC
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Audiant Bone Conductor is a device for Conductive Hearing Loss not correctable by conventional reconstructive surgery The ABC will, in most cases, essentially close the air-bone gap. The patients hearing acuity with the ABC will be limited to the patients sensorineural acuity (cochlear reserve). In most cases, the ABC patient will not attain hearing thresholds less than (better than) the patients pre-op audiometric bone conduction thresholds. A prospecitve patients's performance with the ABC can generally be predicted by the results obtatined with a convetional Bonde Conduction Hearing Aid. Subjective sound qality and compfort may be higher with the ABC, however. Any prospective ABC patient who has not attempted to utilize a convetional B.C. aid should be allowed a trial evaluation of the same and offered the choice of a B.C. aid or the ABC before implantation. In general, the prospective ABC candidate should meet all of the following criteria: • A high level of commitment and complete understanding of the implications of surgical implantation. • Inability or demonstrated unwillingness to utilize a conventionla air or bone conduction hearing aid. A conventional aid should be adequately trialed by	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
		the patient. • A substantial bilateral conductive impairment with adequate sensori-neural acuity. Audiometric bone conduction thresholds in the speech frequencies (500, 1K, 2K) on the implant side should: o Average not more than 25 dB o Contain no individual frequency greater than 40. • Unaided speech reception threshold not less than 40 dB in the impanted ear seech discrimination score of not less than 80%.		

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patient's bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patient's bone rather than via the middle ear - a process known as direct bone conduction.	Identical to both predicates
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an external electronic transducer, a battery, volume controls, and an external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical to Alpha 1(S) Substantially Equivalent to ABC
Transducer	Traditional bone conduction transducer	Inductive coupling of an external magnet and coil to an implanted magnet	Traditional bone conduction transducer	Identical to Alpha 1(S)
Power Supply	Zinc-air battery	AA battery	Zinc-air battery	Identical to Alpha 1(S) Substantially Equivalent to ABC
Sound Processing	Digital	Analog	Digital	Identical to Alpha 1(S)
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Simple volume control	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical to Alpha 1(S)
Frequency Processing Range	125 – 8kHz	336– 12kHz	125 – 8kHz	Identical to Alpha 1(S)
Max Gain (60dB SPL)	38 dB	Unavailable	38 dB	Identical to Alpha 1(S)
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	Unavailable	29 dB	Identical to Alpha 1(S)
Accessories/Options	Direct audio input via FM jack	Telecoil	Direct audio input via FM jack	Identical to Alpha 1(S)

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Patient Contact Materials for Biocompatibility Purposes (external device)	Fotoplast-Lac	Biocompatible plastic	Fotoplast-Lac	Identical to Alpha 1(S) Substantially Equivalent to ABC
Patient Contact Materials for Biocompatibility Purposes (external device)	Titanium Grade 2 and 4	Titanium Grade 5 and Silicone Elastomer	Titanium Grade 2 and 4	Identical to Alpha 1(S) Substantially Equivalent to ABC
Sterilization	Steam sterilization of surgical implant	Provided Sterile	Steam sterilization of surgical implant	Identical to Alpha 1(S) Substantially Equivalent to ABC
Peak Output at 90 dB SPL	115 dB	118 dB	115 dB	Identical to Alpha 1(S) Substantially Equivalent ABC
Frequency range per ANSI S3.22-2009	280-5000 Hz	336– 12kHz	280-5000 Hz	Identical to Alpha 1(S) See Discussion Below
Total harmonic distortion per ANSI S3.22-2009	<3%	3-9%	<3%	Identical to Alpha 1(S) Substantially Equivalent to ABC
Equivalent input noise:	17 dB SPL	Unavailable	17 dB SPL	Identical to Alpha 1(S)

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Battery current drain	0.95 mA	52 mA	0.95 mA	Identical to Alpha 1(S)
Processor:	16 Band, 4 Channel WDRC	Standard OP Amp	16 Band, 4 Channel WDRC	Identical to Alpha 1(S)
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	None	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical to Alpha 1(S)
Compression Attack Time (minimum)	0.25 ms	1 ms	0.25 ms	Identical to Alpha 1(S) See Discussion Below
Compression Release Time (maximum)	8192 ms	350 ms	8192 ms	Identical to Alpha 1(S) See Discussion Below
Patient Volume Control Wheel	38 dB Range	Unavailable	38 dB Range	Identical to Alpha 1(S)
Force Application Methods	Headband or Softband	Magnetic to implanted magnet	Magnetic to implanted magnet (Alpha 1(M) Version)	Identical to ABC
Connection of implant to the skull	Not Applicable	1 Titanium screw	5 Titanium Screws	Substantially Equivalent – see discussion below

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

4. DISCUSSION OF DIFFERENCES

4.1. The differences in specifications identified in the comparison table above between the predicate Otomag Bone Conduction Hearing device, the Audiant Bone Conductor and the modified version of the Otomag device, as reflected in the above SE table are discussed in the following paragraphs. A detailed discussion of each device change is contained in Section 13 – Device Description / Description of Changes.

4.2. The differences in specifications identified in the comparison table above between the predicate devices and the modified Otomag device as reflected in the above SE table are the following.

4.2.1. **Indications for Use:**

4.2.1.1. The changes in the Indications For Use statement simply add the additional Magnetic Implant version of the product to the overall statement including an age limitation for use of the Magnetic Implant configuration (Alpha 1(M)) to patients 5 years of age or older. These changes do not impart a new intended use for the product and do not raise new questions of safety and effectiveness.

4.2.2. **Patient Contact Materials:**

4.2.2.1. The Magnetic Implant contains new patient contacting materials. The implant is made of (b)(4) [redacted] In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible. The implant material for the Alpha1 (M) is biocompatible grade Titanium. See FDA Forms 3654 included for each grade of titanium used in the implant. The implant material for the Audiant is biocompatible grade Titanium and silicone. For this criteria the Alpha1 (M) implant and the Audiant implant can be considered substantially equivalent. The addition of new patient contact materials that are biocompatible does not raise new questions of safety and effectiveness.

4.2.3. **Sterilization:**

4.2.3.1. The Magnetic Implant is provided clean but not sterile and intended to be sterilized via gravity sterilization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The addition of an appropriately specified and validated sterilization cycle does not raise new questions of safety and effectiveness.

4.2.4. **Force Application Method:**

4.2.4.1. The new Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 5 different strength magnetic spacers provided with the product. Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device.

4.2.4.2. The approach of using a magnetic implant to attach the sound processor is employed by the Xomed Audiant Bone Conductor listed as an additional predicate in the table above. The Audiant Bone Conductor cleared in K855059 and K861971 employs the same technology as the Alpha 1(M) configuration for the attachment of the sound processor. See Section 4.3 below for a detailed discussion regarding the Audiant device.

4.2.5. **Connection of implant to the skull**

4.2.5.1. The Audiant implant is held to the skull with one 4 mm length screw whereas the Alpha1 (M) implant is held to the skull with five (5) 4 mm length screws. Validation was performed on screw retention force for the Alpha1 (M) recommended screws and showed that the screw holding strength was significantly more than that generated by the attraction of the external magnetic spacer and that the screws are unlikely to dislodge over the expected lifetime of the product. Therefore the Alpha1 (M) implant and the Audiant implant can be considered substantially equivalent.

4.3. **Audiant Device and Magnetic Attachment Method Detailed Discussion**

4.3.1. As with all bone conduction hearing devices that employ a headband or softband to secure the sound processes to the patient's skull, the Otomag device utilizes a standard (external) bone conduction transducer and conducts sound via vibrations to the skull by vibrating the outside of the skin. In this regard the Alpha 1(M) version of the Otomag device is identical to the previous Alpha 1(S) version. However, the modified Alpha 1(M) version of the devices utilizes an implanted magnet to hold the external processor to the side of the head. The Otomag magnet plays no part in the physical or mechanical workings of the transducer. Similarly, the Audiant device also employs a samarium cobalt magnet implanted under the skin onto the skull. This magnet assembly serves two independent purposes in the Audiant device.

4.3.1.1. The first purpose of the Audiant implant magnet is to provide method of alignment / attachment of the external inductive coil assembly which contains an opposing polarity samarium cobalt magnet. This attachment / alignment methods is identical to that employed by the Alpha 1 (M) configuration of the Otomag device.

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4.3.1.2. The second purpose of the magnet, which is not employed by the Otomag device, (b)(4) [redacted] (b)(4) [redacted] When the inductive field is activated by the sound processor then the implanted magnet is vibrated and this vibration is bone conducted to activate the cochlea and inner ear. The Audiant implanted magnet both plays and active part in the signal transmission and works with the external magnet to hold the coil in place and to compress the skin.

5. CONCLUSION

5.1. The Intended Use of the modified version of Otomag Bone Conduction Hearing System remains the same as the predicate Alpha 1 (S) device (unmodified version) and is substantially equivalent to the Intended Use of the Audiant Bone Conductor Device. Performance data demonstrate that the modified device meet or exceed the applicable requirements.

5.2. The modified version of the Otomag Conduction Hearing System is substantially equivalent to the predicate Otomag device cleared in K100193 and the Audiant cleared K855059 and K861971 and that the differences between the three devices:

5.2.1. Do not raise any new issues of safety and effectiveness

5.2.2. Do not amount to a change in the “fundamental scientific technology” of the device with regard to the Otomag predicate K100193

5.2.3. Do not present any adverse health effect or safety risks to patients when used as intended.

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Section 12: Executive Summary

1. INTRODUCTION

1.1. The following section contains the Executive Summary for the Otomag Bone Conduction Hearing System, including the Alpha 1(M) version. This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

2. DEVICE DESCRIPTION

2.1. The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M).

2.1.1. In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

2.1.2. In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. The pressure applied by the magnetic attraction between the implant and the sound processor is equivalent to that in the Alpha 1 (S) configuration.

2.2. The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

3. INDICATIONS FOR USE

3.1. The Intended Use for the device is identical to the predicate cleared in K100193.

3.2. The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

3.2.1. Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

3.2.2. Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

3.2.3. Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

4. CONTRAINDICATIONS

4.1. Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

4.1.1. A hearing loss of sudden onset;

4.1.2. A rapidly progressing hearing loss;

4.1.3. Pain in either ear;

4.1.4. Tinnitus of sudden recent onset, or unilateral tinnitus;

4.1.5. Unilateral or markedly asymmetrical hearing loss of unknown origin;

4.1.6. Vertigo (e.g. dizziness)

5. SUBSTANTIAL EQUIVALENCE

5.1. The changes to the device that are the subject of this 510(k) relate to the addition of another device configuration to the product family. The additional configuration, called Alpha 1(M) includes a Magnetic Implant that is placed in bone beds behind and above the patient's ear to provide for attachment of the sound processor without the use of the headband or softband. This change impacts detailed engineering specifications, labeling and patient contact materials, but does not alter the overall performance of the device. Due to the specificity of the Indications for Use statement for the prior version of the device, minor wording changes are also required.

5.2. The following table summarizes and compares data on the Otomag Bone Conduction Hearing System cleared in K100193 (primary predicate device) and the Audiant Bone Conductor cleared in K855059 / K861971 (secondary predicate device) to the modified Alpha 1 (M) version of the device that is the subject of this 510(k) submission.

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Classification	874.3300	874.3300	874.3300	Identical to both predicates
Class	Class II	Class II	Class II	Identical to both predicates
Product Code	LXB	LXB	LXB	Identical to both predicates
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	The Audiant Bone Conductor is a device for Conductive Hearing Loss not correctable by conventional reconstructive surgery	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting, and single-sided deafness	Identical to Alpha 1(S) Substantially Equivalent to ABC
Indications for Use	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz). The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.	The Audiant Bone Conductor is a device for Conductive Hearing Loss not correctable by conventional reconstructive surgery The ABC will, in most cases, essentially close the air-bone gap. The patients hearing acuity with the ABC will be limited to the patients sensorineural acuity (cochlear reserve). In most cases, the ABC patient will not attain hearing thresholds less than (better than) the patients pre-op audiometric bone conduction thresholds. A prospecitve patients's performance with the ABC can generally be predicted by the results obtained with a convetional Bonde Conduction Hearing Aid. Subjective sound qality and compfort may be higher with the ABC, however. Any prospective ABC patient who has not attempted to utilize a convetional B.C. aid should be allowed a trial evaluation of the same and offered the choice of a B.C. aid or the ABC before implantation. In general, the prospective ABC candidate should meet all of the following criteria: • A high level of commitment and complete understanding of the implications of surgical implantation. • Inability or demonstrated unwillingness to utilize a conventionla air or bone conduction hearing aid. A conventional aid should be adequately trialed by the patient.	The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).	Substantially Equivalent – See discussion below

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Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
		• A substantial bilateral conductive impairment with adequate sensori-neural acuity. Audiometric bone conduction thresholds in the speech frequencies (500, 1K, 2K) on the implant side should: o Average not more than 25 dB o Contain no individual frequency greater than 40. • Unaided speech reception threshold not less than 40 dB in the impanted ear seech discrimination score of not less than 80%.		

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Design	A sound processor transmits sound vibrations that are conducted through the patients bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patient's bone rather than via the middle ear - a process known as direct bone conduction.	A sound processor transmits sound vibrations that are conducted through the patient's bone rather than via the middle ear - a process known as direct bone conduction.	Identical to both predicates
Sound Processor	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Sound Processor consists of an external electronic transducer, a battery, volume controls, and an external microphone within a plastic housing.	Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone within a plastic housing.	Identical to Alpha 1(S) Substantially Equivalent to ABC
Transducer	Traditional bone conduction transducer	Inductive coupling of an external magnet and coil to an implanted magnet	Traditional bone conduction transducer	Identical to Alpha 1(S)
Power Supply	Zinc-air battery	AA battery	Zinc-air battery	Identical to Alpha 1(S) Substantially Equivalent to ABC
Sound Processing	Digital	Analog	Digital	Identical to Alpha 1(S)
Patient Fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Simple volume control	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Identical to Alpha 1(S)
Frequency Processing Range	125 – 8kHz	336– 12kHz	125 – 8kHz	Identical to Alpha 1(S)
Max Gain (60dB SPL)	38 dB	Unavailable	38 dB	Identical to Alpha 1(S)
Acousto-Mechanical Gain at 60 dB SPL and 1600 Hz	29 dB	Unavailable	29 dB	Identical to Alpha 1(S)
Accessories/Options	Direct audio input via FM jack	Telecoil	Direct audio input via FM jack	Identical to Alpha 1(S)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Patient Contact Materials for Biocompatibility Purposes (external device)	Fotoplast-Lac	Biocompatible plastic	Fotoplast-Lac	Identical to Alpha 1(S) Substantially Equivalent to ABC
Patient Contact Materials for Biocompatibility Purposes (external device)	Titanium Grade 2 and 4	Titanium Grade 5 and Silicone Elastomer	Titanium Grade 2 and 4	Identical to Alpha 1(S) Substantially Equivalent to ABC
Sterilization	Steam sterilization of surgical implant	Provided Sterile	Steam sterilization of surgical implant	Identical to Alpha 1(S) Substantially Equivalent to ABC
Peak Output at 90 dB SPL	115 dB	118 dB	115 dB	Identical to Alpha 1(S) Substantially Equivalent ABC
Frequency range per ANSI S3.22-2009	280-5000 Hz	336– 12kHz	280-5000 Hz	Identical to Alpha 1(S) See Discussion Below
Total harmonic distortion per ANSI S3.22-2009	<3%	3-9%	<3%	Identical to Alpha 1(S) Substantially Equivalent to ABC
Equivalent input noise:	17 dB SPL	Unavailable	17 dB SPL	Identical to Alpha 1(S)

Specification / Characteristic	Original Otomag Bone Conduction Hearing System K100193 (predicate device)	Audiant Bone Conductor (ABC) K861971(predicate device)	Modified Otomag Bone Conduction Hearing System	Comparison
Battery current drain	0.95 mA	52 mA	0.95 mA	Identical to Alpha 1(S)
Processor:	16 Band, 4 Channel WDRC	Standard OP Amp	16 Band, 4 Channel WDRC	Identical to Alpha 1(S)
Crossover Frequency Options	0-1.25, 0.25-2.75, 1.75-7.75 kHz	None	0-1.25, 0.25-2.75, 1.75-7.75 kHz	Identical to Alpha 1(S)
Compression Attack Time (minimum)	0.25 ms	1 ms	0.25 ms	Identical to Alpha 1(S) See Discussion Below
Compression Release Time (maximum)	8192 ms	350 ms	8192 ms	Identical to Alpha 1(S) See Discussion Below
Patient Volume Control Wheel	38 dB Range	Unavailable	38 dB Range	Identical to Alpha 1(S)
Force Application Methods	Headband or Softband	Magnetic to implanted magnet	Magnetic to implanted magnet (Alpha 1(M) Version)	Identical to ABC
Connection of implant to the skull	Not Applicable	1 Titanium screw	5 Titanium Screws	Substantially Equivalent – see discussion below

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6. DISCUSSION OF DIFFERENCES

6.1. The differences in specifications identified in the comparison table above between the predicate Otomag Bone Conduction Hearing device, the Audiant Bone Conductor and the modified version of the Otomag device, as reflected in the above SE table are discussed in the following paragraphs. A detailed discussion of each device change is contained in Section 13 – Device Description / Description of Changes.

6.2. The differences in specifications identified in the comparison table above between the predicate devices and the modified Otomag device as reflected in the above SE table are the following.

6.2.1. **Indications for Use:**

6.2.1.1. The changes in the Indications For Use statement simply add the additional Magnetic Implant version of the product to the overall statement including an age limitation for use of the Magnetic Implant configuration (Alpha 1(M)) to patients 5 years of age or older. These changes do not impart a new intended use for the product and do not raise new questions of safety and effectiveness.

6.2.2. **Patient Contact Materials:**

6.2.2.1. The Magnetic Implant contains new patient contacting materials. The implant is made of (b)(4) [redacted] In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible. The implant material for the Alpha1 (M) is biocompatible grade Titanium. See FDA Forms 3654 included for each grade of titanium used in the implant. The implant material for the Audiant is biocompatible grade Titanium and silicone. For this criteria the Alpha1 (M) implant and the Audiant implant can be considered substantially equivalent. The addition of new patient contact materials that are biocompatible does not raise new questions of safety and effectiveness.

6.2.3. **Sterilization:**

6.2.3.1. The Magnetic Implant is provided clean but not sterile and intended to be sterilized via gravity sterilization at the healthcare facility immediately prior to implantation. The Physician's Manual contains appropriate instructions for sterilization of the implant in accordance with the requirements of ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices. In addition, the specified sterilization cycle is a commonly available cycle and has been validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The addition of an appropriately specified and validated sterilization cycle does not raise new questions of safety and effectiveness.

6.2.4. **Force Application Method:**

6.2.4.1. The new Alpha 1(M) configuration of the device utilizes a magnetic field to apply the necessary force to the patient's mastoid in order to appropriately conduct sound. The force generated by the magnetic field is adjustable through 5 different strength magnetic spacers provided with the product. Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device.

6.2.4.2. The approach of using a magnetic implant to attach the sound processor is employed by the Xomed Audiant Bone Conductor listed as an additional predicate in the table above. The Audiant Bone Conductor cleared in K855059 and K861971 employs the same technology as the Alpha 1(M) configuration for the attachment of the sound processor. See Section 4.3 below for a detailed discussion regarding the Audiant device.

6.2.5. **Connection of implant to the skull**

6.2.5.1. The Audiant implant is held to the skull with one 4 mm length screw whereas the Alpha1 (M) implant is held to the skull with five (5) 4 mm length screws. Validation was performed on screw retention force for the Alpha1 (M) recommended screws and showed that the screw holding strength was significantly more than that generated by the attraction of the external magnetic spacer and that the screws are unlikely to dislodge over the expected lifetime of the product. Therefore the Alpha1 (M) implant and the Audiant implant can be considered substantially equivalent.

7. APPLICATION OF DESIGN CONTROLS

7.1. In accordance with 21 CFR 820.30 all the changes described in this submission were subject to the Design Control Program and Associated Procedures of both Sophono and Otomag. The major elements of the Design Control System applied to these changes included:

7.1.1. Design and Development Planning
7.1.2. Development of Design Outputs
7.1.3. Risk Analysis / Risk Management
7.1.4. Verification and Validation
7.1.5. Design Review
7.1.6. Design Transfer

8. SUMMARY OF PERFORMANCE TESTING

8.1. As a result of the application of risk analysis and the differences identified in the substantial equivalency comparison table, the following verification and validation activities were completed to ensure that the differences between the original predicate device and the modified version of the Otomag Bone Conduction Hearing System do not raise new questions of safety and effectiveness.

8.2. Risk Areas identified as a result of risk analysis included:

8.2.1. Material Biocompatibility
8.2.2. Implant Anchoring
8.2.3. Force Application to patient skin / mastoid

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8.2.4. Sealing of Magnetic Implant

8.3. The following section outlines the categories of Verification and Validation testing that were conducted and rationale for those areas where additional testing was unnecessary as a result of the scope of changes.

8.4. **Performance Testing:**

8.4.1. **Implant Anchoring:** Implant anchoring using titanium bone screws (Leibinger 4mm facial plating screws) were validated for this use in validation protocols (b)(4) [redacted] contained in Appendix C to this overall submission.

8.4.2. **Force Application:** Validation was performed to show that the range of forces that can be generated using the variety of magnetic spacers meets specifications derived from national and international standards and is substantially equivalent to the forces generated by the softband and headband versions of the device. This testing is documented in validation documents (b)(4) [redacted] contained in Appendix C to this overall submission.

8.4.3. **Sealing of Magnetic Implant:** (b)(4) [redacted]

8.4.4. **Sound Processor:** The sound processor itself was not modified and therefore additional performance testing of this part of the device was not necessary

8.4.5. **Vibration Transmission:** The method, mechanics, and materials used to transmit vibration from the sound processor to the patient are unchanged in the Alpha 1(M) configuration. The metal disc and magnetic spacers used in the Alpha 1(M) configuration are identical in material and vibration application method to the Fotoplast encased magnets used in Alpha 1(S) configuration of the device (headband and softband versions). Frequency response testing was completed for all configurations and is document in (b)(4) [redacted] contained in Appendix C to this overall submission.

8.4.6. **Magnet Anchoring:** Anchoring of the magnet within the titanium case for the implant was evaluated after cyclic magnetic loading of the implant assembly to simulate over 100 years of typical use. The results of the testing showed no loosening of the magnets within the implant casing. This testing is documented in DG-42 contained in Appendix C to this overall submission.

8.5. **Sterilization Validation including Sterile Packaging:**

8.5.1. The sterilization process specified in the Physician's Manual was validated in accordance with ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices. The validation was performed by Nelson Laboratories and the protocol and final report documenting this validation is contained in Appendix D to this overall submission. In addition, the Physician's Manual contains the information required by ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

8.6. **Contamination Testing of Non-Sterile Implant Assembly:**

8.6.1. Validation testing was performed to demonstrate that the finished magnetic implant assembly is not contaminated in any way that could affect its safety and efficacy. The validation test results included in Appendices B and C, demonstrate that contamination due to the manufacturing processes and handling is being adequately removed by final cleaning processes. Testing was performed on finished, packaged implants. The testing focused on microbial contamination, particulate contamination, endotoxins, and other process contaminants as listed below:

8.6.1.1. Bio burden Level per DIN ISO 11737-1

8.6.1.2. Particulate Contamination Level per ISO 8536-4

8.6.1.3. Endotoxin/LAL per ANSI/AAMI ST72:2002 and the FDA Guidance documents describing LAL Testing.

8.6.1.4. Cytotoxicity Testing per ISO 10993-5

8.7. **Biocompatibility Testing:**

8.7.1. In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible.

8.8. **Software:**

8.8.1. No changes were made to either the embedded software in the sound processor or the fitting software associated with the device; therefore no software testing is associated with this modification to the device.

8.9. **Electrical Safety Testing:**

8.9.1. The changes made to the modified version of the device have no effect/impact on electrical safety, and therefore no additional electrical safety testing was required.

8.10. **EMC Testing:**

8.10.1. The changes made to the modified version of the device have no effect/impact on EMC performance, and therefore no additional EMC testing was required.

8.11. **Animal / Clinical Testing**

8.11.1. Animal and Clinical studies were not deemed necessary to validate the changes in the Alpha 1(M) version of the device.

9. CONCLUSION

9.1. The Intended Use of the modified version of Otomag Bone Conduction Hearing System remains the same as the predicate Alpha 1 (S) device (unmodified version) and is substantially equivalent to the Intended Use of the Audiant Bone Conductor Device. Performance data demonstrate that the modified device meet or exceed the applicable requirements.

9.2. The modified version of the Otomag Conduction Hearing System is substantially equivalent to the predicate Otomag device cleared in K100193 and the Audiant cleared K855059 and K861971 and that the differences between the three devices:

9.2.1. Do not raise any new issues of safety and effectiveness

9.2.2. Do not amount to a change in the “fundamental scientific technology” of the device with regard to the Otomag predicate K100193

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9.2.3. Do not present any adverse health effect or safety risks to patients when used as intended.

Section 13: Device Description / Description of Changes

1. General Introduction

1.1. The following section contains both a detailed description of the device in its various configurations as well as a detailed description of the planned changes to the device which are the subject of this 510(k).

1.1.1. The changes described in section 9 below introduce a new configuration into the Otomag Bone Conduction Hearing System family. The new configuration (Alpha 1(M)) uses an implantable magnet encased in titanium as a retention system for the sound processor instead of a headband or softband as was used in the prior version of the device cleared under K100193.

1.1.2. The addition of the Alpha 1(M) configuration of the product requires no change in intended use of the device, but does require minor wording changes to the Indications for Use statement. In addition, this new configuration introduces new material, performance and design specifications to the product as well as revisions to product labeling. No changes to software or to the sound processor are being made as a part of introducing this additional configuration.

1.2. The content of the Device Description sections below (sections 2-8) are intended to fulfill the device description requirements from 21 CFR 807.87. Section 9 is intended to describe in detail each planned device change.

2. Device Introduction

2.1. The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and the Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

2.1.1. In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

2.1.2. In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. Vibration is not primarily transmitted through the magnetic implant.

2.2. The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

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3. Indications For Use:

3.1. The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

3.1.1. Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

3.1.2. Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.

3.1.3. Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

4. Classifying Regulation and Product Code

4.1. Regulation Number: 21 CFR 874.3300

4.2. Product Code: LXB

5. Detailed Device Description

5.1. Device and Company Nomenclature

5.1.1. The Otomag Alpha 1 Sound Processor may also be called the Alpha 1 Sound Processor, the Sound Processor, or Alpha 1. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.2. The Otomag Alpha 1(S) Configuration may also be called the Alpha 1(S) or 1(S) configuration. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.3. The Otomag Alpha 1(M) Configuration may also be called the Alpha 1(M) or 1(M) configuration. These terms are used synonymously throughout this document, any accompanying attachments, and product labeling.

5.1.4. Sophono, Inc (b)(4) [redacted]
(b)(4) [redacted]

5.2. Description of the Alpha 1(S) Configuration

5.2.1. In the Alpha 1(S) configuration, the Sound Processor can be used with a

headband or softband. Both the headband and softband are equipped with magnets encapsulated by Fotoplast (plastic) materials.

5.2.2. For this configuration, a metal disc is screwed into the Alpha 1 Sound Processor (Figure 3). The magnets on the headband or softband magnetize to the Alpha 1 Sound Processor metal disc (Figure 1, Boxes B, D, E).

5.2.3. The softband holds the Alpha 1 to the side of the head by adjusting its elastic band and securing the fit with a Velcro closure (Figure 1, Boxes A-D). The headband holds the Alpha 1 to the side of the head by means of a springy metal bow (Figure 1, Boxes E & F). The figure shows the headband and softband with and without the Alpha 1 Sound Processor attached via the magnets.

Figure 1: Alpha 1(S) Configuration / Headband, Softband, and Sound Processor

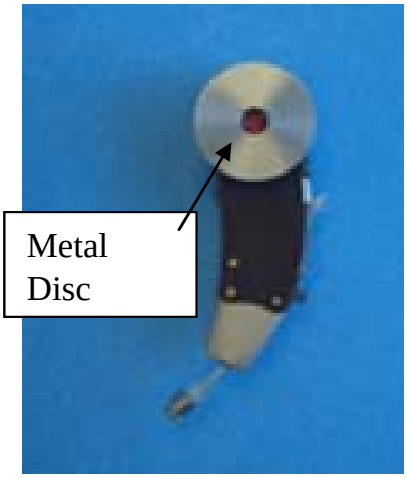

Figure 2: Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment to Headband / Softband

5.3. Description of the Alpha 1 (M) Configuration (Addition to Product Family)

5.3.1. In the Alpha 1(M) configuration, the Alpha 1 Sound Processor is used with an Otomag Magnetic Implant (similar to cochlear implant magnets) and a plastic magnetic spacer. The plastic magnetic spacers are equipped with magnets encapsulated by Fotoplast (plastic) materials. Figure 3 below shows the details of the configuration.

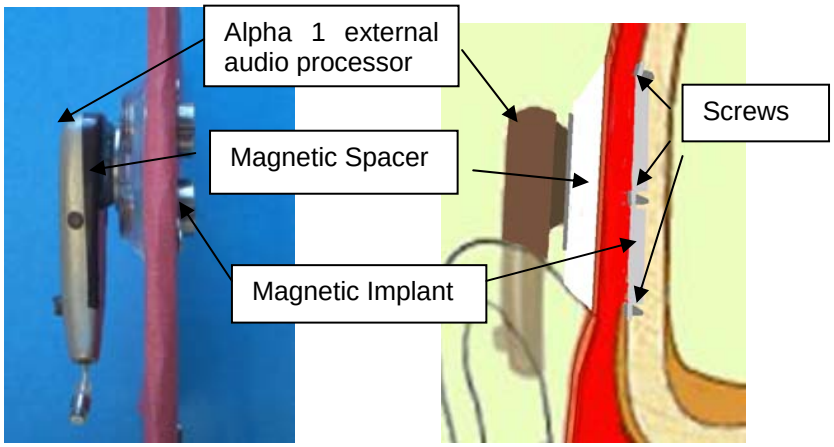

Figure 3: Alpha 1 (M) Magnetic Implant System

5.3.2. For this configuration, the same metal disc used in the Alpha 1(S) configuration is used to attach the sound processor to plastic magnetic spacer. The magnets within the plastic magnetic spacer are then additionally used to secure the external assembly (sound processor and spacer) to the magnetic implant across the patient's skin.

5.3.3. To ensure that appropriate pressure is applied between the sound processor and the patient's skin / bone, various strengths of magnetic spacers are available (5 sizes - labeled 1 dot to 5 dot).

5.3.4. The magnetic implant is screwed to the skull with Stryker self-tapping titanium facial plating screws. The implant consists of two magnets (similar to cochlear implant magnets) hermetically sealed in a titanium case that are recessed into bone beds at the surgical implant site. See the Physician's Manual in Section 15 of the overall submission for detailed implantation instructions.

5.4. Description of the Otomag Alpha 1 Sound Processor

5.4.1. A key component of the Otomag System is the Alpha 1 Sound Processor, which is similar to a behind the ear air conduction hearing with a traditional bone conduction vibrator. The Alpha 1 Sound Processor utilizes proprietary software. The Alpha 1 Sound Processor is available for left or right sides with or without an external microphone, and with or without an FM jack.

5.4.2. The Alpha 1 Sound Processor consists of an internal electronic transducer, a battery, volume and programming controls, and an internal or external microphone (Figure 4) within a plastic housing. The microphone opening is situated in the bottom of the housing and the vibrator in the upper part of the housing. The volume control with integrated switch and the battery compartment

are accessible to the patient on the housing. The programming socket is situated beneath a cover. The programming socket is used for initial programming of the hearing device, as well as when adjustments are needed. No part of the sound processor has prolonged user contact.

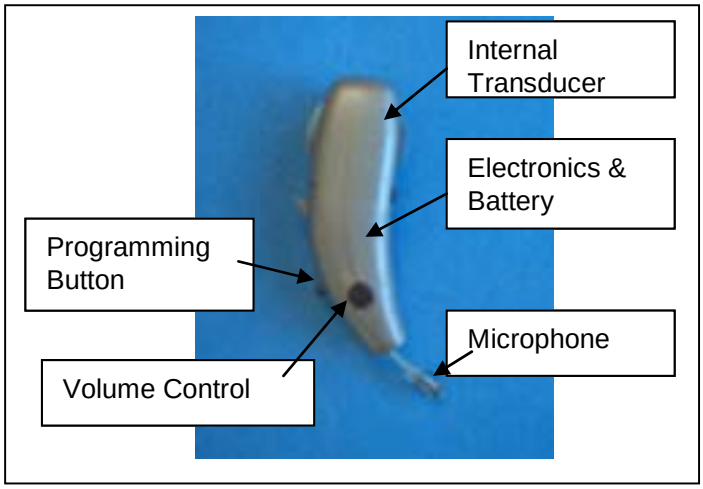

Figure 4: Alpha 1 Sound Processor

5.4.3. Sound Processor Circuit Description

5.4.3.1. (b)(4) [redacted]

5.4.3.2. As an alternative to sound reception with the microphone, an electromagnetic signal can also be received by means of an FM link on those Alpha 1 Sound Processors that have an FM jack. The jack is compatible with the Phonak MLxi FM receiver boot.

5.4.3.3. The housing and transducer are the same as is used in the Starkey Laboratories Viennatone bone conduction sound processor.

5.4.4. Gravity 2 Software Description

5.4.4.1. (b)(4) [redacted]

(b)(4) [redacted] designed as an open platform hearing

processor programming software. (b)(4) [redacted]

(b)(4) [redacted]

5.4.4.2. (b)(4) [redacted]

5.4.4.3. [redacted]

(b)(4) [redacted]

5.5. Magnetic Implant

5.5.1. The implant consists of two (b)(4) [redacted] magnets hermetically sealed in a titanium housing as shown in Figure 5. The implant is manufactured for (b)(4) [redacted] documentation associated with the implant's performance as a retention mechanism for the sound processor can be seen in Appendix C to the overall submission. Biocompatibility information, including material specifications for the implant can be found in Appendix B to the overall submission. Each implant is welded, cleaned, and 100% leak tested by the manufacturer using formally validated processes.

5.5.2. The magnetic implant is placed in 3 mm deep bone beds as shown in Figure 6 and Figure 7. The implant is secured using 4 mm titanium facial plating screws.

Figure 5: Magnetic Implant

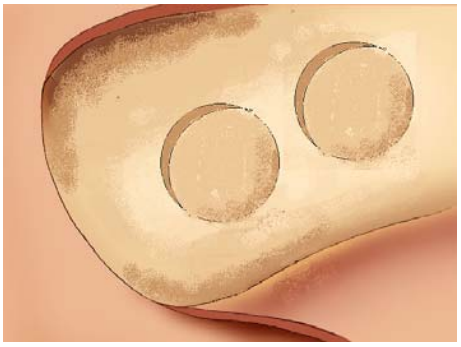

Figure 6: Bone Beds

5.5.3. The magnetic implant is supplied to the physician clean but non-sterile, in sealed packaging to prevent contamination. The device is intended to be steam sterilized at the healthcare facility prior to implantation. Instructions and requirements for performing steam sterlization are included in the Physician's Manual contained in Section 15 to the overall submission.

(b)(4)

[redacted]

Figure 7: Implant Secured into Bone Beds

5.6. Magnetic Spacer

5.6.1. The spacer consists of a nickel plated neodymium iron boron magnet encapsulated in 100% Fotoplast S IO. (b)(4) [redacted] (b)(4) [redacted] Both plastic materials are those commonly used for the production of custom ear molds. Complete material specifications can be found in Appendix B to the overall submission. Five magnetic strengths of the spacer are available to accommodate for variations in skin thicknesses and holding requirements to obtain approximately (b)(4) [redacted] of holding force.

Figure 8: Magnetic Spacer

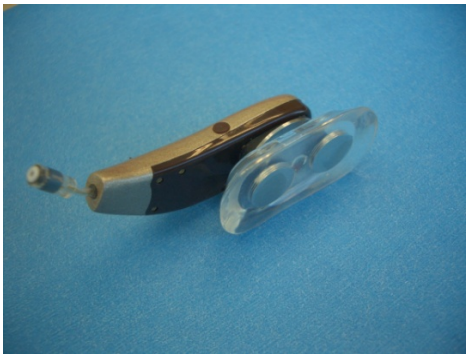

Figure 9: Sound Processor Attached to Magnetic Spacer

5.6.2. As specified in the Physician Manual, the Alpha 1(M) is supplied with two fitting gages. These gages, labeled “Go” and “No-Go” are used in conjunction with a fitting test which is intended to identify the appropriate range of magnetic spacers that ensure proper function, patient comfort, and device performance.

5.6.2.1. The fitting test incorporates the use of two different weights that attached to the magnetic spacer. The smaller weight applies approximately (b)(4) weight to the magnetic spacer and is intended to ensure a minimum attachment force between the implant and the magnetic spacer is achieved. This smaller weight is referred to and labelled as the "Go" gage. The larger weight applies approximately (b)(4) of weight to the magnetic spacer and is intended to ensure that too much force is not applied to the skin between the implant and the spacer. This larger weight is referred to and labelled as the "No-Go" gage. The mass of these weights, through experimentation, was chosen in order to achieve a range of retention forces in the normal direction of (b)(4). This provides the fitting physician with a range of normal forces to allow the physician to balance performance and patient comfort.

5.7. Retention Clip / Lanyard

5.7.1. Sophono offers an optional clip / lanyard that attaches to the sound processor assembly and to the user's clothing. The intention of this optional accessory is to prevent damage to the sound processor assembly should it become dislodged from the user.

5.8. Magnetic Implant Packaging

5.8.1. Primary Packaging: The primary packaging for the Alpha 1 (M) Sound Processor Implantable Device is a high density polyethylene (HDPE) tube (b)(4) with a screw top lid supplied by the Implant Vendor (b)(4) The lid is covered with a perforated shrink band to provide a tamper- evident seal. This package is opened by the clinician at the time the implant is transferred into the sterilization pouch described in the labeling. The implant label is placed on the primary package. This label contains key symbols, the words "Non-Sterile", the serial number of the implant, quantity, and manufacturer information.

5.8.2. Secondary Packaging: The secondary packaging consists of a small corrugated box (8"x6"x1.5", P/N S0043) into which the primary packaging is inserted along with a copy of the Physician's Manual. The box is sealed with packaging tape and the shipping contents label is applied to the outside of the box.

5.9. Healthcare Facility Sterilization

5.9.1. As described above, the magnetic implant is intended to be sterilized at the healthcare facility just prior to implantation. The implant is transferred from the primary packaging described in 5.8.1 to a specified sterilization pouch and sterilized using the following specifications. The Physician Manual contains detailed instructions for the sterilization process

5.9.1.1. Limitations on Reprocessing: Single Sterilization Only

5.9.1.2. Presterilization Decontamination / Cleaning / Disinfection: None Required

5.9.1.3. Cycle Type: Gravity

5.9.1.4. Sterilization Time: 15 minutes minimum

5.9.1.5. Sterilization Cycle Temperature: 132 degrees C / 270 degrees F

5.9.1.6. Drying Time: 30 minutes minimum

5.9.1.7. Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)

5.9.1.8. Storage in Sterile State: Not Allowed – Sterilization immediately pre-implant only

6. Patient-Contacting Components and Materials

6.1. The components of the Otomag System that are patient contacting are the Fotoplast components on the headband / softband, the Fotoplast Magnetic Spacer, and the titanium magnetic implant. All materials used in the Alpha 1 device are materials commonly used in medical devices in the same applications (external tissue contact, implant). Biocompatibility information for these materials is contained in Section 17 and Appendix B of the overall submission. Each Magnetic Implant is cleaned to remove any manufacturing process contaminants.

6.2. Fotoplast-Lac and Fotoplast S IO

6.2.1. The Fotoplast S IO is the material that directly encapsulates the magnets in the softband and headband. The Fotoplast-Lacquer 3 is a light-curing one-component lacquer used to coat the Fotoplast S IO encapsulated magnets. This Fotoplast-Lacquer 3 material is in direct skin contact with healthy skin behind the ear, at the site of bone conduction. Both materials have been found biocompatible for their intended use. These materials are commonly used to fabricate hearing aid earmolds and thus have years of use in the ear canal without biocompatibility problems.

6.3. Titanium

6.3.1. In accordance with the flowchart in FDA General Program Memorandum #G95-1, Appendix C, the titanium material used in the implant and associated anchoring screws is not a polymer, is a metal alloy, and does not contain toxic substances, therefore biocompatibility requirements for the material are met. The titanium material used in the magnetic implant is well established as biocompatible and is used in many medical implant applications.

6.3.1.1. Implant Case: (b)(4) [redacted] (b)(4) [redacted]

6.3.1.2. Implant Base: (b)(4) [redacted] (b)(4) [redacted]

6.3.2. The bone screws used to anchor the magnetic implant are also titanium. These screws are manufactured by Stryker Leibinger and are a legally marketed device which was cleared under K970912 for use as self threading bone screw.

6.3.2.1. Screws (according to Stryker IFU): CP Titanium (commercially pure) or Ti 6 Al V 4 – Complies with ASTM F67-06 (for CP Ti) and ASTM F136-08e1 (for Ti 6 Al V 4)

7. Kit Configurations

7.1. The Otomag System will be available in two kit configurations (e.g., Alpha 1 (S) with appropriate means of attachment, Alpha 1 (M) with appropriate magnetic spacers) or the components may be ordered separately. Each kit or component will be labeled appropriately and will include the Patient User Manual and / or the Physician Instructions for Use as appropriate.

7.2. Each Alpha 1 Sound Processor will be available in right or left sided versions, with either an internal or external microphone, and with or without an FM jack. Alpha 1 Sound Processor configurations are show in Table 3.

Table 3		
Sound Processor Configurations		
Right sided	Internal Microphone	With FM Jack
	External Microphone	
Left sided	Internal Microphone	
	External Microphone	
Right sided	Internal Microphone	Without FM Jack
	External Microphone	
Left sided	Internal Microphone	
	External Microphone	

7.3. An example of a component that is likely to be sold separately is an Alpha 1 (S) Sound Processor. Because it will not be known if the patient prefers a softband or headband, the Alpha 1 (S) will likely be shipped separately from the softband or headband.

7.4. Sophono, Inc. will also distribute to qualified hearing healthcare providers the Otomag Gravity 2 Fitting Software.

8. Specifications and Characteristics

8.1. Device Technical Specifications

8.1.1. Alpha 1 Sound Processor Specifications

8.1.1.1. Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB

8.1.1.2. Maximum Gain at 60 dB SPL: 38 dB

8.1.1.3. Peak Output at 90 dB SPL: 115 dB

8.1.1.4. Frequency range per ANSI S3.22-2009: 280-5000 Hz

8.1.1.5. Frequency processing range: 125-8000 Hz

8.1.1.6. Total harmonic distortion per ANSI S3.22-2009: <3%

8.1.1.7. Equivalent input noise: 17 dB

8.1.1.8. Battery current drain: 0.95 mA

8.1.1.9. Processor: 16 Band, 4 Channel WDRC

8.1.1.10. Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz

8.1.1.11. Compression Attack Time: 0.25 ms

8.1.1.12. Compression Release Time: 8192 ms

8.1.1.13. Patient Volume Control Wheel: 38 dB range

8.1.1.14. Power Supply: 1.3 V, #675 Zinc Air Battery

8.1.2. Magnetic Spacer Specifications

(b)(4)

[redacted]

8.1.3. Magnetic Implant Specifications

(b)(4)

[redacted]

9. Description of Changes

9.1. The following section contains a summarized description of the changes to the device that include Indications for Use, additional hardware, and labeling. It should be noted that the changes described below do not constitute a change in intended use of the device, or the fundamental scientific principles of the device.

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C1	**Indications for Use**	Minor wording change in the Indications for Use statement to add the term "..or magnetic implant" to the end of the first paragraph. The new paragraph now reads: "The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband, Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:…" In addition, the following paragraph was removed because it was redundant with the first paragraph: "The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband."	None: Changes in Indications for Use statement are minor and do not result in a new Intended Use for the device. Specific impacts of design changes associated with this Indications for Use change are analyzed in each additional line item in this table.	None

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C2	**Force Application Method**	Addition of the magnetic spacer in 5 strengths, to be used in conjunction with the magnetic implant, to mimic the pressure applied by the softband or headband. Spacers are chosen by the fitting physician, based on tissue thickness, to ensure an application force of between approximately 1 and 2.5 N. Material of the magnetic spacer is identical to the skin contact materials present in the headband and the softband (Fotoplast Lacquer 3). Part of the function of the magnetic spacer is identical to the prior version of the device which utilized a magnetic field to hold the sound processor to the headband or softband. In addition to holding the Sound Processor, the magnetic spacer additionally holds the Sound Processor assembly (Sound Processor and magnetic spacer) to the patient's skin through the creation of an attractive magnetic field.	None: • Patient Contact materials for this component are identical to the prior version of the device • The switch from pressure application via the headband or softband to an attractive magnetic field does not impact risk assessment as long as forces are equivalent	• Otomag Softband, Headband, and Magnetic Implant Static Force Verification / Validation Protocol, DG-35 • Headband and Softband Static Force Test Protocol and Report, DG-38 • Implant Magnetic Coupling Static Force Test Protocol, DG-39 • Implant Magnetic Coupling Tangential Static Force Test Protocol and Report, DG-41 Validations showed magnetic attachment mechanism via magnetic implant is equivalent to headband / softband versions of the device.

Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C3	**Force Application Method / Patient Contact Materials**	Addition of the magnetic implant, to be used in conjunction with the magnetic spacer, to mimic the pressure applied by the softband or headband. Patient contact material of the magnetic implant is Titanium. Magnets are hermetically sealed within the titanium case. The magnet is of similar design and the same construction methods as is used in currently available cochlear implants. Screws used to anchor the implant in the bone beds are included with the device and are 4 mm titanium bone screws manufactured by Stryker Leibinger and cleared under K970912.	The addition of the implanted magnet raises the following new risks not present in the prior version of the device • Biocompatibility related the implant As discussed immediately above, the switch from pressure application via the headband or softband to an attractive magnetic field does not impact risk assessment as long as forces are equivalent	• See Appendix B for Biocompatibility information for the magnetic implant • See Appendix C for microbial, endotoxin and particulate test results • Otomag Magnetic Implant Screw Retention Force Validation Protocol, DG-36: Showed the retention force of the 5 retention screws far exceeds the forces applied to the implant during operation. • Screw Retention Force after 100yr Cyclic Loading Protocol and Report, DG-43: Showed screw retention maintained after cyclic loading • Implant Screw Retention Force after Vibration Exposure Protocol and Report, DG-45: Showed screw retention maintained after severe vibration exposure.

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Change Number	Affected Area	Description of Change	Impact of Change on Risk Analysis	Additional Required Mitigation
C4	**Labeling**	Primary Device Labeling has been modified to include clear identification of which configuration of the device is included (Alpha 1(S) or Alpha 1(M)) Physician's Manual has been revised to include implant and explant instructions, magnetic spacer fitting instructions, and additional Warnings / Cautions related to the magnetic implant. Users Manual has been revised to include additional user instructions for placement of the Sound Processor with the magnetic implant, and additional Warnings / Cautions related to the magnetic implant. A label has been developed for the magnetic implant packaging to correctly identify this portion of the device.	None: Additional instructions are intended to ensure safe, effective use of the device. New Warnings and Cautions are included as a result of detailed risk analysis. The labeling changes themselves only serve to lower overall risk associated with the device	None

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Physician Manual

Alpha I (S) & Alpha I (M)
Bone Conduction Hearing Systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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1 About this Manual

This Physician Manual provides a description of the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. This manual provides the information necessary for the physician to prescribe the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems to the appropriate patient population. Please read this manual thoroughly before prescribing the system.
A Patient Instruction Manual is included with each **Alpha I (S)** & **Alpha I (M)** Bone Conduction Hearing System and should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

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2 Introduction

Warnings and Cautions Overview

The following section contains a description of all physician related Warnings and Cautions associated with the Otomag Bone Conduction Hearing Systems. Additional patient and use related Warnings and Cautions can be found in the Patient User Manual. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to physician instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warnings

Warning	▪ Thoroughly read the Physician Manual and the Patient Manual before prescribing the Otomag System. ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection. ▪ Purchased screws may be provided non-sterile and if so must be sterlized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection. ▪ Excessive, long term use of magentic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test. ▪ Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this warning may result in prolonged healing, further irritation, or infection.

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Precautions

Caution	▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual. ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws. ▪ Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches. ▪ The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or pain, numbness, or tingling occurs.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product Description

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag System is configured in either of two configurations. The first configuration is the Alpha 1 (S), where the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), where the Otomag Sound Processor is attached magnetically to an implanted magnet. The Headband, Softband, or Magnetic Implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patient Selection Criteria

- Patients to be fitted with the Otomag Alpha 1 (S) Sound Processor and its Headband or Softband may be any age.
- Patients to be fitted with the Otomag Alpha 1 (M) Sound Processor and its Magnetic Implant should be 5 years old or older.
- Patients and/or patient guardians must be able to understand that the Otomag System will not restore hearing to normal and will not prevent additional hearing

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impairment resulting from conditions such as disease, old age hearing loss, genetic hearing loss, ototoxic drugs or noise induced hearing loss.

Possible Adverse Effects

General

It is possible that a reaction to the materials of the Headband, Softband, or Magnetic Implant could occur. Such a circumstance may necessitate that use of the device be discontinued. Please report any adverse effects to Sophono, Inc. The address and phone number for Sophono, Inc. are listed at beginning and end of this Physician Manual. If a reaction to the Headband or Softband occurs, Sophono will supply appropriate instructions so that the device can be sent to the laboratory for analysis.

Risks that may occur during surgery:

The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, dural exposure, CSF leak, perforation of sigmoid sinus, subdural hematoma and noticeable changes in head noise.

	Warning ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System.

Risks that may occur after surgery:

Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma, inflammatory reaction, skin breakdown or skin necrosis.

It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant.

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⚠	**Warning** ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform MRI on a patient wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.

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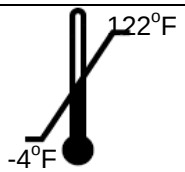
Other Symbols on Equipment and Labeling

Symbol	Description
	Consult Physician Manual
	Batch Code or Lot Number
	Serial Number
	Keep Away From Rain / Keep Dry
	Manufacturer
	MR Unsafe: Device should not be worn when patient is undergoing an MRI
	Product is Latex Free
	Interference may occur in the area of equipment which is labeled with the following symbol.
	Temperature Limitation: The sound processor is designed to operate within the temperature ranges of 41oF (+5oC) to 104oF (+40oC). The processor should not be subject to temperatures below -4oF (-20oC) or above 122oF (+50oC) at any time.

3 Patient Fitting Procedures

Alpha 1 (S) System: Instructions for Placement of the Softband or Headband and Alpha 1 Sound Processor

	Notes ▪ Record the product and lot or serial numbers for the Alpha 1 Sound Processor in the patient file and send the patient to a qualified audiologist for proper programming of the Alpha 1 Sound Processor.

The Otomag Softband is an elastic Softband similar to a sweat band used in sports. The Alpha 1 (S) Sound Processor magnetically adheres to the Softband via a magnetic pad sewn into the band. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by an audiologist.

- To use the Otomag Softband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Softband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Softband around the patient's head, quite loosely at first by slipping the end of the band through the slot next to the magnetic pad and attaching the mating Velcro ® loops and hooks to each other.
- Place the magnetic pad against the mastoid or other boney location.
- Tighten the Softband by adjusting the Velcro® strap until it is close-fitting enough to ensure effective sound transmission, but not tight enough to cause discomfort. The Softband is too loose if it slips off of the head, can be rotated easily around the head or no sound transmission can be heard. The Softband is too tight if the patient complains of pain or discomfort while wearing the Softband. Make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

	Warning ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

The Otomag Headband is a springy Headband, similar to that used for earphone devices. It comes in one size and is not adjustable. The Alpha 1 (S) Sounds Processor magnetically adheres to the Headband via a magnetic pad fitted to the Headband. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by the audiologist.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- To use the Otomag Headband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Headband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Headband on the patient's head and place the magnetic pad against the mastoid or other boney location.

The choice of a Headband or Softband is a matter of patient preference.

Alpha 1 (M) System: Compatible Screws

	Notes ▪ The Alpha 1 (M) implant requires 5 screws for implantation that are **NOT** included with the implant.

Screws

The Alpha 1 (M) implant requires 5 screws to be used to affix the implant to the skull. These screws are NOT included as part of the Alpha 1 (M) implant system and must be obtained separately.

The implant bracket holes are sized to accept Stryker/Leibinger 1.7 mm diameter Craniomaxillofacial titanium Self Tapping Screws, (Gold) and 1.7 mm diameter Self Drilling Screws (Silver) in 4 mm lengths and 1.9 mm Emergency Screws (Purple) in 3 mm lengths.

Craniomaxillofacial Titanium Screws	***1.7 mm dia. x 4.0 mm Self Tapping***	***1.7 mm dia. x 4.0 mm Self Drilling***	***1.9 mm dia. x 3.0 mm Emergency***
Stryker/Leibinger Part Numbers	*50-17004*	*50-17904*	*50-19004*

While all screw sizes / types specified above have been validated for this application, the Stryker/Leibinger 1.7mm x 4 mm self drilling screws, part number 50-17904 is considered optimal.

Other commercially available craniomaxillofacial titanium screws may be used as long as the screw shaft diameter is less than 2.0 mm and the screw head size is greater than 2.45 mm. Screw must be 4 mm in length (3mm for emergency screws).

The screws must be sterile prior to implantation. If the screws are not purchased sterile, refer to the screw manufacturer's instructions for sterilization.

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	Warning ▪ Purchased screws may be provided non-sterile and if so must be sterlized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection.

	Caution ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws.

If the initial attempt to place a screw does not work and the screw hole becomes "stripped" emergency "rescue" screws can be threaded into the stripped hole. The largest size screw that can be used is 1.9 mm in diameter.

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Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

	Warning ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriate can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Immediately seal the autoclave pouch.

	Caution ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be sterilized a single time by gravity steam sterilization (autoclaving). The following sterilization parameters have been validated for sterilization of the implant.

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Limitations on Reprocessing: Single Sterilization Only

Presterilization Decontamination / Cleaning / Disinfection: None Required

Cycle Type: Gravity

Sterilization Time: 15 minutes minimum

Sterilization Cycle Temperature: 132 degrees C / 270 degrees F

Drying Time: 30 minutes minimum

Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)

Storage in Sterile State: Not Allowed – Sterilization immediately pre-implant only

Sterilization Pouch Specifications

To ensure the validated parameters are replicated appropriately, the following is to be used to individually pouch each implant prior to performing the sterilization cycle:

Manufacturer: Cardinal Health, http://www.cardinal.com, 800.964.5227

Catalog Number: 92510

Size: 5.5” x 10” Paper Self Seal Pouch

Materials: Arjowiggins 60g/m^2 Paper / CN PET 12/CPP40 Micron

Total Product Area: 0.035 m^2

Paper Area: 0.035 m^2

Ink: Medical Grade

⚠	**Caution** ▪ Refer to the original manufacturer’s instructions for use for specific directions on how to appropriately use these sterilization pouches.

Pre-Surgical Training Requirements

Before attempting to implant the Otomag Implant, surgeons are required to complete training provided by Sophono, Inc. During the training they will receive guidance regarding the procedure, a thorough understanding of the device and surgical procedure and other important information. Contact Sophono Customer Services at the contact number listed in Section 6 of this manual to arrange training.

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Surgical Risks

The implantation of the Otomag Implant requires a surgical procedure involving the removal of tissue and bone. As with any surgical procedure involving a general anesthetic, certain risks exist. Those risks include the risk of infection from poor hygiene or non-sterile technique, irritation of tissues during the implantation procedure, unintended cuts and abrasions, and irritation of tissues due to unintended exposure to implant materials. The implant is made of materials considered to be hypo-allergenic but in the case of unintended damage to the device, a patient could come in contact with substances that could generate an adverse reaction.

Surgical Site Preparation:

The hair should be clipped and the scalp shaved at the incision site immediately before surgery. With the incision site skin free of gross contamination, apply antiseptic (such as iodophors, alcohol-containing products, or chlorhxidine gluconate) in the area of the proposed incision to an area large enough to allow for the extension of the incision or creation of a new incision or drain sites (if necessary).

Pre-Surgical Antibiotic Prophylaxis:

Antibiotic prophylaxis should be considered if the surgeon determines that this surgical procedure may be associated with a considerable risk of infection or if a post operative infection would cause a serious hazard to the patient's recovery or well being.

Surgical Implantation Steps

Step 1 - Making The Incision

The proper position for the implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant will be placed. The incision must be large enough to allow placement of the implant. See Figure 1.

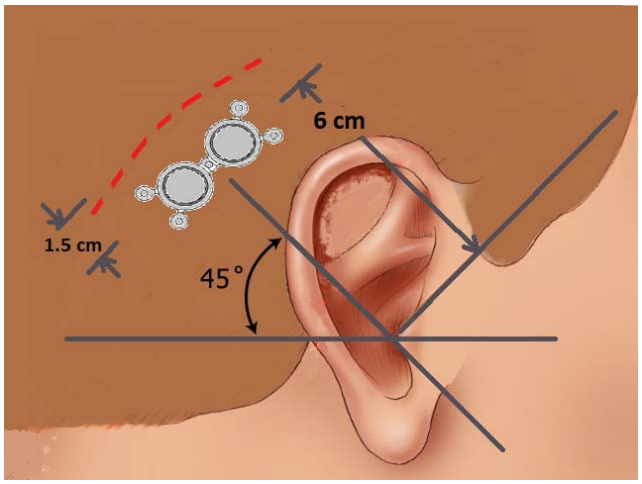

Figure 1 : Incision Location

Step 2 - Create a bone bed (optional)

The implant is approximately 2.6 mm thick and optimal tissue thickness over the implant is 4 mm to 5 mm.

To create a bone bed, mark the position of the implant magnets on the bone and drill the bone bed to a depth of approximately 3 mm. The implant magnets have a diameter of 10 mm.

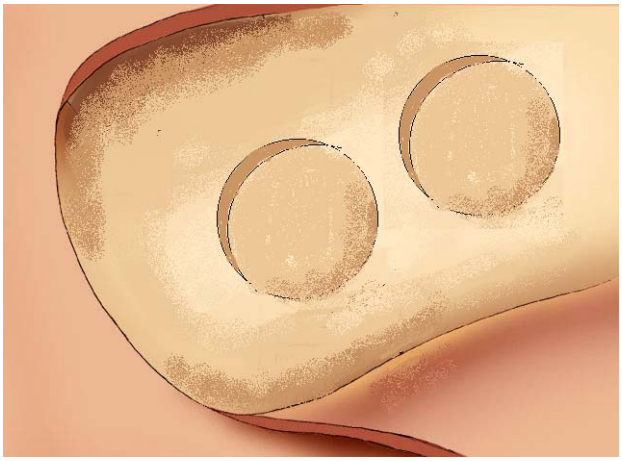

Figure 2: Bone Beds

Step 3 - Implant Placement

After creation of the bone bed, install the magnetic implant using the specified screws such that the implant is oriented with the “This Side Up” label facing out. In addition, be sure to place the implant so that the small fiduciary mark is located in the most anterior and superior location. Place one screw in each of the bracket holes to securely attach the implant to the skull. The surface of the implant should be nearly flush with the surface of the mastoid.

(b)(4)

[redacted]

Figure 3: Implant Installation Diagram

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Step 4 - Tissue Thinning and Closing the Incision

If the tissue flap is thicker than 6 mm, thin down a 10 mm wide strip of tissue to 5 mm directly over the implant magnets. Suture the incision closed.

Implant Surgical Removal Steps

Step 1 - Making The Incision

The implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant has been placed. The incision must be large enough to allow removal of the implant. See Figure 1 above.

Step 2 - Implant Removal

Remove each of the 5 screws holding the magnetic implant in place. It may be necessary to excise bone or tissue growth occurring over the face of the implant. Once the screws are removed the implant can be lifted carefully from the bone or bone beds. Suture incision closed.

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Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system and patient comfort. The Alpha 1 (M) configuration is supplied with five strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid.

The spacers are labeled with "dots" to indicate magnetic strength. Magnetic strength increases based on the number of dots present on the spacer. One dot is the lowest strength and five dots is the highest strength.

Several magnetic spacer strengths may be applicable to an individual patient. To determine the appropriate magnetic spacer for a patient use the "Go" and "No-Go" gages as follows.

Using the "Go" gage to determine the weakest appropriate magnetic spacer

1. *Starting with the one dot magnetic spacer, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the magnetic spacer poles align with the implant poles and the strongest magnetic attraction is achieved.*
2. *Ask the patient to sit upright with their head in a typical vertical position. Attach the "Go" gage clip to the patient's clothing.*
3. *Hang the "Go" gage disk from the magnetic spacer.*
4. *If the magnetic spacer detaches from the side of the patient's head, then the spacer is too weak and the process should be repeated with increasing magnetic spacer strengths until the magnetic spacer remains attached to the side of the head while attached to the "Go" gage disk.*
5. *The lowest dot number magnetic spacer that passes the "Go" test indicates the weakest magnetic spacer strength that should be recommended to the patient.*

Using the "No -Go" gage to determine the strongest applicable magnetic spacer

1. *Starting with the lowest dot number magnetic spacer that passes the "Go" test, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the poles align with the implant poles and the strongest magnetic attraction is achieved.*
2. *Again, ask the patient to sit upright with their head in a typical vertical position. Attach the "No-Go" gage clip to the patients clothing.*
3. *Hang the "No-Go" gage disk from the magnetic spacer.*

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4. *The magnetic spacer **should detach** from the head from the weight of the disk. If the magnetic spacer detaches from the head then the magnetic spacer is one of the appropriate spacers for the patient.*
5. *Repeat this process, increasing magnetic spacer strength one dot at a time until the magnetic spacer **does not detach** from head.*
6. *The highest number magnetic spacer that **detaches** from the head using the "No-Go" test indicates the highest magnetic spacer strength that **should be used** by the patient on a regular basis.*
7. *Any magnetic spacer that remains attached during the "No-Go" test is too strong and should not be recommended for patients long term use.*
8. *If all magnetic spacers used in the "No-Go" test detach when the "No-Go" disc is attached, then all of the spacers tested in the "No-Go" test may be appropriate for the particular patient.*

Several spacer magnet strengths may be applicable for an individual patient. The patient should be prescribed the lowest dot magnet strength that is both comfortable, functions correctly and fits with their age and lifestyle.

	Warning ▪ Excessive, long term use of magentic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test.

.

	Caution ▪ The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or if pain, numbness, or tingling occurs.

Placement of the Alpha 1 (M) Audio Processor

Approximately 4 weeks after the incision site has healed and all signs of inflammation are gone, the patient may be fit with the Alpha 1 (M) Audio Processor.

	Warning ▪ Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this warning may result in prolonged healing, further irritation, or infection.

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4 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a biocompatible titanium case. Only the titanium case of the implant is in contact with patient tissue.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid: Fotoplast Lacquer 3 (light-curing one-component lacquer)

NO components or packaging for the Otomag Bone Conduction Hearing System contain latex.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction sound processor
- Fully programmable digital hearing system
- programs (programmable by audiologist)
- 4 channels
- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery

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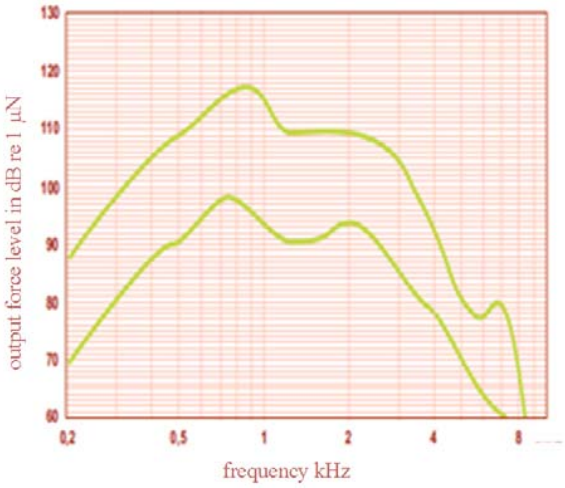
Alpha 1 Sound Processor Performance Data

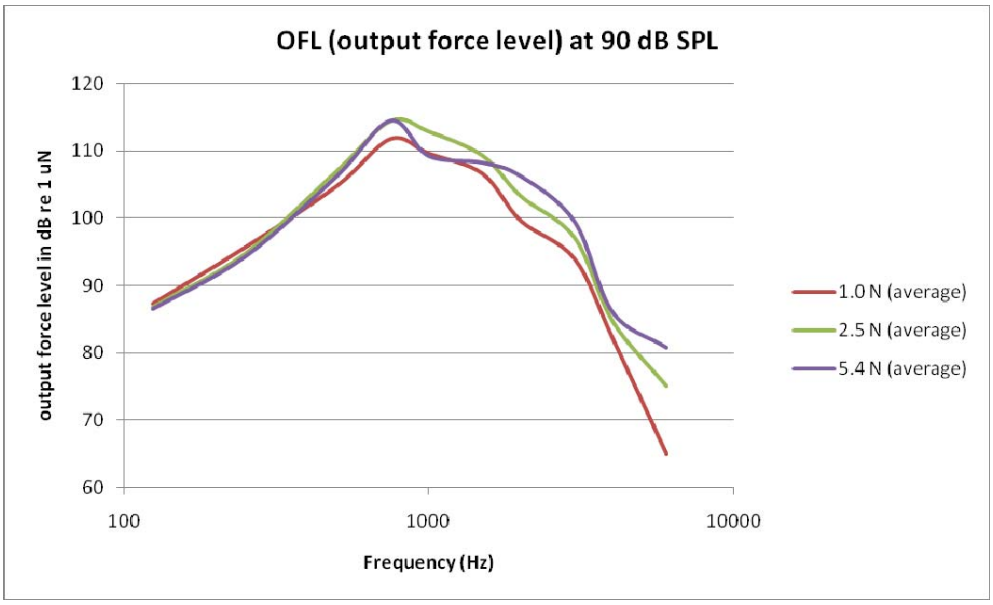
(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

(Measured according to DIN IEC 60118-9. Averages include all configurations of softband, headband, and magnetic spacers for a given normal force)



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- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 µN
- Peak Output at 90 dB SPL: 115 dB re 1 µN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

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5 Storage and Handling

Storage

⚠	**Caution** ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -20 C (-4 F) or above +50 C (122 F) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Handling

⚠	**Caution** ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 Professional Support

For more information or to report concerns, contact:

Sophono, Inc.

903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663
postmaster@sophono.com

Manufactured for: Sophono, Inc. 903 Brooklawn Dr., Boulder, Colorado 80303 USA +1 (303) 564-1663

Printed in U.S.A.

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Patient User Manual

Alpha I (S) & Alpha I (M)
Bone Conduction Hearing Systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

Rx Only

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 About this Manual

This Patient Manual provides a description of the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. Please read this manual thoroughly before using the system.

This Patient Instruction Manual included with each Alpha I (S) & Alpha I (M) Bone Conduction Hearing System should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

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2 Introduction

Dear Customer:

Congratulations on the purchase of your new Otomag Bone Conduction Hearing System!

The Otomag Bone Conduction Hearing System includes a family of Sound Processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag Bone Conduction Hearing System is supplied in either of two configurations. The first configuration is the Alpha 1 (S), in which the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), in which the Otomag Sound Processor is attached magnetically to a Magnetic Implant placed behind the patient's ear. The Headband, Softband, or Magnetic Implant holds the Sound Processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for patients with conductive hearing loss, patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and patients who suffer from single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software package allow for programming the Otomag System for individual patient hearing loss.

This Patient Manual will help you quickly gain confidence with your new Otomag Bone Conduction Hearing System. If you have further questions please consult your hearing healthcare provider.

General Information

A hearing device will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of a hearing device does not permit a user to attain full benefit. The use of a hearing device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading.

	Note ▪ **NO** components or packaging of the Otomag Bone Conduction Hearing System contain **latex**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warnings and Cautions Overview

The following section contains a description of all patient related Warnings and Cautions associated with the Otomag Bone Conduction Hearing System. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to patient instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warning	▪ Thoroughly read Patient Manual before using the Otomag Bone Conduction Hearing System. ▪ Rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in personal injury and damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not obtain an Magnetic Resonance Imaging (MRI) procedure while wearing an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire. ▪ Do not attempt to recharge batteries. ▪ If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device.
Caution	▪ Read this Patient User Manual and keep it available so you can refer to it when needed. ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4 °F (-20 °C) or above 122 °F (+50 °C) at any time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Caution	▪ To avoid damage to the device, do not store the Otomag System near magnets or magnetic devices. ▪ Remove the Sound Processor, Headband and Softband before x-rays of the head and neck ▪ Remove the Sound Processor, Headband, and Softband during radiation therapy ▪ Portable and mobile RF (radio frequency) communications equipment can affect the performance of the Sound Processor. ▪ Interference may occur in the area of equipment which is labeled with the following symbol: ▪ Dispose of batteries and electronic items in accordance with your local regulations. ▪ When navigating through security in airports remove the Sound Processor, Headband and Softband and have them screened through the x-ray screening process. The Sound Processor, Headband and Softband contain metal that may activate the airport security metal detectors. ▪ Do not use the Alpha 1 Sound Processor, Headband or Softband while participating in contact sports. Hard physical contact with the device or a blow to the head in the area of the Alpha 1 Sound Processor, Headband or Softband may result in damage to the device or device failure. ▪ Clean the Alpha 1 Processor, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case. ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device. ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

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3 Operating Instructions

Insertion of the battery

Size 675 batteries are required for your Alpha I Sound Processor.

See Figure 1 for details. Open the battery compartment (1) with a fingernail and insert the battery (2) so that the plus (+) sign on the battery and the plus (+) sign on the battery compartment are on the same side. Close the battery compartment with a finger. The Sound Processor is now switched on.

⚠	**Caution** ▪ Dispose of batteries and electronic items in accordance with your local regulations.

Switch off your Sound Processor whenever you're not using it by pivoting the battery compartment fully out. This will help preserve battery life. The Alpha 1 has a low battery indicator that generates a tone when it is time to replace the battery. Your hearing healthcare provider can adjust the volume and tone of the low battery indicator for you.

Figure 1. Alpha I Sound Processor

⚠	**Warning** ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals ▪ Do not attempt to recharge batteries. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire

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Start-up and Operation

Switch on the Alpha 1 Sound Processor by pivoting the battery compartment fully in.

Positioning the Sound Processor

Alpha 1 (S)

To place the Alpha 1 (S) Sound Processor, simply guide it into the vicinity of the magnetic pad in the Softband or Headband. The magnetic forces will bring it to its correct position. See Figure 2.

Figure 2. Positioning the Alpha I (S) Sound Processor on the Softband

⚠	**Warning** ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 3.

Figure 3. Positioning the Alpha I (M) Sound Processor on the Magnetic Implant

⚠	**Warning** ▪ If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device.

⚠	**Caution** ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient.

Volume Control

The volume can be adjusted with the small wheel that is situated on the outside of the Alpha 1 Sound Processor. Using the tip of the index finger, apply slight pressure on the rotary button and simultaneously turn forward to increase volume. Turn the rotary button in the opposite direction to reduce volume.

You can switch off the Sound Processor by opening the battery access door. As soon as you take off the device, switch it off. See Figure 4 for details.

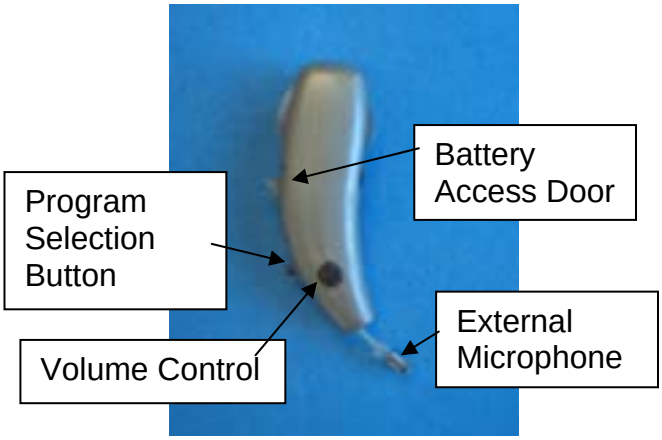

Figure 4. Alpha I Sound Processor

Program Selection Button

The Alpha 1 Sound Processors offer four program settings for different hearing situations. By pressing the small button on the Sound Processor, the programs can be activated. For each activated program you will hear a corresponding signal tone for recognition.

- Program 1: Instrument beeps once

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- Program 2: Instrument beeps twice
- Program 3: Instrument beeps three times
- Program 4: Instrument beeps four times

Your hearing healthcare provider will inform you when each of the programs should be used

Removing the Sound Processor

To remove the Alpha 1 Sound Processor, pull **ONLY** on the steel disk. See Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

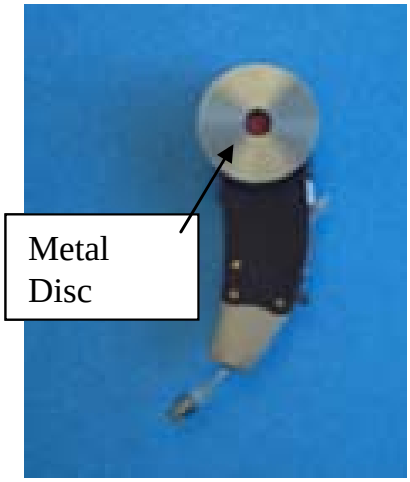

Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

	Note ▪ If you remove the Sound Processor without switching it off, it generates a vibrating tone which leads to high battery consumption. Therefore, always properly switch off the Sound Processor when you are not wearing it.

	Caution ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device.

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If Your Sound Processor Does Not Function

Check the following if the Sound Processor is not functioning properly:

- The device is properly switched on and the battery compartment is fully closed
- The battery is not dead
- The battery surface is clean.

If the device still is not functioning properly, see your hearing healthcare provider.

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4 Product Maintenance

Cleaning and Care

Sound Processor

- Have your Sound Processor checked at regular intervals as specified by your hearing professional.
- To clean your Sound Processor, wipe it with a soft cloth or a Clorox® type disinfecting wipe
- The battery compartment may be cleaned by wiping it out with a DRY cotton swab or a cotton swab that has been moistened by a Clorox® type disinfecting wipe.

	Note ▪ Remove the Sound Processor, Softband, and Headband during the application of hairspray or styling gels. If hairspray or gel comes in contact with the Sound Processor it may become sticky and difficult to clean

- If the Sound Processor becomes soaked with water:
  - Immediately open the battery door and remove the battery
  - Put the Sound Processor in a container with drying capsules such as Dri-aid kit or similar overnight. Drying kits are available from most hearing care professionals.

	Caution ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case

- The Sound Processor is provided in a plastic case which may be used to store the processor. This case may be cleaned with a Clorox® type disinfecting wipe. Make sure the case is completely dry before storing the Sound Processor in it.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

⚠	**Caution** ▪ The Sound Processor is designed to operate within the temperature ranges of 41°F (+5°C) to 104°F (+40°C). The processor should not be subject to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor ▪ Do not expose the Sound Processor to strong sunlight ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case

Softband and Headband

- The Headband can be cleaned with a Clorox® type disinfecting wipe.
- The Softband may be submerged and hand washed with a mild clothes washing detergent (with or without a small amount of color safe bleach) and air dried or may be cleaned with a Clorox® type disinfecting wipe.

Magnetic Spacer

- The Magnetic Spacer can be cleaned with a Clorox® type disinfecting wipe.

⚠	**Caution** ▪ Clean the Alpha 1 Processor, Magnetic Spacer, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Damage and Replacement

The expected live span for the Sound Processor, Magnetic Spacer, Softband, and Headband is approximately 4 years depending on use, wear, and tear. The Sound Processor will need to be repaired or replaced when it no longer produces adequate vibrations or the sounds become highly distorted. The Softband should be replaced when it becomes damaged or the elastic begins to be stretched out and it can no longer be tightened adequately for sound transmission. The Headband should be replaced when it becomes damaged or no longer has enough spring force to press the magnetic pad against the head for adequate sound transmission. Replacement Headbands and Softbands may be purchased through your hearing healthcare provider from Sophono, Inc.

5 Accessories

If your Alpha 1 Sound Processor has a jack for an FM boot, you may plug the boot of a Phonak MLxi FM receiver into the bottom of the Sound Processor.

If you are concerned about the Alpha 1 Sound Processor falling off your head, a clip and tether are available so that the Sound Processor can be tethered to a garment you're wearing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a Titanium case.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid: Fotoplast Lacquer 3 (light-curing one-component lacquer)

NO components or packaging for the Otomag Bone Conduction Hearing System contain latex.

Alpha 1 Sound Processor Technical Characteristics

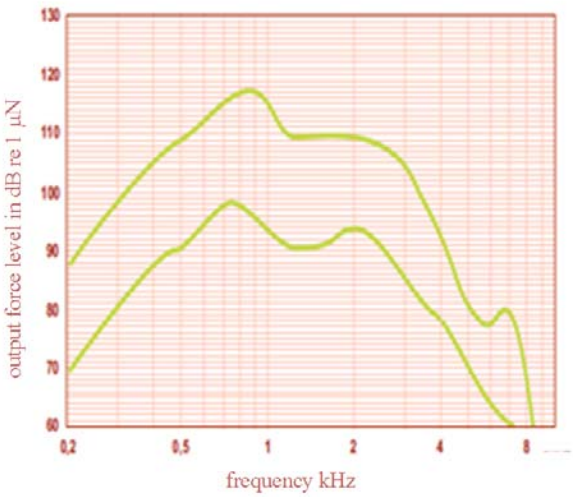
- Magnetically coupled bone conduction Sound Processor
- Fully programmable digital hearing system
- Programs (programmable by audiologist)
- 4 channels
- 16 frequency bands

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery)

Alpha 1 Sound Processor Performance Data

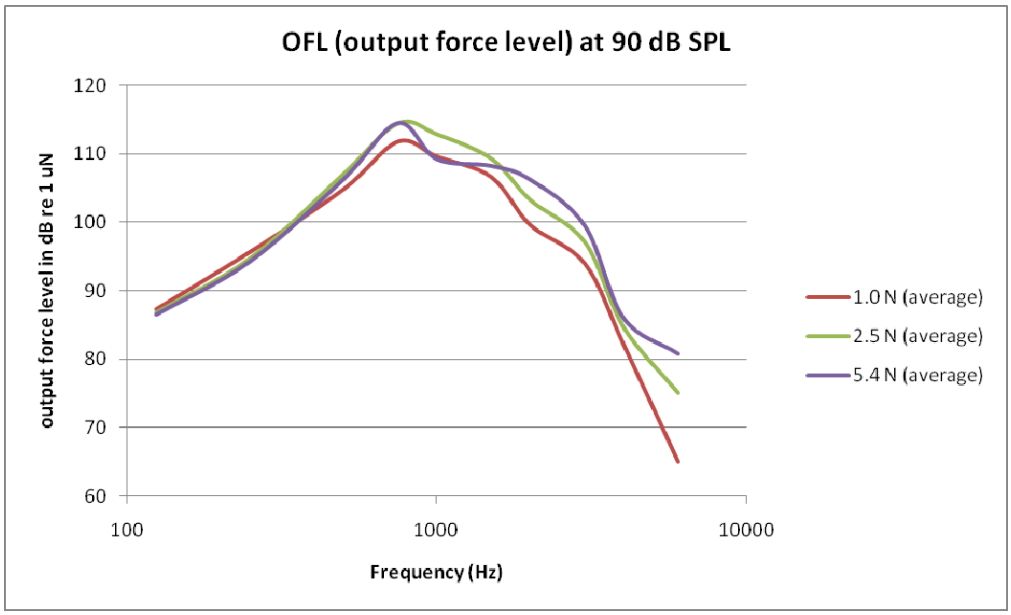
(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

(Measured according to DIN IEC 60118-9. Averages include all configurations of softband, headband, and magnetic spacers for a given normal force)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 µN
- Peak Output at 90 dB SPL: 115 dB re 1 µN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

7 Professional Support

For more information or to report concerns contact:

Sophono, Inc.

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Boulder, Colorado 80303
USA
+1 (303) 564-1663
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Manufactured for: Sophono, Inc. 903 Brooklawn Dr., Boulder, Colorado 80303 USA
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 08: Declarations of Conformity and Summary Reports

1. Conformity with Standards

1.1. The Otomag Bone Conduction Hearing System and its development process conforms with all applicable requirements of the following National and International Standards.

1.1.1. ISO 14971:2007: Medical devices – application of risk management to medical devices;

1.1.2. FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

1.1.3. ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices

1.1.4. ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

1.1.5. ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

1.1.6. AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

1.1.7. AAMI/ANSI ST8:2008, Hospital steam sterilizers

1.1.8. AAMI/ANSI ST67:2003/(R) 2008, Sterilization of health care products – Requirements for products labeled “STERILE”

1.1.9. AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization

1.1.10. AAMI/ANSI ST79:2006, A1:2008,A2: 2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

1.1.11. AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices

1.1.12. ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

1.1.13. ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications

1.2. FDA Form #3654 has been completed for each of the standards referenced above. These forms are included in Appendix A to the overall submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F136 - 08e1 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy f...

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] # NA		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: NA

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F136 - 08e1 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy f...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

NA - No deviations or adaptations were made in the use of the standard

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Department of Health and Human Services
Food and Drug Administration

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F67-06, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, ...

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 8-129		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: NA

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F67-06, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, ...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

NA - No deviations or adaptations were made in the use of the standard

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI ST81:2004,Sterilization of medical devices - Information to be provided by the manufacturer for the processing of ...

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-295		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☑
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: Labeling reusable medical devices for reprocessing in healthcare facilities: FDA Reviewer Guidance OD

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI ST81:2004,Sterilization of medical devices - Information to be provided by the manufacturer for the processing of ...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3.10	Sterilization	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

The standard was followed although the device is not intended to be resterilized: it is provided to the end user non-sterile.

DESCRIPTION

Instructions and parameters are provided for proper moist heat sterilization of the device prior to use.

JUSTIFICATION

Information is appropriate for sterilization of the device prior to use.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Remainder	Remaining sections of Standard	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

NA

DESCRIPTION

NA

JUSTIFICATION

Remainder of Standard does not apply to Sterilization. Purpose of referencing STP is only to validate sterilization instructions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI / ISO 17665-1:2006, Sterilization of health care products -- Moist heat -- Part 1: Requirements for the developme...

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-261		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: AAMI TIR 13:1997, Principles of Industrial Moist Heat Sterilization

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

NA - No deviations or adaptations were made in the use of the standard

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilit

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-280	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilit

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Packaging, preparation, and sterilization	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Utilized 8.1, 8.2, 8.3.1, 8.3.3, 8.3.4, 8.4.4, and 8.6.1

DESCRIPTION

Options selected were applicable for the targeted testing on the device. Options outline desired packaging and sterilization method

JUSTIFICATION

See above

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Installation, care, and maintenance of sterilizers	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

NA

DESCRIPTION

Utilized all of section 9 as pertains to steam sterilizers

JUSTIFICATION

NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Remainder	Remaining sections of Standard	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

NA

DESCRIPTION

NA

JUSTIFICATION

Standard is intended to be used by healthcare facilities. Only sections applicable to lab sterilizer validation were used.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization. (Sterility)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-201	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization. (Sterility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	Performance	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
4.4.1

DESCRIPTION
Section defines performance requirements and documents needed for sterilization.

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
5.6 Sterilization

DESCRIPTION
Section outlines requirements for sterilization test

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Remainder	Remaining sections of Standard	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
Remainder of Standard is N/A to Sterilization. Purpose of STP that references standard is only to validate sterilization instructions.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products - Requirements for products labeled "STERILE" 1st editi...

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-276:	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products - Requirements for products labeled "STERILE" 1st editi...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
NA

JUSTIFICATION
NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI ST8:2008, Hospital steam sterilizers. (Sterility)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-264		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: (1)Guidance on Premarket Notification[510(k)]Submissions for Sterilizers... (2)Addendum to Sterilizer....

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI ST8:2008, Hospital steam sterilizers. (Sterility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
NA

DESCRIPTION
The sterilizer used to conduct testing on the device conforms to this standard

JUSTIFICATION
Sterilizer is used in testing device. Use of this standard is not intended to test device's conformity to standard.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI TIR 12:2004, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Faciliites

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3]	# NA	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Labeling reusable medical devices for reprocessing in healthcare facilities: FDA Reviewer Guidance OD

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI TIR 12:2004, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Faciliites

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Sterilization	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
6.1-6.5

DESCRIPTION
Standard sections are used to validate sterilization procedures for recommendation to healthcare facilities

JUSTIFICATION
Device will be provided Non-sterile to end user, but information is appropriate for sterilization of device prior to use

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Remainder	Remaining sections of Standard	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
NA

DESCRIPTION
NA

JUSTIFICATION
Remainder of Standard is N/A to Sterilization. Purpose of STP that references standard is only to validate sterilization instructions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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Department of Health and Human Services
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 17664:2004. Sterilization of Medical Devices - Information to be provided by the manufacturer for the processing of rester...

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3]	# NA	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 17664:2004. Sterilization of Medical Devices - Information to be provided by the manufacturer for the processing of rester...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3.10	Sterilization	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

NA

DESCRIPTION

Section 3.10 outlines information regarding sterilization to be provided by medical devices manufacturer

JUSTIFICATION

NA

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Remainder	Remaining sections of Standard	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

NA

DESCRIPTION

NA

JUSTIFICATION

Remainder of Standard does not apply to Sterilization. Purpose of referencing STP is only to validate sterilization instructions.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	14971	ISO	Medical Devices: Application of risk management to medical devices	Second Edition	03/01/2007
2	#G95-1	FDA	Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	N/A	05/01/1995
3	17665-1	ISO	Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices	First Edition	08/15/2006
4	17664-1	ISO	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	First Edition	03/01/2004
5	15223-1	ISO	Medical Devices: Symbols to be used with medical device labels, labelling and information to be supplied	First Edition	04/15/2007
6	TIR 12:2004	AAMI	Designing, Testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2004	03/28/2005
7	ST8:2008	AAMI / ANSI	Hospital Steam Sterilizers	2008	3/24/2009

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ST67:2003 / (R) 2008	AAMI/ANSI	Sterilization of health care products - Requirements for products labeled "STERILE"	2008	12/4/2008
2	ST77:2006	AAMI/ANSI	Containment devices for reusable medical device sterilization	2006	1/16/2007
3	ST79:2006 A1:2008, A2:2009	AAMI/ANSI	Comprehensive guide to steam sterilization and sterility assurance in health care facilities	2006	7/24/2006
4	ST81:2004	AAMI/ANSI	Information to be provided by the manufacturer for the processing of resterilizable medical devices	2004	12/13/2004
5	F136-08e1	ASTM	Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Applications	2008	12/2008
6	F67-06	ASTM	Standard Specification for Unalloyed Titanium for Surgical Implant Applications	2006	06/01/2006
7					

Please include any additional standards to be cited on a separate page.

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Indications for Use

510(k) Number: K102199

Device Name: Otomag Bone Conduction Hearing System

Indications for Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 07: 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) Summary: Otomag Bone Conduction Hearing System

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

Submitter: Sophono, Inc.

Establishment Registration Number: Not Yet Assigned

Contact Information:

Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
Ph: 303-546-1663
Fax: 720-222-2432
Contact: Jim Kasic
Email: jkasic@comcast.net

Date Prepared: July 27, 2010

Name of Device: Otomag Bone Conduction Hearing System

Common Name: Bone Conduction Hearing System

Classification Name: Hearing Aid

Device Classification:

- Classification: II
- Classification Panel: Ear, Nose and Throat
- Regulation Number: 874.3300
- Product Code: LXB

Predicate Device:

Otomag Bone Conduction Hearing System, Unmodified Version – K100193

Xomed Audiant Bone Conductor - K855059 / K861971

Device Description:

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Technological Characteristics:

The technological characteristics of the version of the Otomag Bone Conduction Hearing System are equivalent to those of the predicate device. Items that are identical between the modified version and the predicate are:

- Overall Device Performance
- Fundamental Technology (bone conduction)
- Software

Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Through non-clinical performance testing and evaluation, the identified technological differences do not raise new questions of safety and effectiveness.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

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- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Performance Standards:

The design of the Otomag Bone Conduction Hearing System conforms to the following voluntary standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
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- AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
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- AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications

Non-Clinical Performance Testing:

The Otomag Bone Conduction Hearing System has been subjected to extensive safety, performance testing, and verification / validation. Testing of the Otomag Bone Conduction Hearing System included various device performance tests and software validation tests designed to ensure that the device meet all of its functional specifications and is fit for its intended use. Tests have also been performed to ensure the device complies with industry and safety standards. The testing information presented in this submission demonstrates the device’s performance is substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Conclusion:

Based on the non-clinical performance testing, the modified version of the Otomag Bone Conduction Hearing System is as safe and effective and considered to be substantially equivalent to the predicate Otomag device cleared in K100193 and the Audiant cleared K855059 and K861971 and that the differences between the three devices:

- Do not raise any new issues of safety and effectiveness
- Do not amount to a change in the “fundamental scientific technology” of the device with regard to the Otomag predicate K100193
- Do not present any adverse health effect or safety risks to patients when used as intended.

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(b)(4) Testing

(b)(4) Testing

Section 07: 510(k) Summary

510(k) Summary: Otomag Bone Conduction Hearing System

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Submitter: Sophono, Inc.

Establishment Registration Number: Not Yet Assigned

Contact Information:

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Fax: 720-222-2432
Contact: Jim Kasic
Email: jkasic@comcast.net

Date Prepared: July 27, 2010

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Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Through non-clinical performance testing and evaluation, the identified technological differences do not raise new questions of safety and effectiveness.

Device Indications For Use:

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- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
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- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- AAMI/ANSI ST8:2008, Hospital steam sterilizers
- AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products – Requirements for products labeled “STERILE”
- AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization
- AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications

Non-Clinical Performance Testing:

The Otomag Bone Conduction Hearing System has been subjected to extensive safety, performance testing, and verification / validation. Testing of the Otomag Bone Conduction Hearing System included various device performance tests and software validation tests designed to ensure that the device meet all of its functional specifications and is fit for its intended use. Tests have also been performed to ensure the device complies with industry and safety standards. The testing information presented in this submission demonstrates the device’s performance is substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Conclusion:

Based on the non-clinical performance testing, the modified version of the Otomag Bone Conduction Hearing System is as safe and effective and considered to be substantially equivalent to the predicate Otomag device cleared in K100193 and the Audiant cleared K855059 and K861971 and that the differences between the three devices:

- Do not raise any new issues of safety and effectiveness
- Do not amount to a change in the “fundamental scientific technology” of the device with regard to the Otomag predicate K100193
- Do not present any adverse health effect or safety risks to patients when used as intended.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 13, 2011

SOPHONO, INC
C/O REGLERA, LLC
555 ZANG STREET
SUITE 100
LAKEWOOD, COLORADO 80228
ATTN: CLAY ANSELMO

510k Number: K102199

Product: OTOMAG BONE CONDUCTION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K102199|S2

May 10, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Room 2443

FDA CDRH DMC
MAY 13 2011
Received K10

Attn: **Vasant K. Dasika, PhD**
Email: Vasant.Dasika@fda.hhs.gov

Biomedical Engineering Scientific Reviewer
Ear, Nose, and Throat Devices Branch
DONED/ODE/CDRH
US FDA

RE: K102199 – Sophono Otomag Bone Conduction Hearing System
Request for Additional Information dated January 20, 2011

510(k) Applicant / Manufactured by:
Jim Kasic
President and CEO
Sophono Inc.
3022 Sterling Cr,
Boulder, CO 80301

510(k) Contact / Submission Correspondent:
Clay Anselmo
Reglera LLC
555 Zang Street
Lakewood, CO 80228 USA
Phone (Mobile): 303-907-2955
Fax: 303-832-6700
Email: **anselmoc@reglera.com**

Dear Dr. Dasika,

We received FDA's request for additional information dated January 20, 2011 in response to our 510(k) application, K102199, for the Sophono Otomag Bone Conduction Hearing System. To address the issues raised in this request for additional information, we are providing the following information in response for your review.

The attached document reflects our response to the thirteen (13) deficiencies listed in the January 20, 2011 Additional Information request and the additional request regarding electromagnetic immunity sent to Sophono via email on February 22, 2011. In several cases, the responses below refer to information submitted to FDA as a part of interactive review. Wherever this is the case, we have made reference to the date and method used to submit the information.

If you have any questions or if further information is needed, please feel free to contact me at any time using the contact information contained above. We greatly appreciate your time and attention to this matter.

Sincerely,

Clay Anselmo,
Submission Correspondent
Reglera LLC.

cc: Jim Kasic., Sophono Inc.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sophono 510(k) K102199 – Request for Additional Information

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Appendix 2 Updated Physician Manual

Appendix 3 Updated Patient Manual

Appendix 4 Vibration Transfer Comparative Study – Magnetic Retention Force vs. Spring Force, (b) [redacted]

Appendix 5 EMC Immunity Test Report, (b) (4) [redacted]

Appendix 6 Allen ME, et al. (1994) Acceleration perturbations of daily living: a comparison to "whiplash". SPINE 19(11): 1285-90.

Appendix 7 Exponent Failure Analysis Associates. (b) (4) [redacted] (b) (4) [redacted] (b) [redacted].

Appendix 8 Badran, K., et al., Long-term complications of bone-anchored hearing aids: a 14-year experience. J Laryngol Otol, 2009. 123(2): p. 170-6.

Appendix 9 McDermott, A.L., et al., The birmingham pediatric bone-anchored hearing aid program: a 15-year experience. Otol Neurotol, 2009. 30(2): p. 178-83.

Appendix 10 Ali, S., et al., Bone-anchored hearing aid A single-stage procedure in children. Int J Pediatr Otorhinolaryngol, 2009. 73(8): p. 1076-9.

Appendix 11 Hobson, J.C., et al., Complications of bone-anchored hearing aid implantation. J Laryngol Otol, 2010. 124(2): p. 132-6.

Appendix 12 Kohan, D., L.G. Morris, and T. Romo, 3rd, Single-stage BAHA implantation in adults and children: is it safe? Otolaryngol Head Neck Surg, 2008. 138(5): p. 662-6.

Appendix 13 Lloyd, S., et al., Updated surgical experience with bone-anchored hearing aids in children. J Laryngol Otol, 2007. 121(9): p. 826-31.

Appendix 14 Priwin, C. and G. Granstrom, The bone-anchored hearing aid in children: a surgical and questionnaire follow-up study. Otolaryngol Head Neck Surg, 2005. 132(4): p. 559-65.

Appendix 15 Revised 510(k) Summary containing revised Contraindications

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APPENDIX 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 2

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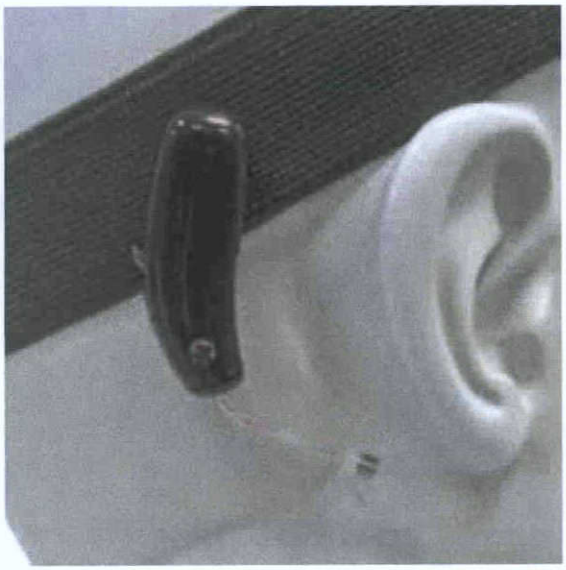
Sophono

Physician Manual



Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Company Information

Contact information:

Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-PROSTATUS@fda.hhs.gov or 301-796-8118
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 About this Manual

This Physician Manual provides a description of the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. This manual provides the information necessary for the physician to prescribe the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems to the appropriate patient population. Please read this manual thoroughly before prescribing the system.
A Patient Instruction Manual is included with each **Alpha I (S)** & **Alpha I (M)** Bone Conduction Hearing System and should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

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2 Introduction

Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patients using the Alpha 1(M) configuration of the device, which utilizes a magnetic implant, should not undergo magnetic resonance imaging (MRI) without having the implant removed prior to scanning.

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Patient Selection Criteria

- Patients to be fitted with the Otomag Alpha 1 (S) Sound Processor and its Headband or Softband may be any age.
- Patients to be fitted with the Otomag Alpha 1 (M) Sound Processor and its Magnetic Implant should be 5 years old or older.
- Patients and/or patient guardians must be able to understand that the Otomag System will not restore hearing to normal and will not prevent additional hearing impairment resulting from conditions such as disease, old age hearing loss, genetic hearing loss, ototoxic drugs or noise induced hearing loss.

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Warnings and Cautions Overview

The following section contains a description of all physician related Warnings and Cautions associated with the Otomag Bone Conduction Hearing Systems. Additional patient and use related Warnings and Cautions can be found in the Patient User Manual. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to physician instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warnings

Warning	▪ Thoroughly read the Physician Manual and the Patient Manual before prescribing the Otomag System. ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform scanning with Magnetic Resonance Imaging (MRI) on an patient using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize appropriately can result in serious infection. ▪ The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device. ▪ Purchased screws may be provided non-sterile and if so must be sterlized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection. ▪ Excessive, long term use of magentic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test. ▪ Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this

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	warning may result in prolonged healing, further irritation, or infection.

Precautions

Caution	▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient. ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant. ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual. ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws. ▪ Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches. ▪ The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or pain, numbness, or tingling occurs.

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Product Description

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag System is configured in either of two configurations. The first configuration is the Alpha 1 (S), where the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), where the Otomag Sound Processor is attached magnetically to an implanted magnet. The Headband, Softband, or Magnetic Implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Possible Adverse Effects

General

It is possible that a reaction to the materials of the Headband, Softband, or Magnetic Implant could occur. Such a circumstance may necessitate that use of the device be discontinued. Please report any adverse effects to Sophono, Inc. The address and phone number for Sophono, Inc. are listed at beginning and end of this Physician Manual. If a reaction to the Headband or Softband occurs, Sophono will supply appropriate instructions so that the device can be sent to the laboratory for analysis.

Risks that may occur during surgery:

The risks involved in surgery and complications related to surgery include the normal risks of the operative procedure and general anesthesia. These include pain, blood clots, and/or circulatory problems, infection, cardiac arrest, and even death. Specific risks related to operating on the mastoid include infection, inflammation, numbness or stiffness about the ear, dural exposure, CSF leak, perforation of sigmoid sinus, subdural hematoma and noticeable changes in head noise.

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⚠	**Warning** ▪ To avoid potential performance and / or safety issues, adhere carefully to patient selection criteria. ▪ Carefully consider the potential patient's medical history to rule out allergies and other reactions to device materials prior to prescribing the Otomag System.

Risks that may occur after surgery:

Potential risks after surgery include inflammation and complications associated with general anesthesia. Potential risks related to the implant following surgery include infection, reparative granuloma, inflammatory reaction, skin breakdown or skin necrosis.

It is possible that a reaction to the implant materials and or failure of the implanted device can occur and may necessitate an operation to remove and/or replace the implant.

The magnetic implant associated with the Alpha 1(M) configuration of the device is not compatible with Magnetic Resonance Imaging (MRI). If MRI is required, the implant must be removed prior to scanning.

⚠	**Warning** ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not perform scanning with Magnetic Resonance Imaging (MRI) on an patient using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Other Symbols on Equipment and Labeling

Symbol	Description
	Consult Physician Manual
LOT	Batch Code or Lot Number
SN	Serial Number
	Keep Away From Rain / Keep Dry
	Manufacturer
MR	MR Unsafe: Device should not be worn when patient is undergoing an MRI
LATEX	Product contains no natural rubber latex
	Interference may occur in the area of equipment which is labeled with the following symbol.
122°F -4°F	Temperature Limitation: The sound processor is designed to operate within the temperature ranges of 41oF (+5oC) to 104oF (+40oC). The processor should not be subject to temperatures below -4oF (-20oC) or above 122oF (+50oC) at any time.
NON STERILE	Device provided Non-Sterile

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 Patient Fitting Procedures

Alpha 1 (S) System: Instructions for Placement of the Softband or Headband and Alpha 1 Sound Processor

	Notes ▪ Record the product and lot or serial numbers for the Alpha 1 Sound Processor in the patient file and send the patient to a qualified audiologist for proper programming of the Alpha 1 Sound Processor.

The Otomag Softband is an elastic Softband similar to a sweat band used in sports. The Alpha 1 (S) Sound Processor magnetically adheres to the Softband via a magnetic pad sewn into the band. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by an audiologist.

- To use the Otomag Softband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Softband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Softband around the patient's head, quite loosely at first by slipping the end of the band through the slot next to the magnetic pad and attaching the mating Velcro ® loops and hooks to each other.
- Place the magnetic pad against the mastoid or other boney location.
- Tighten the Softband by adjusting the Velcro® strap until it is close-fitting enough to ensure effective sound transmission, but not tight enough to cause discomfort. The Softband is too loose if it slips off of the head, can be rotated easily around the head or no sound transmission can be heard. The Softband is too tight if the patient complains of pain or discomfort while wearing the Softband. Make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

	Warning ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

The Otomag Headband is a springy Headband, similar to that used for earphone devices. It comes in one size and is not adjustable. The Alpha 1 (S) Sounds Processor magnetically adheres to the Headband via a magnetic pad fitted to the Headband. No surgery is required and the Alpha 1 (S) can be used immediately after being programmed by the audiologist.

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- To use the Otomag Headband, attach the Alpha 1 (S) Sound Processor to the magnetic pad on the Headband.
- Test that the Alpha 1 works by putting it on yourself, plugging your ears, and introducing sound.
- Put the Headband on the patient's head and place the magnetic pad against the mastoid or other boney location.

The choice of a Headband or Softband is a matter of patient preference.

Alpha 1 (M) System: Compatible Screws

	Notes ▪ The Alpha 1 (M) implant requires 5 screws for implantation that are **NOT** included with the implant.

Screws

The Alpha 1 (M) implant requires 5 screws to be used to affix the implant to the skull. These screws are NOT included as part of the Alpha 1 (M) implant system and must be obtained separately.

The implant bracket holes are sized to accept Stryker/Leibinger 1.7 mm diameter Craniomaxillofacial titanium Self Tapping Screws, (Gold) and 1.7 mm diameter Self Drilling Screws (Silver) in 4 mm lengths and 1.9 mm Emergency Screws (Purple) in 3 mm lengths.

Craniomaxillofacial Titanium Screws	***1.7 mm dia. x 4.0 mm Self Tapping***	***1.7 mm dia. x 4.0 mm Self Drilling***	***1.9 mm dia. x 3.0 mm Emergency***
Stryker/Leibinger Part Numbers / 510(k) Clearance Numbers	*50-17004 / K970912*	*50-17904 / K970912*	*50-19004 / K963739*

While all screw sizes / types specified above have been validated for this application, the Stryker/Leibinger 1.7mm x 4 mm self drilling screws, part number 50-17904 is considered optimal.

Other commercially available craniomaxillofacial titanium screws may be used as long as the screw shaft diameter is less than 2.0 mm and the screw head size is greater than 2.45 mm. Screw must be 4 mm in length (3mm for emergency screws).

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The screws must be sterile prior to implantation. If the screws are not purchased sterile, refer to the screw manufacturer's instructions for sterilization.

	Warning ▪ Purchased screws may be provided non-sterile and if so must be sterlized prior to implantation according to the manufacturers instructions. Failure to sterilize appropriate can result in serious infection.

	Caution ▪ Refer to the screw's original manufacturer's instructions for use for specific directions on how to use the screws.

If the initial attempt to place a screw does not work and the screw hole becomes "stripped" emergency "rescue" screws can be threaded into the stripped hole. The largest size screw that can be used is 1.9 mm in diameter.

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Alpha 1 (M) System: Instructions for Sterilization and Placement of the Magnetic Implant and Alpha 1 Sound Processor

Point of Use Sterilization Instructions:

⚠	**Warning** ▪ The Alpha 1 (M) Magnetic Implant is provide non-sterile and must be sterlized prior to implantation according to the provided instructions. Failure to sterilize a device appropriately can result in serious infection.

The Alpha 1 (M) magnetic implant is provided clean but NOT sterile. It is not necessary to clean the implant prior to sterilization. To prepare the implant for steam sterilization use the following steps:

- Unscrew the cap on the magnetic implant container.
- Without touching the magnetic implant, transfer the implant into the autoclave pouch. Transfer can be simply accomplished by inverting the implant container over the open top of the autoclave pouch.
- Place a single steam sterilization indicator into the pouch with the implant.
- Immediately seal the autoclave pouch.

⚠	**Caution** ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been placed in or with another patient.

Exact compliance is required with the sterilization equipment manufacturer's instructions for use, maintenance, and periodic monitoring. The Alpha implant can be re-sterilized two additional times by gravity steam sterilization (autoclaving) if it is not used during the implantation procedure. The following sterilization parameters have been validated for sterilization of the implant.

Limitations on Reprocessing: Magnetic implants may be re-sterilized two additional times if not used during the implant procedure. Implants should be stored in the sterilization pouch. However, the implant must be transferred to a new sterilization pouch just prior to resterilization and implant.

Presterilization Decontamination / Cleaning / Disinfection: None Required

Cycle Type: Gravity

Sterilization Time: 15 minutes minimum

Sterilization Cycle Temperature: 132 degrees C / 270 degrees F

Drying Time: 30 minutes minimum

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Packaging: Cardinal Health Self Sealing Autoclave Pouch (P/N 92510)

Storage in Sterile State: Final sterilization immediately pre-implant only

Upon completion of sterilization verify that both sterilization indicator strips (interior and on exterior of package) indicate the steam cycle was completed correctly. Follow manufacturer instructions for interpretation of these indicators. If both the indicators do not show completion of the sterilization cycle, repeat the cycle.

⚠	**Warning** ▪ The Alpha 1 (M) Magnetic Implant is not intended to be flash steam sterilized. Flash steam sterilization has not been validated to effectively sterilize the device.

Sterilization Pouch Specifications

To ensure the validated parameters are replicated appropriately, the following is to be used to individually pouch each implant prior to performing the sterilization cycle:

Manufacturer: Cardinal Health, http://www.cardinal.com, 800.964.5227

Catalog Number: 92510

Size: 5.5" x 10" Paper Self Seal Pouch

Materials: Arjowiggins 60g/m^2 Paper / CN PET 12/CPP40 Micron

Total Product Area: 0.035 m^2

Paper Area: 0.035 m^2

Ink: Medical Grade

⚠	**Caution** ▪ Refer to the original manufacturer's instructions for use for specific directions on how to appropriately use these sterilization pouches.

Internal Steam Indicator Strip

As described above, each time an implant is steam sterilized, place a single indicator strip labeled for use with the specified gravity steam sterilization cycle into the inside of the specified pouch. Follow manufacturer's instructions for interpretation of results.

Pre-Surgical Training Requirements

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Before attempting to implant the Otomag Implant, surgeons are required to complete training provided by Sophono, Inc. During the training they will receive guidance regarding the procedure, a thorough understanding of the device and surgical procedure and other important information. Contact Sophono Customer Services at the contact number listed in Section 6 of this manual to arrange training.

Surgical Risks

The implantation of the Otomag Implant requires a surgical procedure involving the removal of tissue and bone. As with any surgical procedure involving a general anesthetic, certain risks exist. Those risks include the risk of infection from poor hygiene or non-sterile technique, irritation of tissues during the implantation procedure, unintended cuts and abrasions, and irritation of tissues due to unintended exposure to implant materials. The implant is made of materials considered to be hypo-allergenic but in the case of unintended damage to the device, a patient could come in contact with substances that could generate an adverse reaction.

Surgical Site Preparation:

The hair should be clipped and the scalp shaved at the incision site immediately before surgery. With the incision site skin free of gross contamination, apply antiseptic (such as iodophors, alcohol-containing products, or chlorhxidine gluconate) in the area of the proposed incision to an area large enough to allow for the extension of the incision or creation of a new incision or drain sites (if necessary).

Pre-Surgical Antibiotic Prophylaxis:

Antibiotic prophylaxis should be considered if the surgeon determines that this surgical procedure may be associated with a considerable risk of infection or if a post operative infection would cause a serious hazard to the patient's recovery or well being.

Surgical Implantation Steps

Step 1 - Making The Incision

The proper position for the implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant will be placed. The incision must be large enough to allow placement of the implant. See Figure 1.

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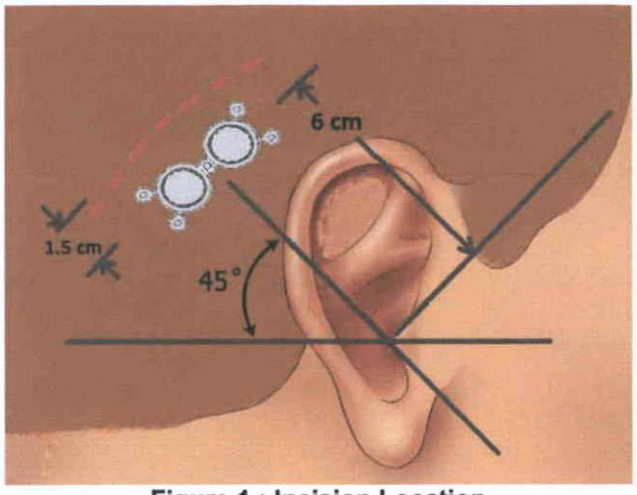

Figure 1 : Incision Location

Step 2 - Create a bone bed (optional)

The implant is approximately 2.6 mm thick and optimal tissue thickness over the implant is 4 mm to 5 mm.

To create a bone bed, mark the position of the implant magnets on the bone and drill the bone bed to a depth of approximately 3 mm. The implant magnets have a diameter of 10 mm.

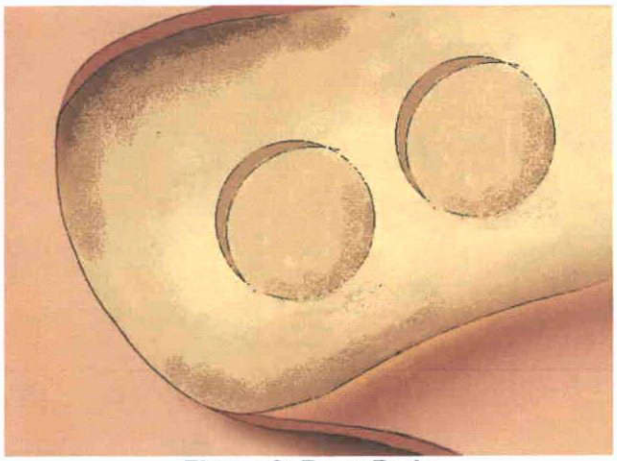

Figure 2: Bone Beds

Step 3 - Implant Placement

After creation of the bone bed, install the magnetic implant using the specified screws such that the implant is oriented with the "This Side Up" label facing out. In addition, be sure to place the implant so that the small fiduciary mark is located in the most anterior and superior location. Place one screw in each of the bracket holes to securely attach the implant to the skull. The surface of the implant should be nearly flush with the surface of the mastoid.

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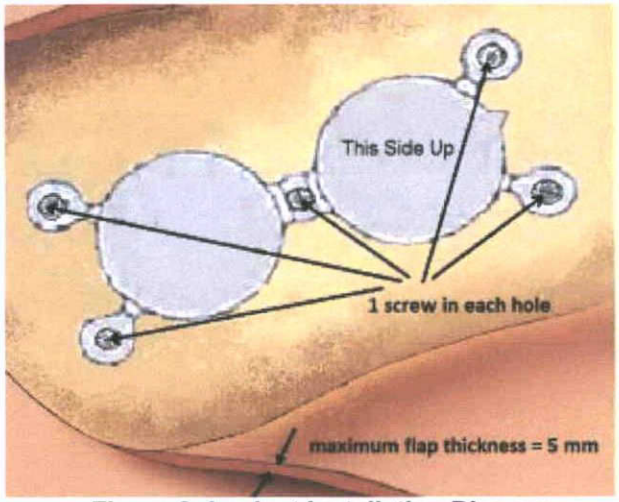

Figure 3: Implant Installation Diagram

Step 4 - Tissue Thinning and Closing the Incision

If the tissue flap is thicker than 6 mm, thin down a 10 mm wide strip of tissue to 5 mm directly over the implant magnets. Suture the incision closed.

Implant Surgical Removal Steps

Step 1 - Making The Incision

The implant is 6 cm from the ear canal at a 45-degree angle posterior and superior to the ear canal. The incision should be made 7.5 to 8 cm from the external ear canal (1.5 to 2 cm from the location of the implant so the incision is not directly over the implant). After making the incision, expose the skull where the implant has been placed. The incision must be large enough to allow removal of the implant. See Figure 1 above.

Step 2 - Implant Removal

Remove each of the 5 screws holding the magnetic implant in place. It may be necessary to excise bone or tissue growth occurring over the face of the implant. Once the screws are removed the implant can be lifted carefully from the bone or bone beds. Suture incision closed.

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Instructions for Placement / Sizing of the Magnetic Spacers

Magnetic Spacer Selection

As with the Headband and Softband, application of appropriate pressure to the mastoid by the Sound Processor is essential for proper functioning of the system and patient comfort. The Alpha 1 (M) configuration is supplied with five strengths of magnetic spacers to allow the fitting physician to adjust the force applied to the mastoid.

The spacers are labeled with "dots" to indicate magnetic strength. Magnetic strength increases based on the number of dots present on the spacer. One dot is the lowest strength and five dots is the highest strength.

Several magnetic spacer strengths may be applicable to an individual patient. To determine the appropriate magnetic spacer for a patient use the "Go" and "No-Go" gages as follows.

The "Go" and "No-Go" gages used in the selection of the appropriate magnetic spacers may be re-used with multiple patients. However, prior to using with another patient the accessories must be cleaned and disinfected using an EPA-registered hospital disinfectant wipe.

Using the "Go" gage to determine the weakest appropriate magnetic spacer

1. *Starting with the one dot magnetic spacer, place the magnetic spacer over the implant. Magnetic attraction will pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the magnetic spacer poles align with the implant poles and the strongest magnetic attraction is achieved.*
2. *Ask the patient to sit upright with their head in a typical vertical position. Attach the "Go" gage clip to the patient's clothing.*
3. *Hang the "Go" gage disk from the magnetic spacer.*
4. *If the magnetic spacer detaches from the side of the patient's head, then the spacer is too weak and the process should be repeated with increasing magnetic spacer strengths until the magnetic spacer remains attached to the side of the head while attached to the "Go" gage disk.*
5. *The lowest dot number magnetic spacer that passes the "Go" test indicates the weakest magnetic spacer strength that should be recommended to the patient.*

Using the "No -Go" gage to determine the strongest applicable magnetic spacer

1. *Starting with the lowest dot number magnetic spacer that passes the "Go" test, place the magnetic spacer over the implant. Magnetic attraction will*

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pull the magnetic spacer toward the implant. The magnetic spacer has two poles. Rotate the magnetic spacer 360 degrees until the poles align with the implant poles and the strongest magnetic attraction is achieved.

2. *Again, ask the patient to sit upright with their head in a typical vertical position. Attach the "No-Go" gage clip to the patients clothing.*
3. *Hang the "No-Go" gage disk from the magnetic spacer.*
4. *The magnetic spacer **should detach** from the head from the weight of the disk. If the magnetic spacer detaches from the head then the magnetic spacer is one of the appropriate spacers for the patient.*
5. *Repeat this process, increasing magnetic spacer strength one dot at a time until the magnetic spacer **does not detach** from head.*
6. *The highest number magnetic spacer that **detaches** from the head using the "No-Go" test indicates the highest magnetic spacer strength that **should be used** by the patient on a regular basis.*
7. *Any magnetic spacer that remains attached during the "No-Go" test is too strong and should not be recommended for patients long term use.*
8. *If all magnetic spacers used in the "No-Go" test detach when the "No-Go" disc is attached, then all of the spacers tested in the "No-Go" test may be appropriate for the particular patient.*

Several spacer magnet strengths may be applicable for an individual patient. The patient should be prescribed the lowest dot magnet strength that is both comfortable, functions correctly and fits with their age and lifestyle.

⚠	**Warning** ▪ Excessive, long term use of magentic spacers that are too strong may lead to pain and or pressure necrosis for the patient. Always recommend to the patient the lowest magnetic strength spacer that passes the "Go" test.

⚠	**Caution** ▪ The patient should be instructed to select a lower strength spacer if the pressure on the skin is uncomfortable or if pain, numbness, or tingling occurs.

Placement of the Alpha 1 (M) Audio Processor

Approximately 4 weeks after the incision site has healed and all signs of inflammation are gone, the patient may be fit with the Alpha 1 (M) Audio Processor.

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⚠	**Warning** ▪ Do not use of the Alpha 1(M) configuration of the device if the skin contact area of the sound processor is compromised in any way (i.e. – unhealed incision, psoriasis, or eczema). Failure to follow this warning may result in prolonged healing, further irritation, or infection.

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4 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

⚠	**Caution** ▪ Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a biocompatible titanium case. Only the titanium case of the implant is in contact with patient tissue.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

Portion of Headband or Softband that presses against the mastoid (bony protrusion on the skull located directly behind the ear): Fotoplast Lacquer 3 (light-curing one-component lacquer)

The components and packaging for the Otomag Bone Conduction Hearing System contain no natural rubber latex.

The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

Questions? Contact FDA/CDRH/OCE/DIDPO/CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118
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Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction sound processor
- Fully programmable digital hearing system
- programs (programmable by audiologist)
- 4 channels
- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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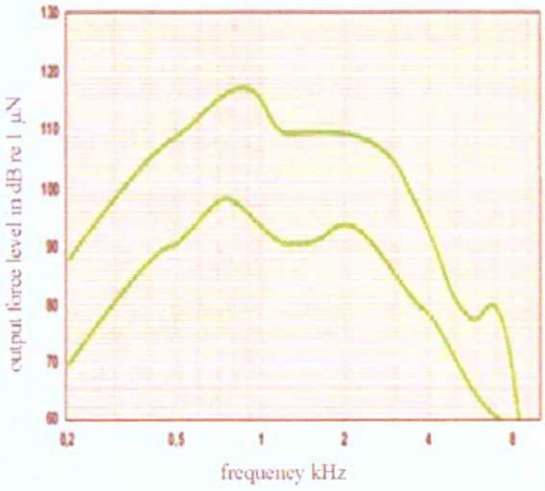
Alpha 1 Sound Processor Performance Data

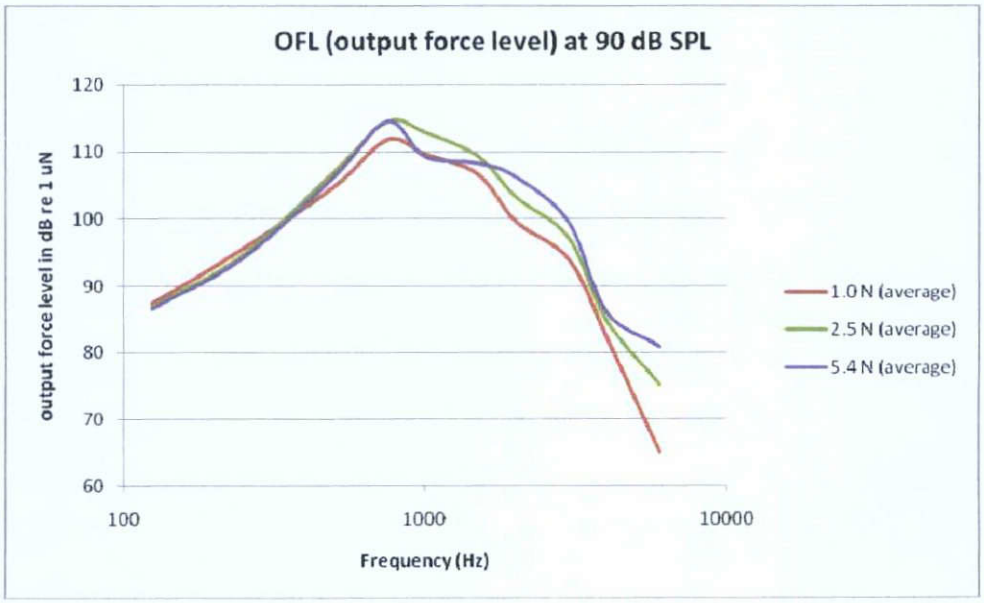
(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

(Measured according to DIN IEC 60118-9. Averages include all configurations of softband, headband, and magnetic spacers for a given normal force)



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- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 μN
- Peak Output at 90 dB SPL: 115 dB re 1 μN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

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5 Storage and Handling

Storage

⚠	**Caution** ▪ To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -20 C (-4 F) or above +50 C (122 F) at any time. ▪ To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Handling

⚠	**Caution** ▪ Prior to use, inspect packaging to verify that it is intact and has not been damaged. If the packaging is damaged, do not use the device and return it to Sophono, Inc. Please see the address and phone number for Sophono, Inc. at the end of this Physician Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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6 Professional Support

For more information or to report concerns, device malfunctions, adverse events, or patient complaints, please contact:

Sophono, Inc.

903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663
postmaster@sophono.com

Manufactured for: Sophono, Inc. 903 Brooklawn Dr., Boulder, Colorado 80303 USA +1 (303) 564-1663

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APPENDIX 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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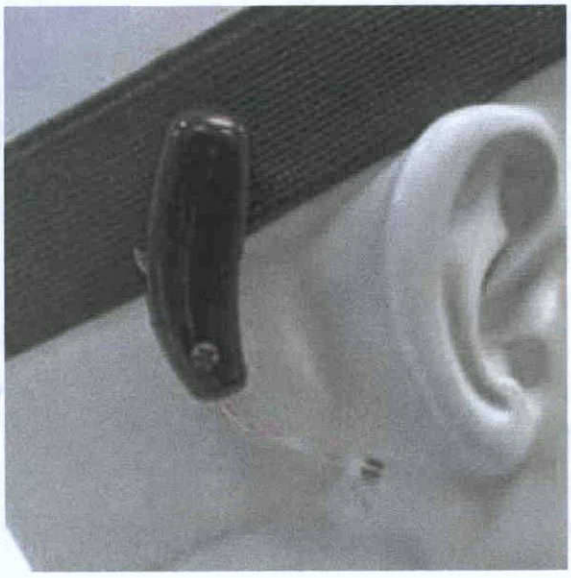
Sophono

Patient User Manual



Alpha I (S) & Alpha I (M)
Bone Conduction Hearing Systems

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Company Information

Contact information:

Professional Support:
Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado 80303
USA
+1 (303) 564-1663

- Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Questions? Contact FDA/CDRH/OCE/DIDPO/OIS/STATUS@fda.hhs.gov or 301-796-8118
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Questions? Contact FDA/CDRH/OCE/DID/FOIA STATUS@fda.hhs.gov or 301-796-8118

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1 About this Manual

This Patient Manual provides a description of the Alpha I (S) & Alpha I (M) Bone Conduction Hearing Systems. This manual includes a description of the system's features, performance, intended use, and important safety information. Please read this manual thoroughly before using the system.

This Patient Instruction Manual included with each Alpha I (S) & Alpha I (M) Bone Conduction Hearing System should be referred to for information regarding:

- Kit Contents
- Instructions for Use
- Patient Warnings and Precautions
- Important Things to Remember
- Maintenance
- Customer Support

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	Warning ▪ Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.
	Caution ▪ Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	Notes ▪ Symbol indicates important general information for using the system successfully.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 Introduction

Dear Customer:

Congratulations on the purchase of your new Otomag Bone Conduction Hearing System!

The Otomag Bone Conduction Hearing System includes a family of Sound Processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag Bone Conduction Hearing System is supplied in either of two configurations. The first configuration is the Alpha 1 (S), in which the Otomag Sound Processor is attached magnetically to a Headband or Softband. The second configuration is Alpha 1 (M), in which the Otomag Sound Processor is attached magnetically to a Magnetic Implant placed behind your ear. The Headband, Softband, or Magnetic Implant holds the Sound Processor against the head, and vibration is transduced through direct contact with your skin and the bone below.

The Otomag System is designed for use for patients with conductive hearing loss, patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and patients who suffer from single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software package allow for programming the Otomag System for individual patient hearing loss.

This Patient Manual will help you quickly gain confidence with your new Otomag Bone Conduction Hearing System. If you have further questions please consult your hearing healthcare provider.

General Information

A hearing device will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of a hearing device does not permit a user to attain full benefit. The use of a hearing device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading.

	Note ▪ The components and packaging of the Otomag Bone Conduction Hearing System contain **no** natural rubber **latex**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Note ▪ The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

Indications for Use

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Contraindications for the Otomag Alpha 1 Sound Processor connected to the Otomag Headband, Softband, or Magnetic Implant are as follows:
Any factor that would cause a clinician to refer you for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- Hearing loss occurring suddenly;
- Hearing loss that grows worse rapidly;
- Pain in either ear;
- A sudden recent onset of ringing or a similar sensation in the ears, also known as tinnitus. Tinnitus may be bilateral (occurring in both ears) or unilateral (occurring in one ear);
- Unilateral or markedly asymmetrical (not equal in both ears) hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

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Patients using the Alpha 1(M) configuration of the device, which utilizes a magnetic implant, should not undergo magnetic resonance imaging (MRI) without having the implant removed prior to scanning.

Note: While the contraindications listed above may affect the process of hearing aid fitting, it should be noted that the treatment plan for use of the Otomag Alpha 1 Sound Processor may vary with worsening or improving hearing. Your treatment plan will be determined by your hearing health specialists.

Warnings and Cautions Overview

The following section contains a description of all patient related Warnings and Cautions associated with the Otomag Bone Conduction Hearing System. Knowledge of the following information is essential for safe operation of the device. Specific Warnings and Cautions pertaining to patient instructions are included in the body of the manual and are indicated by the appropriate symbol.

Warning	▪ Thoroughly read Patient Manual before using the Otomag Bone Conduction Hearing System. ▪ Rule out allergies and other reactions to device materials prior to prescribing the Otomag System. ▪ A blow to the head in the area of the Otomag Alpha 1 Sound Processor may result in personal injury and damage to the device or device failure. ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight. ▪ Do not undergo scanning with Magnetic Resonance Imaging (MRI) if you are using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband. ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire. ▪ Do not attempt to recharge batteries. ▪ If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device.
Caution	▪ Read this Patient User Manual and keep it available so you can refer to it when needed. ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient. ▪ Keep Otomag System components away from magnetic data

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	storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices.

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Caution

- To avoid damage to the device, do not subject the Alpha 1 Sound Processor to temperatures below -4 °F (-20 °C) or above 122 °F (+50 °C) at any time.
- To avoid damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.
- Remove the Sound Processor, Headband and Softband before x-rays of the head and neck
- Remove the Sound Processor, Headband, and Softband during radiation therapy
- Portable and mobile RF (radio frequency) communications equipment can affect the performance of the Sound Processor.
- Interference may occur in the area of equipment which is labeled with the following symbol:
- Dispose of batteries and electronic items in accordance with your local regulations.
- When navigating through security in airports remove the Sound Processor, Headband and Softband and have them screened through the x-ray screening process. The Sound Processor, Headband and Softband contain metal that may activate the airport security metal detectors.
- Do not use the Alpha 1 Sound Processor, Headband or Softband while participating in contact sports. Hard physical contact with the device or a blow to the head in the area of the Alpha 1 Sound Processor, Headband or Softband may result in damage to the device or device failure.
- Clean the Alpha 1 Processor, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device.
- To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.
- When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device.
- The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device.
- Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor.
- Do not expose the Sound Processor to strong sunlight.
- Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case.

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3 Operating Instructions

Insertion of the battery

Size 675 batteries are required for your Alpha I Sound Processor.

See Figure 1 for details. Open the battery compartment (1) with a fingernail and insert the battery (2) so that the plus (+) sign on the battery and the plus (+) sign on the battery compartment are on the same side. Close the battery compartment with a finger. The Sound Processor is now switched on.

⚠	**Caution** ▪ Dispose of batteries and electronic items in accordance with your local regulations.

Switch off your Sound Processor whenever you're not using it by pivoting the battery compartment fully out. This will help preserve battery life. The Alpha 1 has a low battery indicator that generates a tone when it is time to replace the battery. Your hearing healthcare provider can adjust the volume and tone of the low battery indicator for you.

Figure 1. Alpha I Sound Processor

⚠	**Warning** ▪ Never store hearing aids and batteries within reach of small children or animals. The batteries are small, easily swallowed, and can poison small children and animals ▪ Do not attempt to recharge batteries. ▪ Do not dispose of your Sound Processor in an incinerator or fire. In no case should batteries be thrown into an open fire

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Start-up and Operation

Switch on the Alpha 1 Sound Processor by pivoting the battery compartment fully in.

Positioning the Sound Processor

Alpha 1 (S)

To place the Alpha 1 (S) Sound Processor, simply guide it into the vicinity of the magnetic pad in the Softband or Headband. The magnetic forces will bring it to its correct position. See Figure 2.

Figure 2. Positioning the Alpha I (S) Sound Processor on the Softband

⚠	**Warning** ▪ When using the Otomag Alpha 1 (S) Softband, make sure that a finger can be placed between the skull and Softband to ensure that the Softband is not too tight.

Alpha 1 (M)

To place the Alpha 1 (M) Sound Processor, simply guide it into the vicinity of the Magnetic Implant. The magnetic forces will bring it to its correct position. See Figure 3. If you have thicker hair, it may be necessary to part your hair over the implant site or shorten the hair at the implant location to ensure an adequate holding force between magnets.

Figure 3. Positioning the Alpha I (M) Sound Processor on the Magnetic Implant

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⚠	**Warning** ▪ If you experience discomfort, pain, numbness, or tingling of the skin in the area of your magnetic implant, remove the sound processor assembly and see your physician for refitting of the device.

⚠	**Caution** ▪ The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband are intended for single-patient use only. Do not use any of these products if they have previously been used with another patient.

Volume Control

The volume can be adjusted with the small wheel that is situated on the outside of the Alpha 1 Sound Processor. Using the tip of the index finger, apply slight pressure on the rotary button and simultaneously turn forward to increase volume. Turn the rotary button in the opposite direction to reduce volume.

You can switch off the Sound Processor by opening the battery access door. As soon as you take off the device, switch it off. See Figure 4 for details.

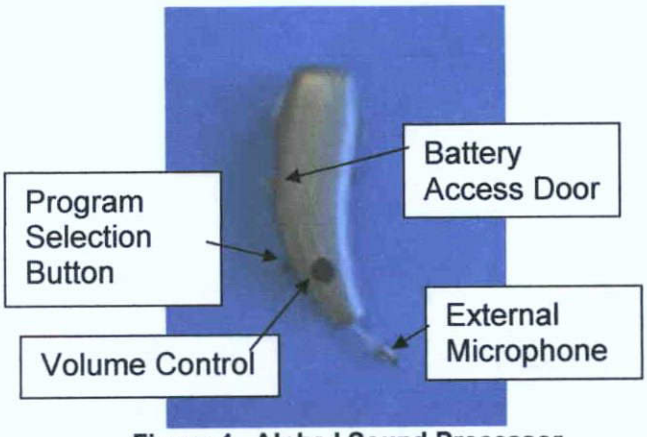

Figure 4. Alpha I Sound Processor

Program Selection Button

The Alpha 1 Sound Processors offer four program settings for different hearing situations. By pressing the small button on the Sound Processor, the programs can be activated. For each activated program you will hear a corresponding signal tone for recognition.

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- Program 1: Instrument beeps once
- Program 2: Instrument beeps twice
- Program 3: Instrument beeps three times
- Program 4: Instrument beeps four times

Your hearing healthcare provider will inform you when each of the programs should be used

Removing the Sound Processor

To remove the Alpha 1 Sound Processor, pull **ONLY** on the steel disk. See Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

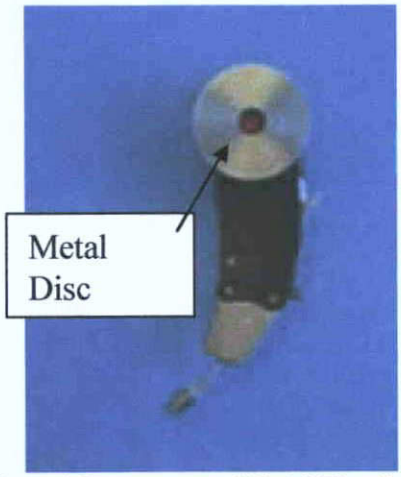

Figure 5. Alpha 1 Sound Processor w/ Metal Disc for Magnetic Attachment

	Note ▪ If you remove the Sound Processor without switching it off, it generates a vibrating tone which leads to high battery consumption. Therefore, always properly switch off the Sound Processor when you are not wearing it.

	Caution ▪ When removing the Sound Processor do not pull on the processor itself, this could result in damage to the device.

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If Your Sound Processor Does Not Function

Check the following if the Sound Processor is not functioning properly:

- The device is properly switched on and the battery compartment is fully closed
- The battery is not dead
- The battery surface is clean.

If the device still is not functioning properly, see your hearing healthcare provider.

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4 Product Maintenance

Cleaning and Care

Sound Processor

- Have your Sound Processor checked at regular intervals as specified by your hearing professional.
- To clean your Sound Processor, wipe it with a soft cloth or a Clorox® type disinfecting wipe
- The battery compartment may be cleaned by wiping it out with a DRY cotton swab or a cotton swab that has been moistened by a Clorox® type disinfecting wipe.

	Note ▪ Remove the Sound Processor, Softband, and Headband during the application of hairspray or styling gels. If hairspray or gel comes in contact with the Sound Processor it may become sticky and difficult to clean

- If the Sound Processor becomes soaked with water:
  - Immediately open the battery door and remove the battery
  - Put the Sound Processor in a container with drying capsules such as Dri-aid kit or similar overnight. Drying kits are available from most hearing care professionals.

	Caution ▪ The Sound Processor is not water proof and should not be worn in heavy rain, in the bath or shower, or in other environments when exposure to heavy moisture is likely. Exposure to moisture may cause damage to the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case

- The Sound Processor is provided in a plastic case which may be used to store the processor. This case may be cleaned with a Clorox® type disinfecting wipe. Make sure the case is completely dry before storing the Sound Processor in it.

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⚠	**Caution** ▪ The Sound Processor is designed to operate within the temperature ranges of 41°F (+5°C) to 104°F (+40°C). The processor should not be subject to temperatures below -4°F (-20°C) or above 122°F (+50°C) at any time. ▪ Protect your Sound Processor from impact and shock. Avoid dropping your Sound Processor ▪ Do not expose the Sound Processor to strong sunlight ▪ Always switch your device off when you remove it. If you do not use your Sound Processor for a long time, remove the battery and store the Sound Processor in its case

Softband and Headband

- The Headband can be cleaned with a Clorox® type disinfecting wipe.
- The Softband may be submerged and hand washed with a mild clothes washing detergent (with or without a small amount of color safe bleach) and air dried or may be cleaned with a Clorox® type disinfecting wipe.

Magnetic Spacer

- The Magnetic Spacer can be cleaned with a Clorox® type disinfecting wipe.

⚠	**Caution** ▪ Clean the Alpha 1 Processor, Magnetic Spacer, Headband, and Softband only as directed. Other common household cleaning chemicals or methods, such as washing machines, bleach, ammonia, or spray cleaners may damage the device. ▪ To avoid damage to the case or the Sound Processor, do not use household soaps or rinse / submerge the case under water and do not wash the case in the dishwasher. Should the case become wet for any reason, allow the case to air dry completely before storing the Alpha 1 Processor in the case.

Retention Clip / Lanyard

- The Retention Clip / Lanyard can be cleaned with a Clorox® type disinfecting wipe.

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Damage and Replacement

The expected live span for the Sound Processor, Magnetic Spacer, Softband, and Headband is approximately 4 years depending on use, wear, and tear. The Sound Processor will need to be repaired or replaced when it no longer produces adequate vibrations or the sounds become highly distorted. The Softband should be replaced when it becomes damaged or the elastic begins to be stretched out and it can no longer be tightened adequately for sound transmission. The Headband should be replaced when it becomes damaged or no longer has enough spring force to press the magnetic pad against the head for adequate sound transmission. Replacement Headbands and Softbands may be purchased through your hearing healthcare provider from Sophono, Inc.

5 Accessories

If your Alpha 1 Sound Processor has a jack for an FM boot, you may plug the boot of a Phonak MLxi FM receiver into the bottom of the Sound Processor.

If you are concerned about the Alpha 1 Sound Processor falling off your head, a clip and tether are available so that the Sound Processor can be tethered to a garment you're wearing.

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6 Technical Data

Information about Magnets

Magnets in the Alpha 1 Headband, Softband, and Magnetic Implant create a permanent magnetic field. A permanent magnetic field is not the same as, and should not be compared to, an electromagnetic field such as that of a mobile telephone or a high-voltage transmission line.

None of the magnets associated with the Otomag System will affect cardiac pacemakers as long as the magnetic parts do not directly contact the pacemaker.

The magnetic implant associated with the Alpha 1(M) configuration of the device is not compatible with Magnetic Resonance Imaging (MRI). If MRI is required, the implant must be removed prior to scanning.

Warning

- Do not undergo scanning with Magnetic Resonance Imaging (MRI) if you are using an Otomag Alpha 1 Sound Processor, Magnetic Implant, Headband, or Softband.

Caution

- Keep Otomag System components away from magnetic data storage media and electronic devices. The Alpha 1 Sound Processor, Magnetic Implant, Headband, and Softband all contain magnets that can potentially damage magnetic data storage media and electronic devices.
- To avoid potential of damage to the device, do not store the Otomag System near magnets or magnetic devices other than the magnetic spacer and implant.

Patient-contacting Materials

Implant Material: The implant consists of a Samarium Cobalt sealed in a Titanium case.

Softband Material: The Softband is constructed of an elastic band and consists of approximately 85% nylon/15% Spandex.

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Portion of Headband or Softband that presses against the mastoid (bony protrusion on the skull located directly behind the ear): Fotoplast Lacquer 3 (light-curing one-component lacquer)

The components and packaging for the Otomag Bone Conduction Hearing System contain no natural rubber latex.

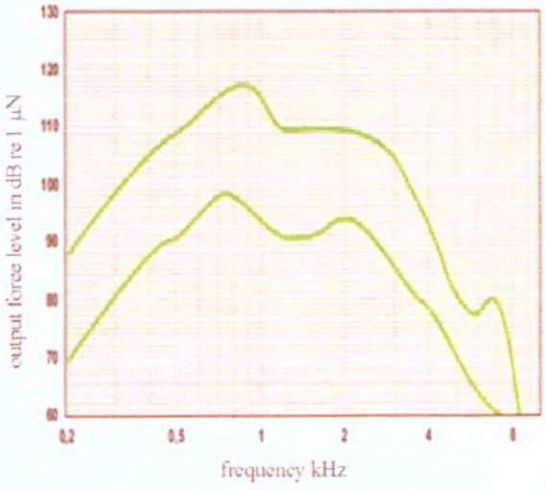
The Magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

Alpha 1 Sound Processor Technical Characteristics

- Magnetically coupled bone conduction Sound Processor
- Fully programmable digital hearing system
- Programs (programmable by audiologist)
- 4 channels
- 16 frequency bands
- Low battery warning
- Automatic noise reduction
- Automatic feedback cancellation
- Volume control
- Outer material of Alpha 1 (S): plastic with a corrosion resistant steel disk
- Weight: 10 g (with battery)

Alpha 1 Sound Processor Performance Data

(Measured according to DIN IEC 60118-9 Hearing Aids Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output)



OFL (Output force level) at 90 dB SPL – Top Line)

OFL (Output force level) at 60 dB SPL – Bottom Line)

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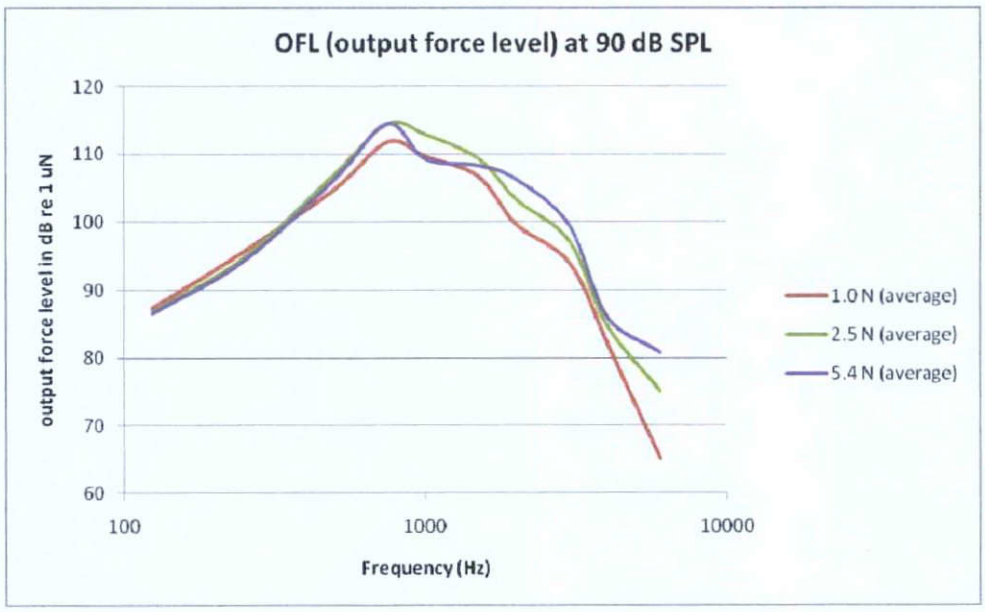
(Measured according to DIN IEC 60118-9. Averages include all configurations of softband, headband, and magnetic spacers for a given normal force)



- Acousto – mechanical gain at 60 dB SPL and 1600 Hz: 29 dB
- Maximum gain at 60 dB SPL: 38 dB re 1 μN
- Peak Output at 90 dB SPL: 115 dB re 1 μN
- Frequency range per ANSI S3.22-2009: 280-5000 Hz
- Frequency Processing Range: 125-8000 Hz
- Total Harmonic Distortion per ANSI S3.22-2009: <3%
- Equivalent input noise: 17 dB SPL
- Battery current drain: 0.95 mA
- Processor: 16 band, 4 Channel WDRC
- Crossover Frequency Options: 0-1.25, 0.25-2.75, 1.75-7.75 kHz
- Compression Attack Time: 0.25 ms
- Compression Release Time: 8192 ms
- Patient Volume Control Wheel: 38 dB range
- Power Supply: 1.3V, #675 Zinc Air Battery

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7 Patient Support

If you experience any device related issues, develop unexpected or excessive symptoms, or have general concerns or questions, please contact your hearing health specialists.

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APPENDIX 4

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Proceedings of the Second IASTED International Conference
BIOMECHANICS
September 7-9, 2005, Benidorm, Spain

MECHANICAL CHARACTERISTICS OF THE HUMAN SKULL BONE

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ABSTRACT

In the first batch of works, experimental tests are performed on post mortem human subjects. Ninety-two tests human skull bones specimens are tested. Skull bones material characteristics are identified by numerical simulations. Three classes are determined for the bone's Young modulus compared to calcination bone percentage. In the second part, a quasi-static compression test is carried out on the skull. Skull material characteristics are deduced according to percentage of bone. The behaviour law for the cranium was established on the basis of its percentage bone. Numerical simulation of this cranium has validated the class and the identified behaviour laws. The results show that elastic-plastic mechanical characteristics must be used for the skull. These results will serve in the definition of a resin material. A physical skull model will be created with this resin using stereolithography. This physical prototype will replace the head of the current models.

KEY WORDS

skull bone / mechanical properties / identification / bending test / finite elements.

1. Introduction

Each year, in industrialized countries, head traumatisms account for 50 to 70 % of accidental deaths. They are the leading cause of death in young people 15 to 24 years old. For seriously injured victims, after-effects are frequent, sometimes irreversible, and handicapping, making their socio-professional reintegration impossible thereafter. This pathology reveals real social, economic and human problems. Moreover, it affects particularly the young and active population.

Different experiments described in scientific literature confirm extreme results' dispersion. Sex, age, the post mortem human subject's (PMHS) physical state before death [1], specimen locations, PMHS preparation, and the cadaver's individual characteristics are very important data. Cadaver diversity causes morphological differences. To take into account these differences, authors such as Barber *et al* [2] tested a single skull. They identified other parameters for the concerned skull zone (frontal, parietal, temporal, zygomatic bones) using McElhaney *et al* [3]'s reference grid. Differences in bone thickness between various zones have been noted. Barber *et al* [2], McElhaney *et al* [3], and Evans *et al* [4] also noticed differences in the skull bone's mechanical characteristics. These authors confirmed variations between right and left bones. Only Hubbard *et al* [5] concluded that location or side bones have no influence on mechanical responses.

It is difficult to compare results because of the diversity of experimental protocols used and the consequent evolution of measurement devices during the last thirty years.

These mechanical characteristics have been used in many finite element models of the head. Results in scientific literature show difficulty using these models in new protection design. Number of brain injuries aren't reproducible for head cadavers and therefore they can't be analysed.

Crandall [6] determined the importance of preservation procedures for human surrogates. One hundred and fifty (150) rib samples from thirteen cows were used for bending tests. He studied six preservation procedures such as frozen and Winckler method [7]. He compared their identified Young modulus with fresh bone. Results showed that the Young modulus of frozen bone is 28 % lower than the Young modulus of fresh bone, the Young modulus of embalmed Winckler bone is lower by 7%. The author concluded that compared to a fresh cadaver, the Winckler method least affects the bone's mechanical characteristics.

This work consists of identifying skull bone constitutive law. In this study, the skull bone is considered to be a one-layer homogeneous material. Results will serve as reference to identify a resin material to be used for the development of a physical skull model. This model will be made with a rapid prototyping technique.

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2. Materials and methods

2.1. Test machine

The speed of the hydraulic machine is between 0 and 80 mm/min (see Fig. 1). The diameter of the cylindrical impactor is 20 mm.

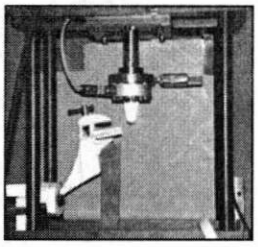

Fig. 1 : Flexible test machine

2.2. Biological sampling

Tests are carried out on anatomic specimens embalmed according to two techniques: formol and Winckler. Head measurements (a, b and c parameters) and head weights are taken (see Fig. 2).

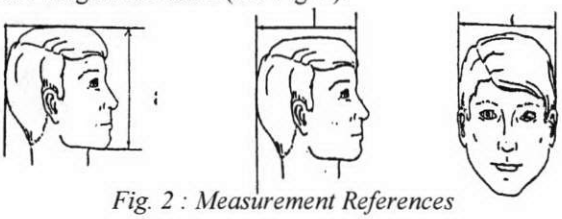

Fig. 2 : Measurement References

2.3. Bending specimen tests

92 test specimens are taken from the frontal and parietal bones of 12 skulls.

Test specimen sample

Specimens are cut from each skull at 0, 45 and 90°, with respect to the sagittal suture.

Specimens preparation

Bone sample is prepared for a simple bending test by modifying one end of the bone specimen into a cylinder with zero degree of freedom (see Fig. 3).

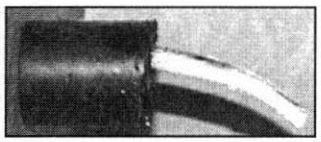

Fig. 3 : Zero degree of freedom test sample

92 bending tests on skull bone samples are carried out in quasi-static speed (40 mm/min). The information is summarized in Table 1 (head reference sample, number of test sample, sex, weight, size, age, cadaver preservation procedure).

The cadavers' average age is 86 years old, where 50 % of the cadavers are male and 58 % are embalmed by Winckler method.

Head	Specimen number	Sex	Weight (kg)	height (m)	Age (year)	Embalming
T 04	6	M	58	1.65	89	Winckler
T 05	8	M	82	1.80	83	Winckler
T 06	10	F	60	1.62	87	Winckler
T 07	9	F	60.5	1.59	88	Winckler
T 08	5	F	80	1.62	89	Formol
T 13	5	F	51	1.62	69	Formol
T 14	6	F	61	1.68	87	Formol
T 15	8	M	72	1.60	84	Winckler
T 16	12	F	63	1.64	88	Formol
T 17	9	M	42	1.70	90	Winckler
T 18	7	M	58	1.72	90	Winckler
T 19	7	M	72	1.81	84	Formol
Minimum			42	1.59	69	
Maximum			82	1.81	90	
Mean			**64**	**1.67**	**86**	
Standard deviation			12	0.07	6	

Tab.1 : General characteristics of tested skull

The frontal bone thickness is greater than the parietal bone thickness. The difference between the right and left parietal bone thickness is negligible.

Skull T06 Force/Displacement curves are presented (see Fig. 4).

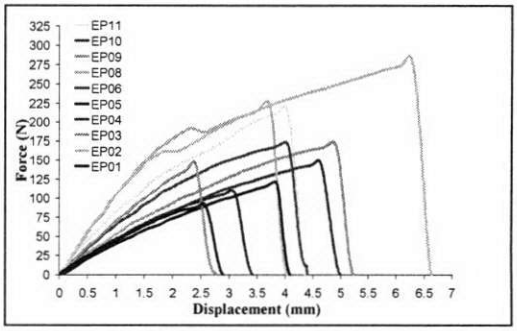

Fig. 4 : Skull T06 Force/Displacement curves

Constitutive laws can be identified with bending tests. Test specimens are considered as a straight beams.

Table 2 summarizes experimental tests results.

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	Mean	Minimum	Maximum	Standard Deviation
Mineralization (%)	**47,5**	39,9	52,6	3,8
Spongy bone thickness / total thickness (%)	**56,8**	37,8	70,4	9,6
Thickness average (mm)	**6,9**	4,9	8,6	1,1
Density average r (kg/m³)	**1938**	1842	2065	57
Analytic Young modulus E (MPa)	**3779**	2522	5194	837

Tab. 2 : Experimental tests results

However, test specimens are not straight beams (thickness are not constant, radius of curvature,...). Therefore, constitutive laws are identified with numerical simulations from real bone specimens.

Three classes are defined from obtained results :

- Class A : % Bone ≤ 40 % (T 14),
- Class B : 40 % < % Bone < 50 % (T 05, T 06, T 07, T 08 , T 13, T 15, T 16, T 19),
- Class C : 50 % ≤ % Bone (T 04, T 17, T 18).

The test specimen number (Nb Sp) whose characteristics have been identified for each skull, mean mineralization (% Bone) and mean Young modulus (E) are summarized in Table 3.

Nb Sp	Skull	% Bone	E (MPa)	Class	% Bone	E (MPa)
5	T14	39.96	1680	**Class A**	**39.96**	**1680**
6	T07	42.33	3033	**Class B**	**46.58**	**3025**
8	T05	44.69	2788			
4	T08	45.15	3425			
6	T16	46.72	3067			
5	T15	47.28	3000			
8	T06	47.37	2788			
6	T19	49.40	3167			
3	T13	49.67	2933			
4	T18	50.03	3850	**Class C**	**51.31**	**3967**
6	T17	51.30	4000			
6	T04	52.60	4050			

Tab. 3 :Identification results according to classes

Comparisons are carried out by class in order to reduce mineralization parameter influences. There is only one skull in Class A, therefore analyses will be carried out in Class B (40 % ≤ % Bone < 50 %) (see Tab. 4) and in Class C (% Bone ≥ 50 %) (see Tab. 6).

		Nb Sp	E (MPa)	Min (MPa)	Max (MPa)	Standard Deviation (MPa)
Frontal bone	**0°**	3	**4000**	3300	4700	700
	45°	6	**3000**	2200	4100	800
	90°	12	**2792**	1500	3800	828
Right parietal bone	**0°**	7	**3071**	2200	3600	439
	45°	2	**2850**	2300	3400	778
	90°	3	**2800**	2400	3200	400
Left parietal bone	**0°**	9	**3056**	2100	3600	493
	45°	2	**2200**	2000	2400	283
	90°	2	**3350**	2800	3900	778

Tab. 4 : Identification results according to sample zone in class B

The Young modulus of the 0° right parietal bone and the 0° left parietal bone are approximately equivalent. There is also a symmetry between the two bones parallel to the sagittal suture.

The Young modulus of the 0° samples is better than all the other zones and orientations.

		Nb Sp	E (MPa)	Min (MPa)	Max (MPa)	Standard deviation (MPa)
Frontal bone	**0°**	1	**5500**			
	45°	1	**3500**			
	90°	4	**4525**	3700	5900	954
Right parietal bone	**0°**	5	**3260**	2400	4200	669
	45°	1	**4600**			
	90°	2	**4450**	3800	5100	919
Left parietal bone	**0°**	0				
	45°	1	**3800**			
	90°	1	**3000**			

Tab. 5 : Identification of results according to sample zone in class C

The Young Modulus of Class C are better than the Class B modulus according to sample zones.

A database has been created which will be completed later. New tests will be carried out for certain bones in certain orientations and on younger subjects.

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3. Validation with a skull compressive test

3.1. Experimental protocol

Quasi-static axial loads are applied to the skull taken from a cadaver in order to quantify the mechanical response of the global structure (see Fig. 5). A flat rigid impactor delivered impacts to the temporo-parietal region of the fixed skull. The test speed is 40 mm/min.

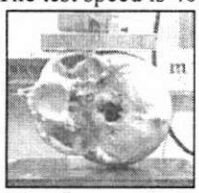

Fig. 5 : Test configuration

3.2. Experimental test results

3.2.1 Anatomical study

Measurement data

The compressed skull is taken from a cadaver, of a 74 years old male (weight 55 kg, height 1.67 m) embalmed by Winckler method. Measurements before testing are: A = 169 mm, B = 180 mm, C = 152 mm.

The skull weight is 1170 g. The mean bone percentage value obtained after specimens mineralization is 47.8 %.

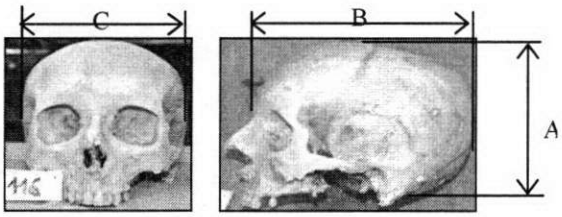

Fig. 6 : Tested skull measurements

Bone lesions analysis

Skull fractures have been noted according to X-rays and directly observed on skull (see Fig. 7).

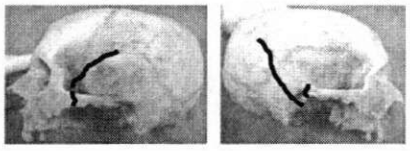

Fig. 7 : Bone lesions observed after test

Zygomatic, parietal, right and left temporal bone fractures have been noted. Fractures are linked to each other travelling toward the skull base (for the right side).

3.2.2. Mechanical study

Force/Displacement curve (see Fig. 8) may be deduced from the measurements.

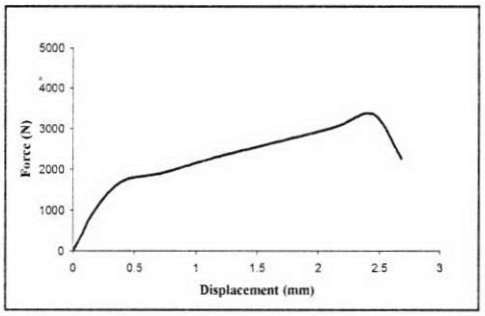

Fig. 8 : Force/Displacement curve

The tested skull has a mean bone percentage value equal to 47.8 %. It is a member of Class B. According to the database, material characteristics of this skull are: $E_{frontal}$ = 2792 MPa, $E_{pariétal}$ = 2800 MPa, E_t = 1800 MPa and σ_y = 18 MPa.

3.3. Compressive test numerical representation

Finite element meshing of the cranium was then performed using software capable of producing a 3D reconstruction semi-automatically and meshing the anatomical elements on the basis of 2D contours (MRI).
In order to realize the most realistic modelling of a cranium compression test, the real dimensions, bone density, and average thickness of the tested cranium were reproduced. The density (equal to 2088 kg/m^3 for the tested skull) and average thickness (equal to 6 mm) are as well represented in the skull finite element one (see Fig. 9). A shell model finite elements was used.

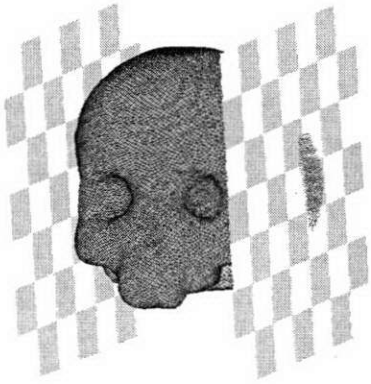

Fig. 9 : Tested skull numerical simulation

Two finite element models have been simulated (see Fig. 10) : an elastic model and an elastic-plastic model.

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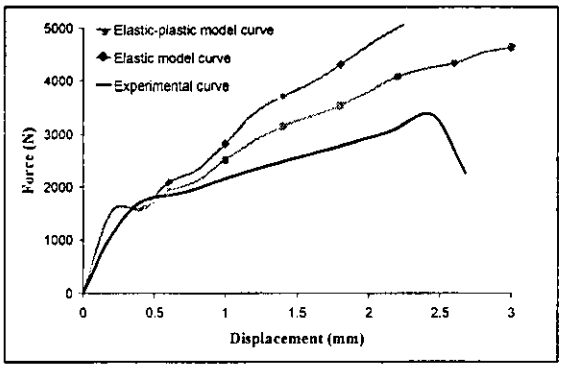

Fig. 10 : Force/Displacement curves

The Force/Displacement curve from the numerical simulation (for the elastic-plastic model) is close to the experimental curve. These results show the importance of using elastic-plastic material property in skull finite element models.

4. Conclusions

Simple bending test specimens have been taken from 12 skulls. Three classes (% Bone ≤ 40 %, 40 % < % Bone < 50 % et 50 % ≤ % Bone) have been defined according to the bone percentage value noted during mineralization. For each class, an average Young modulus is calculated. Results in accordance with orientations and sample zones have been developed.

This work shows the importance of mineralization in cadavers. With the bone percentage value, we can deduce the skull constitutive law. This law can be introduced in a finite element model of the skull.

We also showed that the skull must be considered as an elastic-plastic material. An error of about 30 % (in Force/Displacement curves) is made between elastic and elastic-plastic models.

The results of the shell model finite elements are to be checked more precisely: identification results were highly influenced and biased by element type [8]. Numerical simulation can't be performed using shell mesh and mechanical properties identified with bricks, or vice versa.

This study will permit, in the long term, the finalization of a physical skull model using rapid prototyping technique [9].

5. Acknowledgements

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Transmission properties of bone conducted sound: Measurements in cadaver heads

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In the past, only a few investigations have measured vibration at the cochlea with bone conduction stimulation: dry skulls were used in those investigations. In this paper, the transmission properties of bone conducted sound in human head are presented, measured as the three-dimensional vibration at the cochlear promontory in six intact cadaver heads. The stimulation was provided at 27 positions on the skull surface and two close to the cochlea; mechanical point impedance was measured at all positions. Cochlear promontory vibration levels in the three perpendicular directions were normally within 5 dB. With the stimulation applied on the ipsilateral side, the response decreased, and the accumulated phase increased, with distance between the cochlea and the excitation position. No significant changes were obtained when the excitations were on the contralateral side. In terms of vibration level, the best stimulation position is on the mastoid close to the cochlea; the worst is at the midline of the skull. The transcranial transmission was close to 0 dB for frequencies up to 700 Hz; above it decreased at 12 dB/decade. Wave transmission at the skull-base was found to be nondispersive at frequencies above 2 kHz whereas it altered with frequency at the cranial vault.
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I. INTRODUCTION

The mechanical properties of the human skull in relation to bone conduction (BC) stimulation have been well described in the literature. Many of these reports have focused on vibrations of the relatively thin bones of the skull, while only a few have focused on vibration transmission in the skull-base where the cochleae are situated. In order to obtain a better understanding of BC transmission in the human skull, the vibration transmission in both the cranial vault and the skull-base should be measured.

Several different aspects of skull response produced by BC excitation have been studied. von Békésy (1932) analyzed the vibration mode of the human skull and approximated it as a vibrating thin-shell sphere. The mechanical point impedance, at the mastoid portion and the forehead, with and without skin, has been investigated (Corliss and Coidan, 1955; Smith and Suggs, 1976; Flottorp and Solberg, 1976; Khalil *et al.*, 1979). The most comprehensive study of the mechanical point impedance of the human skull was made by Håkansson *et al.* (1986) on live human subjects with osseointegrated skin-penetrating titanium implants in the parietal bone for attaching bone-anchored hearing aids. In another investigation, Håkansson *et al.* (1996) investigated the linearity of vibration transmission in the skull and found it linear for normal levels and frequencies used for hearing by BC.

Khalil *et al.* (1979) used modal analysis to extract resonance frequencies from two dry skulls. Håkansson *et al.* (1994) used similar techniques to extract resonance frequencies from living human skulls. Also, the vibration of a large part of the human cranial vault has been visualized with holographic interferometry (Ogura *et al.*, 1979; Hoyer and Dörheide, 1983; Dorheide and Hoyer, 1984). Other investigations have aimed at estimating the propagation velocity and type of wave transmission in the human skull (von Békésy, 1948; Zwislocki, 1953; Franke, 1956; Tonndorf and Jahn, 1981).

Theoretical approaches to estimate the skull response during vibration stimulation have also been used. For this, thin-shell theories of spheres with fluid loading were used to achieve analytical results, or finite element analysis was used to obtain the vibration pattern (Advani and Lee, 1970; Hickling and Wenner, 1973; Khalil and Hubbard, 1977; Charalambopoulos *et al.*, 1998; Young, 2002, 2003). These analyses were intended primarily for head injury protection and not for the transmission and hearing of BC sound.

Most of these studies focused on the mechanical properties and vibration transmission characteristics of the human cranial vault. One study by Stenfelt *et al.* (2000) measured skull vibration in three perpendicular directions close to the cochlea with stimulation at the ipsilateral and contralateral mastoid as well as at the forehead. The drawback with that study was that only one dry human skull was used. The current study presents measurements of the cochlear promontory vibration in three perpendicular directions, using stimulation at numerous positions on the skull in intact hu-

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TABLE I. Data of the six human cadaver heads used for the measurements. The circumference was measured as a line going from the center of the forehead passing just above the ear canal openings, over the occiput and back to the mid-forehead.

No.	Sex	Age (years)	Circumference (cm)	Ear-ear via vertex (cm)	Mass (kg)
1	M	60–70	53	31	3.25
2	M	60–70	54	33	3.31
3	M	60–70	56	31	3.43
4	M	60–70	57	34	3.59
5	M	60–70	58	35	3.71
6	M	60–70	58	36	3.78

TABLE II. Typical stimulation vectors at the test positions. The figure given in the table for a particular position and direction should be multiplied by the input force to give the stimulation in that direction at that position.

	Forehead			Vertex			Occiput		
Position	x	y	z	x	y	z	x	y	z
0	0	0.34	−0.94	0	1	0	0	0.09	1
1	0.24	0.34	−0.91	0.45	0.89	0	0.34	0.09	0.94
2	0.58	0.42	−0.69	0.71	0.71	0	0.87	0	0.50
3	0.85	0.17	−0.49	0.98	0.17	0	0.98	−0.14	−0.17
4	0.97	0	−0.26	0.98	−0.17	0	0.98	−0.17	0.03

man heads. Furthermore, the mechanical point impedances at the stimulation positions have been analyzed to reveal the mechanical properties of the human head.

II. MATERIAL AND METHODS

A. The cadaver heads

For the experiments, six male human cadaver heads were used. The heads were severed between the third and fourth vertebra and frozen at the time of autopsy. Apart from being severed, no drilling or cutting of the heads was done during the autopsy; the soft tissues and brain were left intact. No history of the heads was known except that they were male and between 60 and 70 years old; the sizes and weights of the heads are presented in Table I. All heads were defrosted 24 h prior to the measurements. A thin probe thermometer was positioned through the foramen magnum into the center of the brain to verify that the heads were properly defrosted. This thermometer was thereafter removed.

Three imaginary arcs were identified on the skull. The occiput arc connects the two ear canal openings over the most posterior part of the occiput (Fig. 1). On this arc, nine positions were identified. Position 4, the position closest to the ear canal opening, was placed about 20 mm posterior to the entrance to the ear canal, while position 3 was 20 mm posterior to position 4. The others were placed at equal distances, with a distance of 30 mm for the smallest head and 36 mm for the largest head. One position, position 0, was at the midline between the ears.

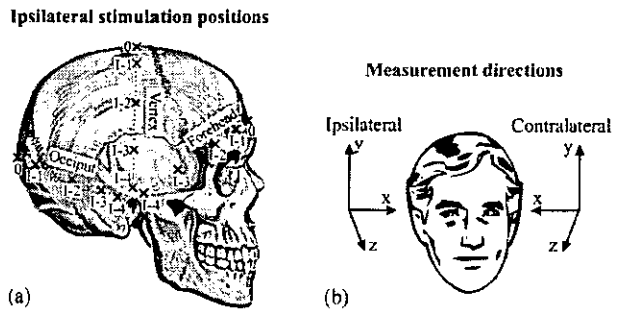

FIG. 1. (Color online) (a) Three stimulation arcs were identified on the heads: forehead, vertex, and occiput. Nine stimulation positions with an approximate spacing of 30 mm were equally spread on each line: the figure shows the positions on the ipsilateral side. (b) The measurement directions of the ipsilateral and contralateral cochleae: x direction—towards the middle of the head, y direction—towards the top of the head, and the z direction—towards the front of the head. The ipsilateral and contralateral x direction points towards each other (180° out of phase) while the two other directions are the same for the ipsilateral and contralateral sides.

At each position a small hole was drilled and tapped (diameter 3 mm). A connector comprising a screw with 3-mm metric threads (M3) was placed in this tapped hole. To further ensure a rigid bond between the connector and the skull, a drop of cyanoacrylate glue (Garf Reef glue™, Garf, Boise, ID, USA) was put into the threaded hole prior to placement of the connector. The connector had also a threaded part to attach a mini-transducer for the vibration excitation; the connector enabled rigid attachment between the transducer and the skull.

The vertex arc is between the ear canal openings passing over the vertex and the forehead arc connects the ear canal openings passing over the center of the forehead. Positions 4 for these two arcs are 30 mm from the ear canal openings, and the rest of the positions are between 31 and 38 mm apart, depending on head size. For each arc, four positions were at each side of the skull with one position at the midline. The heads were excited at 27 positions in total. A 1-cm^2 piece of skin and soft tissue was removed around each stimulation position to enable placement of the connector with attached stimulation transducer.

Three perpendicular directions were defined for the skull vibration measurements. The three directions are shown in Fig. 1 (right): x direction medially (towards the midline of the skull), y direction cranially (towards the top of the skull), and z direction anteriorly (towards the front). It should be noted that the x directions at the two sides of the skull are directed towards each other, while the y and z directions are the same on both sides. The stimulation was applied to the skull bone surface in a direction approximately perpendicular to the skull bone surface. This means that the direction of the vibration stimulation is different at each stimulation position. Table II presents, for one head, the vector components of the stimulation direction according to the coordinate system given in Fig. 1. Although not exactly equal, the stimulation directions at the positions were similar for all heads.

The stimulation direction influences the response direction. For example, if the skull moves as a whole and translational vibration is the dominating mode, the response direction is expected to be similar to the stimulation direction. However, if the dominating mode of vibration is rotational or some type of wave propagation, vibration responses in all spatial directions can be expected.

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One phenomenon that can contribute to the perception of BC sound is the relative motion between the middle ear ossicles and the surrounding bone. This occurs due to the inertial movement of the ossicles. Although the middle ear ossicles move regardless of the vibration direction, the greatest relative motion is obtained when the vibration is along the low-frequency in-and-out motion direction of the stapes (Stenfelt *et al.*, 2002). According to the coordinate system given in Fig. 1, the low-frequency in-and-out motion of the stapes is in the x-z plane, 30° from the x axis and 60° from the z axis.

B. Mechanical impedance measurements

Measurements of the mechanical point impedance[1] were conducted at each stimulation position. The force and acceleration at the attachment point was obtained by a B&K type 8001 impedance head (Brüel and Kjær, Nærum, Denmark). The impedance head was rigidly attached to the connector at the stimulation positions. The cadaver heads were oriented so the impedance head was aligned vertically for each measurement. This was done to avoid excessive shear and bending forces on the force gauge in the impedance head, and also to ensure translational stimulation of the impedance head and connector. The cadaver heads were, for the impedance measurements as well as all other measurements, placed on a pillow to vibrationally decouple the heads from the measurement table.

The outputs from the acceleration and force gauges were supplied to two charge amplifiers (B&K type 2635) and then to the inputs of the measurement system. The PC based software SYSid 6.5 (www.sysid-labs.com), together with a DSP-16+ signal processing card, formed a two-input-channel measurement system that also provided the stimulation signal. The stimulation signal was fed through a power amplifier (D-75, Crown, Elkhart, IN, USA) to a miniaturized bone-transducer, termed the mini-transducer. This transducer has a screw attachment that could connect to either the impedance head or to the screw connectors in the skull. The SYSid measurement system, together with the power amplifier and mini-transducer, was used for all measurements conducted in this investigation.

C. Accelerometer measurements

The vibratory response during excitation was measured as the acceleration of the cochlear promontory in three perpendicular directions. In order to measure the vibration responses in these three directions, a triaxial accelerometer was used (Endevco model 7253C-10, Endevco, San Juan Capistrano, CA, USA). This accelerometer has a size of $15 \times 15 \times 7$ mm^3 and weighs 3.6 g. The triaxial accelerometer was attached to the cochlear promontory by cyanoacrylate glue (Garf Reef glue™, Garf, Boise, ID, USA). To enable positioning of the accelerometer on the cochlear promontory, the auricle was removed and the bony ear canal widened using a drill. To verify that the widening of the ear canal did not affect the vibratory response of the skull, the vibration of the cochlear promontory was measured by a laser Doppler vibrometer before and after the drilling. For these measurements, the vibration transducer was attached to position I-4 on the occiput arc. The two measurements were within the test-retest results found for the vibration measurements when all equipment was removed between the measurements.

D. Laser Doppler vibrometer measurements

The triaxial accelerometer was glued to one cochlear promontory in each of the six heads; on the right side in three and on the left side in three. On the cochlear promontory opposite to the side where the accelerometer was attached, the vibratory response was measured by a laser Doppler vibrometer (LDV)(HLV-1000, Polytec, Waldbronn, Germany). The auricle was removed on this side as well; no drilling of the ear canal was required and the ear canal was left intact. The ear drum was removed together with the malleus and incus. This enabled the laser-beam to reach the cochlear promontory. A good reflection of the laser beam was achieved by a glass bead approximately 5 μm in diameter positioned on the cochlear promontory. Such LDV measurements of BC vibrations have previously been demonstrated reliable (Stenfelt *et al.*, 2002).

The laser head was mounted on an operating microscope with a joystick to control the laser beam. During the measurement, the laser beam was oriented to align with the x direction. Since the stimulation positions were symmetrically spread over the skull, the ipsilateral stimulation positions for the accelerometer measurements served as contralateral positions for the LDV measurements and vice versa. Consequently, the accelerometer and LDV measurements are only expected to be similar, not exactly equal. Also, the LDV measures in one direction (x direction), whereas three perpendicular directions were obtained with the triaxial accelerometer.

E. Stimulation close to the cochlea

After the previously mentioned measurements were finished, the mastoid portion of the temporal bone was drilled open down to the semicircular canals. A connector screw was attached at the point where the three semicircular canals come close together. This was done bilaterally, and then the same measurements repeated with the mini-transducer attached close to the cochlea. The reasons for the measurement with the stimulation close to the cochlea are twofold. First, the stimulation and response are both in the petrous part of the temporal bone that encapsulates the cochlea. Some of the transmission properties in this bone are normally masked by the skull structure response when the stimulation is applied at the skull surface. Such transmission properties can be revealed using this approach. Second, any improvement in the cochlear promontory vibration level with a source close to the cochlea can be quantified.

F. Calibration

The mini-transducer used was similar to the transducers used in the bone-anchored hearing aid (BAHA®, Tjellström *et al.*, 2001). It was the same transducer as the one used in the study of vibration transmission in a dry human cadaver skull (Stenfelt *et al.*, 2000). The calibration of the mini-

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transducer was done on a Skull-Simulator TU-1000 (Håkansson and Carlsson, 1989). This calibration produces the dynamic output force from the transducer for a specific input voltage. The B&K impedance head used for the mechanical impedance measurements was calibrated by two measurements. First, a mass of 50.00 g was attached to the impedance head and the sensitivity of the impedance head was determined (force/acceleration). Then, a measurement was made with the connector unit attached to the impedance head. This measurement was later used for cancellation of the mass below the force gauge and connector unit in the impedance data. During the calibration measurements, the impedance head was driven by a B&K type 4810 mini-shaker.

The low-pass and high-pass filters incorporated in the LDV were used; the low-pass filter cutoff frequency was set at 15 kHz and the high-pass filter was set at 100 Hz. The response of the LDV with these settings was calibrated using an accelerometer (B&K type 4371). According to the manufacturer, this accelerometer has a maximum level deviation of 0.2 dB and a maximum phase deviation of 5°. The accelerometer was mounted on the B&K 4810 mini-shaker and the laser beam aimed perpendicular to the accelerometer surface. With this setup, the amplitude and phase of the LDV were calibrated for the frequencies 0.1 to 10 kHz.

The Endevco model 7253C-10 triaxial accelerometer was calibrated using the LDV. The triaxial accelerometer was mounted with beeswax on a circular adapter attached to the B&K 4810 mini-shaker with the laser beam aimed perpendicular to the accelerometer surface. With this setup, the accelerometer response in the three directions was compared with the calibrated LDV response for frequencies between 0.1 and 10 kHz. Within this frequency range, the maximum level and phase deviation between any direction of the accelerometer and the LDV were 0.2 dB and 3°, respectively. Since this was within the uncertainty limits for the LDV calibration, the sensitivity data given by the manufacturer were used for the triaxial accelerometer.

The rigidity of the glue bond between the cochlear promontory and the triaxial accelerometer was also verified. The laser beam was aimed at the cochlear promontory close to the accelerometer and the vibration response in the x direction measured with both the LDV and accelerometer when the mini-transducer was attached to position occiput arc I-4. With this setup and for frequencies between 0.1 and 10 kHz, the maximum level and phase deviation in any of the six cadaver heads between the LDV and accelerometer measurements were 2.1 dB and 17°, respectively. However, these maximum deviations occurred when the skull showed resonances or antiresonances and were of narrow frequency bandwidth. Discounting these larger deviations of narrow bandwidth, the differences in level and phase between the LDV and accelerometer were bounded by 0.6 dB and 7°, respectively.

G. Distortion

In an investigation by Håkansson *et al.* (1996), the linearity of bone-conducted sound was investigated in live humans for levels corresponding to 77 dB HL. They reported, for those levels, the BC sound transmission to be predominantly linear. In this investigation, the linearity of BC vibration transmission in the skull was not analyzed *per se*. However, the second and third harmonics were studied at each measurement to verify that all equipment functioned properly. The levels of these harmonics were similar to those generated when calibrating the mini-transducer on the skull simulator. Hence, the harmonics in the measurements in this study were chiefly caused by the stimulus generating electronics and the mini-transducer, and not by the vibration transmission through the skull bone. Consequently, any distortion that might be generated in the skull bone was minimal during these tests where the BC stimulation corresponded to levels of 80 to 100 dB HL.

III. RESULTS

A. The mechanical point impedance

The mechanical point impedance was measured at 27 positions on each of the six heads. We considered the heads to be symmetric about the sagittal plane and pooled measurements from the right and left side of the skulls. This pooling produced 12 separate measurements (from the two sides of the six heads) to describe the response at each of four positions (1–4) along the three stimulation arcs (forehead, vertex, and occiput). However, at each of the 0 positions (which are on the sagittal plane), there was only one measurement made in each skull (for a total of six).

The results, as magnitude and phase, of the individual measurements as well as the mean for all positions, are presented in Fig. 2. Similar trends in the impedance data are seen for the individual data at all positions. At the lowest frequencies, below 150–400 Hz, the impedance increases with frequency indicating a mass-controlled system. This is also indicated by a positive phase. At these low frequencies, the head moves as a whole which is reflected in the impedance data.

Depending on position, the maximum magnitude of the mechanical impedance is between 150 and 400 Hz. At the maximum magnitude frequency, the corresponding phase is close to 0° and this frequency is defined as the resonance frequency for the mechanical impedance. Above the resonance frequency, the magnitude of the mechanical point impedance falls with frequency and the accompanying phase drops to approximately −80°, suggesting a stiffness controlled system. At higher frequencies, the phase increases slightly and the average phase of the impedances is between −60° and −20° at 10 kHz. At around 3 kHz, the impedance becomes influenced by the losses in the system. This is seen in the phase as well as in the magnitude data that starts to flatten out above that frequency.

Two general trends can be seen when comparing the impedance data between the positions. First, slightly greater levels of the mechanical point impedances are found at the positions on the occiput arc compared with the other two stimulation arcs. Second, greater impedance magnitudes and higher resonance frequencies are found when moving from the ear canal (position 4) to the mid-sagittal plane (position

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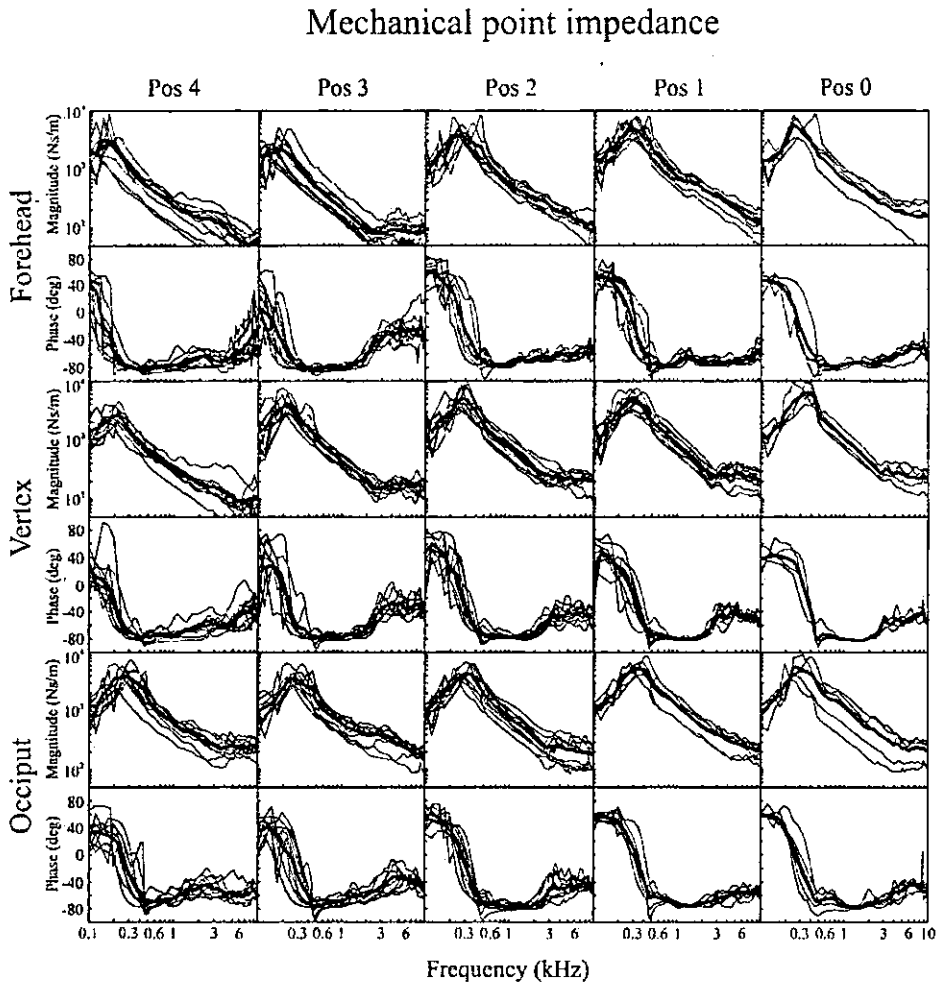

FIG. 2. The mechanical point impedance as magnitude and phase for the positions 0–4 at the three stimulation arcs, forehead, vertex, and occiput. Since the measurement positions are symmetrically spread, the impedance results are pooled to the positions 0–4 regardless of head-side (12 measurements at position 1–4 and 6 measurements at position 0). The individual results are displayed as thin lines and the average as a thick line.

0). We would like to present two possible explanations for the observed results based on (1) geometrical differences and (2) bone thickness and density differences.

The measured point impedance reflects the motion perpendicular to the skull surface at that specific position. However, this motion is a combination of whole head translational and rotational motions as well as local deformation motion of the skull bone. With this in mind, the explanation for the first observation can be that the occiput arc is closer to the skull-base and has a smaller curvature radius than the vertex and forehead arcs. This would give slightly greater stiffness of the bone and corresponding greater impedance magnitude and higher resonance frequency. Another explanation for the first observation can be that the skull bone is thicker along the occiput arc than at the other two arcs. A thicker skull bone would result in a higher stiffness and corresponding higher impedance magnitude and resonance frequency.

The second observation can be explained similarly. The skull is not symmetrical as a sphere but more like an ellipsoid with flat sides. Such geometry produces greater stiffness at positions with a smaller curvature radius and smaller flat sections (as at the sagittal plane) than at positions in the middle of a larger flat section. The sides of the head, where the ears are situated, form a relatively large flat section including the temporal part of the parietal bone. Consequently, the bone close to the ear (positions 3 and 4) is more flexible than the bone close to the sagittal plane (positions 0 and 1), so the impedance and resonance frequency should be elevated closer to the sagittal plane than close to the ear, as shown in Fig. 2. However, the thickness of the skull bone is not constant. In general, slightly thicker skull bone is found around the sagittal plane of the head than at the sides. Such thickness distribution would also produce the result seen in Fig. 2. Since these two phenomena produce similar results, it is difficult to conclude if one is dominating.

B. Accelerance of the cochlea in a single head

With the triaxial accelerometer on the cochlear promontory, the response acceleration was measured in three perpendicular directions (x, y, and z direction) for 27 stimulation positions. The acclerances (acceleration divided by force) from these measurements in one head, as level and phase, are presented in Fig. 3. The results are grouped for each stimulation position; the responses in the x direction are shown with a solid line, in the y direction with a dashed line, and in the z direction with a dotted line. The panels labeled I-1 to I-4 are the results obtained with the stimulation applied at positions 1–4 at the ipsilateral side. Panels labeled C-1 to C-4 are the vibration responses at the cochlear promontory with the stimulation at the positions 1–4 on the contralateral

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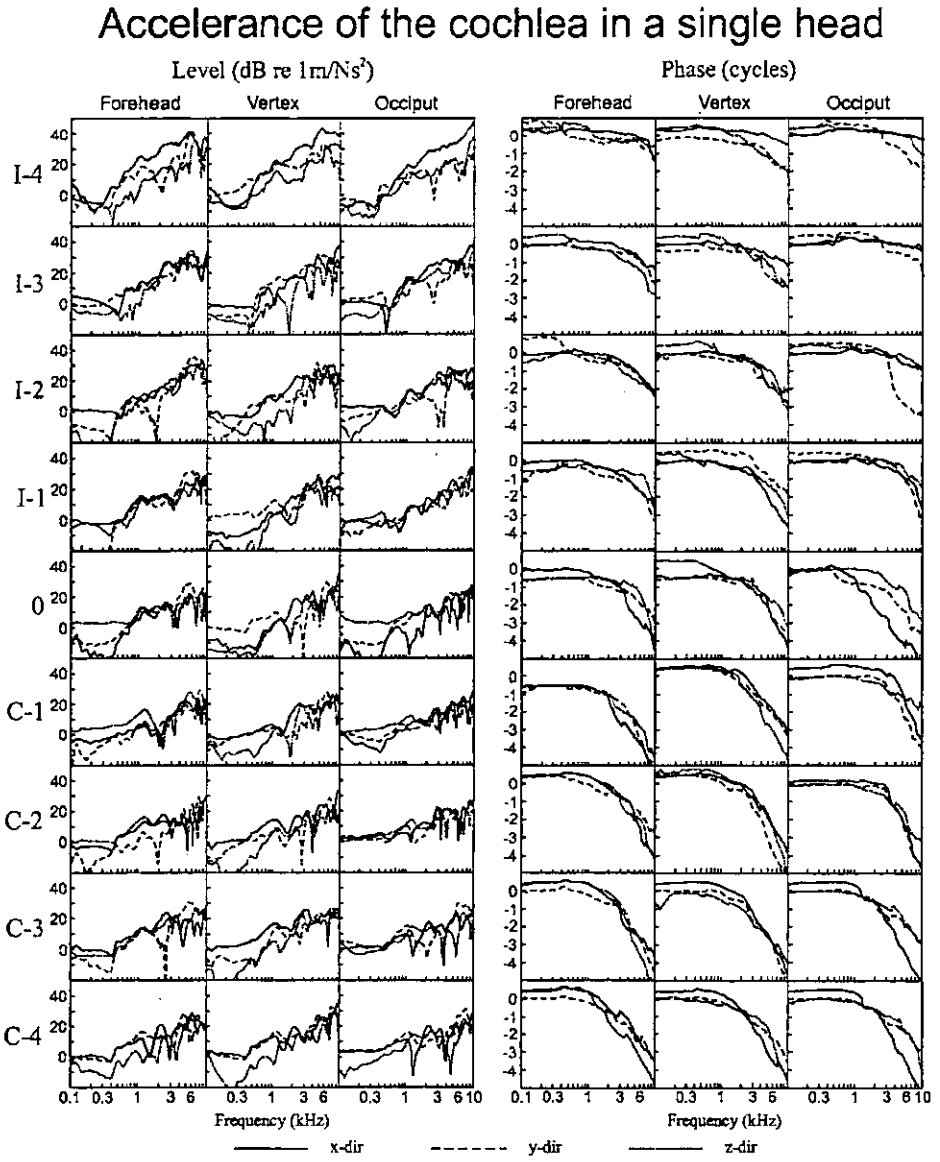

FIG. 3. The accelerance (acceleration/force) as level (*re*: 1 m/Ns^2) and phase (cycles) measured on the cochlear promontory for all three measurement directions (x,y,z) and all stimulation positions (27) in one individual head. The stimulation was applied by a mini-transducer rigidly attached to the skull-bone surface. With the stimulation applied on the ipsilateral side, the results are displayed as I-1 to I-4, with the stimulation at the mid-sagittal plane as 0, and with the stimulation positions on the contralateral side as C-1 to C-4. The results are divided into the stimulation arcs, forehead, vertex, and occiput, and the directions are separated by the patterns: x direction—solid line, y direction—dashed line, and z direction—dotted line.

side; the panels labeled 0 are the results with the stimulation applied on the mid-sagittal plane of the skull.

The level responses should be interpreted as the acceleration level in m/s^2 in the three directions, when the excitation is a vibration of 1 N at the stimulation position. The accumulation of phase is indicative of the time delay, due to vibratory wave transmission in the skull bone between the stimulation position and the cochlear promontory. At low frequencies, approximately below 500 Hz, the responses are similar for all stimulation positions: around 0 dB *re*: 1 m/Ns^2 and a flat phase close to 0 or ±0.5 cycles. At theses low frequencies, the skull moves as a whole (rigid body motion) and the responses are determined by translational and rotational inertia. Since the application of the vibration transducer is approximately perpendicular to the skull surface, the stimulation direction differs between the positions (cf. Table II). The low-frequency response is a function of the relative excitation in the three stimulation vectors and the six degrees of freedom rotational and translational responses.

Above the frequency area of rigid body motion of the skull, the accelerance increases with frequency. The differences between the response directions depend on stimulation position. With the stimulation at positions I-4, the response vibration at the cochlear promontory is greatest in the x direction. Also, the overall accelerance is greatest at positions I-4. In general, for stimulation on the ipsilateral side, the response level decreases and accumulated phase increases with distance between the stimulation position and the cochlear promontory. When the stimulation is applied on the contralateral side, no systematic differences between the positions C-1 and C-4 can be identified; the responses are similar in both level and phase. Except for the stimulation positions closest to the cochlea (I-4), no overall dominating response direction is seen; the response is in all three directions whether the stimulation is applied at the ipsilateral or contralateral side.

The number of antiresonances[2] in the accelerance functions in Fig. 3 increases with distance from the cochlea. Most antiresonances are found when stimulation is on the contralateral side close to the sagittal plane (positions 0 to C-2). A general observation is that these antiresonances do not

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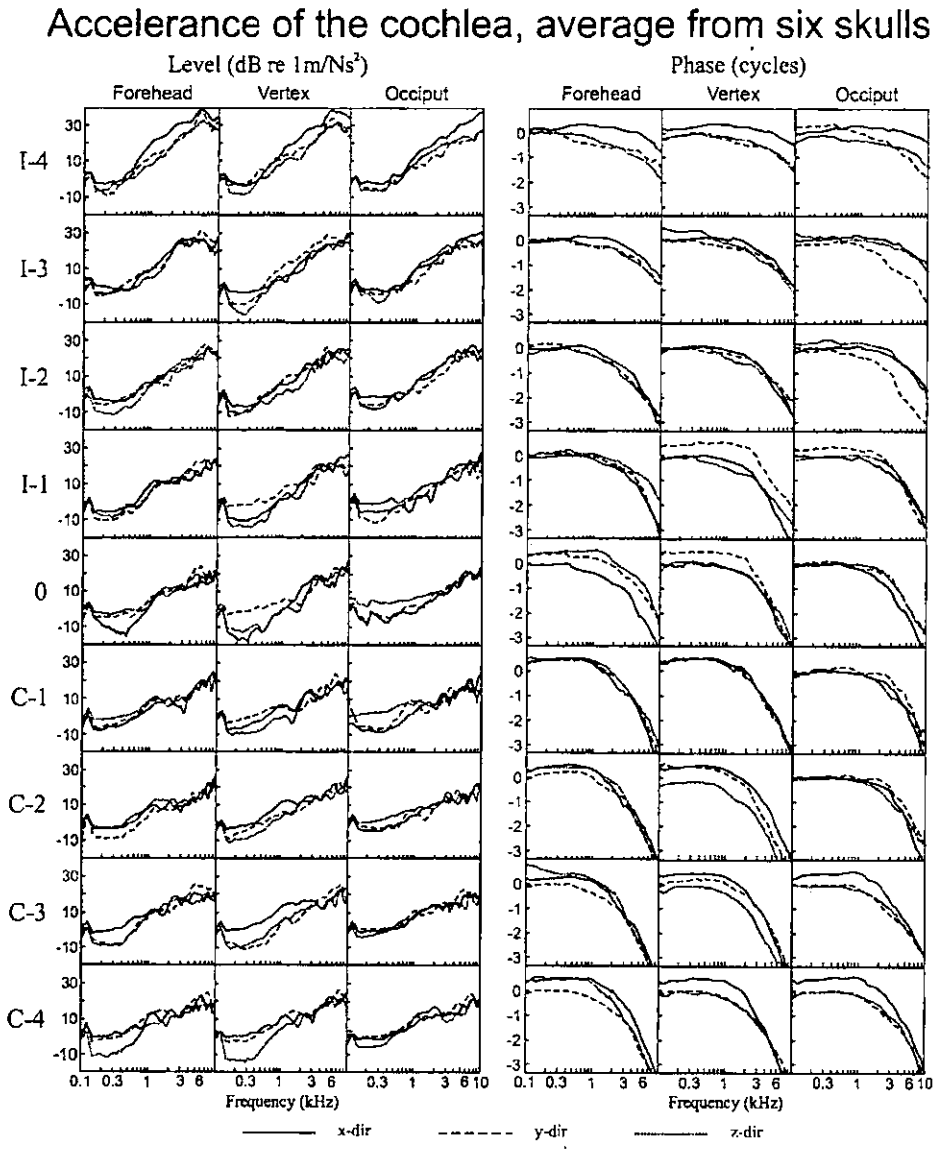

FIG. 4. The average of the accelerance as level and phase from the six heads. The results are averaged for each direction (x, y, and z) and each stimulation position (27). The data have been divided into the stimulation arcs, forehead, vertex, and occiput. The results in the x direction are displayed with a solid line, in the y direction with a dashed line, and in the z direction with a dotted line.

occur in all three directions at the same frequency. The antiresonances can be easily seen in the level response whereas the resonances are difficult to identify by examining the level and phase data in Fig. 3; this indicates that they are highly damped and do not significantly influence the measured response levels.

A phenomenon that may contribute to the vibration response is intracranial standing waves. With a wave speed of approximately 1500 m/s, such intracranial standing waves would produce an antiresonance near 4 kHz and a resonance near 8 kHz that would appear in the contralateral responses. Since it is almost impossible to distinguish between resonances and antiresonances caused by intracranial standing waves and wave transmission in the cranial vault, the results obtained can neither verify nor refute the existence of intracranial standing waves.

C. Average accelerance of the cochlea from six heads

Figure 4 presents the results of the accelerance measurements from the 27 stimulation positions in three directions similar to Fig. 3: the difference is that Fig. 4 presents the average results from all six heads used in this investigation. When the stimulation is applied in the x direction close to the cochlea, that direction produces the greatest responses. When the stimulation is further away from the cochlea, no dominating response direction is found; the response levels are similar in all three directions. At the low frequencies, below approximately 500 Hz, the accelerance level is close to 0 dB *re*: 1 m/Ns^2 and the phase is flat, indicating rigid body motion. At higher frequencies, the accelerance level increases and more phase is accumulated. Also, more phase is accumulated with distance between the stimulation position and the cochlear promontory, indicating longer time delay for the wave transmission in the skull bone. With the stimulation at the ipsilateral side, the accelerance level at frequencies above 500 Hz decreases with distance between stimulation position and the cochlear promontory. When the stimulation is at the contralateral side, no significant difference in the accelerance levels is found.

One way to compare the vibration at the cochlear promontory for different stimulation positions is to calculate a

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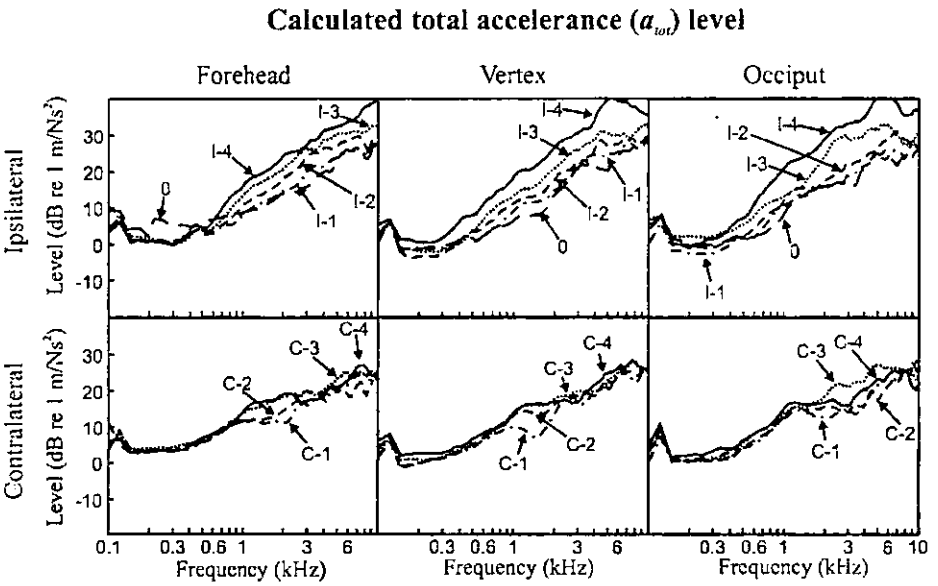

FIG. 5. The average of the total accelerance (a_{tot}) level calculated as the quadratic summation of the accelerances in the three directions from each stimulation position. The results are displayed for the stimulation arcs (forehead, vertex, and occiput) and for the stimulation side of the skull (ipsilateral and contralateral). The accelerance levels with stimulation at the ipsilateral side are displayed as position I-4—solid line, position I-3—dotted line, position I-2—dashed line, position I-1—dashed-dotted line, and position 0 (mid-sagittal plane)—long dashed line. Similarly, the results with contralateral stimulation are position C-4—solid line, position C-3—dotted line, position C-2—dashed line, and position C-1—dashed-dotted line.

single vibration response for each frequency. The total accelerance can be computed as a sum of the three orthogonal accelerance components (quadratic summation). This can be seen as a measure of the vibratory energy. The summation is

$$a_{tot}^2 = a_x a_x^* + a_y a_y^* + a_z a_z^*, \quad (1)$$

where a_{tot} is the calculated accelerance and a_x, a_y, and a_z are the accelerances in the x, y, and z directions, respectively. The * in Eq. (1) indicates the complex conjugate. The total accelerance a_{tot} according to Eq. (1) is presented in Fig. 5. The acclerances with ipsilateral stimulation are presented in one panel for each stimulation arc, and the results with contralateral stimulation in one panel for each stimulation arc (forehead, vertex, and occiput). The results in Fig. 5 are the averages from all six heads investigated; they include the results already found in the single and averaged accelerances (Figs. 3 and 4). At low frequencies, approximately below 500 Hz, no significant difference in accelerance is found between stimulation at the different positions, whether ipsilateral or contralateral. Above 500 Hz and with ipsilateral stimulation, the accelerance level is greatest when the stimulation is closest (position I-4) and worse when it is at the mid-sagittal plane (position 0), gradually decreasing from position 4 to position 0. With the stimulation at the contralateral side, the accelerances are similar. No significant difference can be seen between the three measurement arcs, forehead, vertex, and occiput.

D. Laser Doppler measurements

Accelerances measured with the LDV are presented in Fig. 6 as level and phase averaged from the six heads. The LDV only measures the vibration in one direction, here the x direction, and the results in Fig. 6 are compared with the results in the x direction in Fig. 4. However, the stimulation positions used for the ipsilateral results with the LDV are the same stimulation position used for the contralateral results with the triaxial accelerometer and vice versa. The results using the two measurement techniques are therefore not expected to be exactly equal, only similar. The level correspondence of the accelerance measurement with the LDV and the accelerometer is in general better than 2 dB; however, some exceptions with up to 5-dB differences at limited frequency areas exist. The phase difference of the accelerance between the two measurement methods increases with frequency and are, for most measurements, between 0.1 and 0.5 cycles at 10 kHz. The exception is for stimulation at position C-4 in the vertex arc where the phases differ by more than 1.5 cycles at the highest frequencies. Although the phases differ greatly at some positions, the results obtained with the LDV correspond fairly well with the x direction results obtained with the accelerometer. Unless otherwise stated, the vibration results of the cochlear promontory presented hereafter are from data obtained with the accelerometer.

E. Relative sensitivity, ipsilateral stimulation

From Figs. 3–6 it is clear that the greatest vibration of the cochlear promontory is obtained when the stimulation is closest to the cochlea, i.e., when the stimulation is at positions I-4. To compare the efficiency of vibration transmission, in terms of vibration level, from the ipsilateral positions to the cochlear promontory, the relative accelerance was computed (Fig. 7). All measurements presented in Fig. 7 are compared with position occiput arc I-4 (reference position). The comparisons are conducted for vibration measurements in the x direction and the total vibration response (a_{tot}) according to Eq. (1). In the x direction, relative levels and phases are presented, whereas only the relative levels are presented for total accelerance (a_{tot}).

The general finding of the comparison is that the closer to the cochlea the stimulation position is, the greater the stimulation level and the less phase accumulates (less time delay). The relative total accelerance levels are similar, and the x direction phase differences are close to 0 cycles at frequencies below 500 Hz. This is where the heads move as a whole and the relative a_{tot} results are expected to be similar. However, some differences can occur due to imperfect alignment of the stimulation axis and the heads center of gravity;

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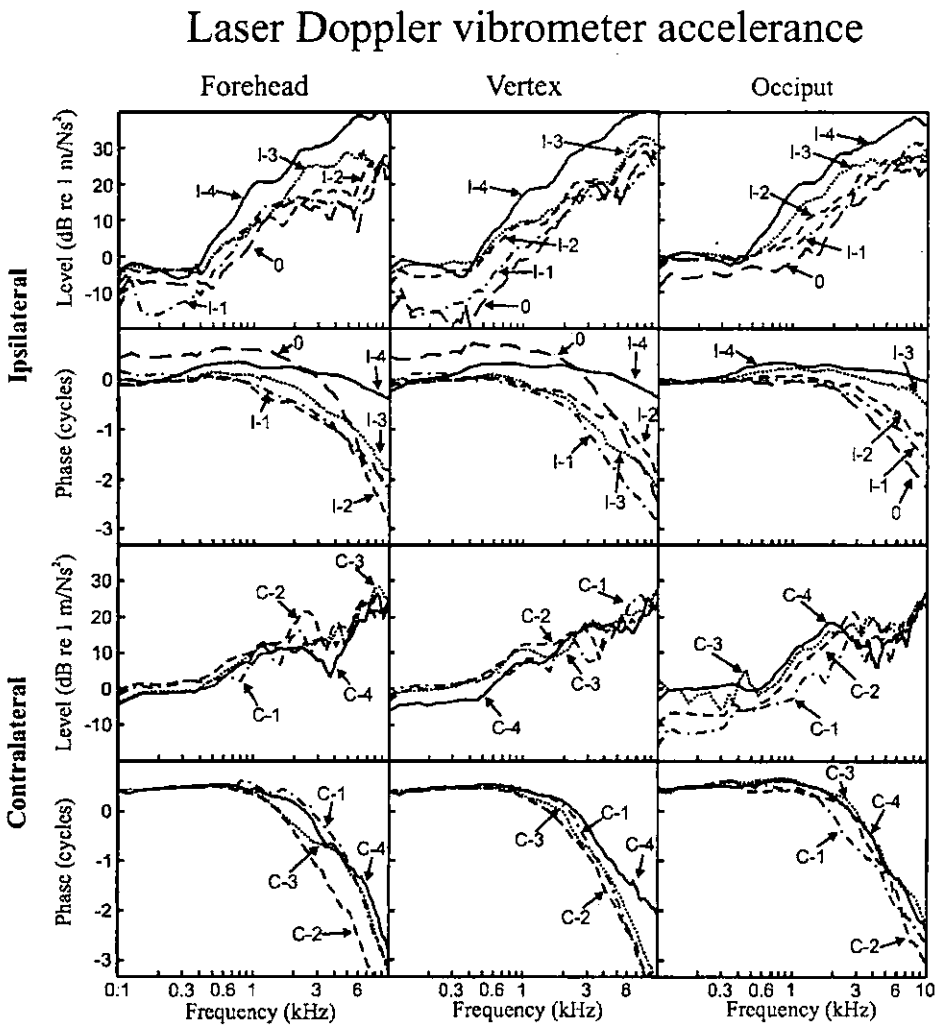

FIG. 6. The accelerance in the x direction as level and phase measured with the laser Doppler vibrometer aimed at the cochlear promontory. The accelerances displayed are the average of the result from the six heads. The results with ipsilateral stimulation are displayed as position I-4—solid line, position I-3—dotted line, position I-2—dashed line, position I-1—dashed-dotted line, and position 0 (mid-sagittal plane)—long dashed line. Similarly, the results with contralateral stimulation are position C-4—solid line, position C-3—dotted line, position C-2—dashed line, and position C-1—dashed-dotted line.

this could give slightly different translational and rotational skull motions. The relative levels of the x direction differ considerably with stimulation position at low frequencies. This is caused by the stimulation direction: at positions close to the cochlea (positions 3 and 4) the stimulation direction is almost solely in the x direction while, at positions further from the cochlea (positions 0–2), it gradually aligns in the y-z plane (cf. Table II).

According to the a_{tot} panels in Fig. 7, the transmission loss increases by approximately 1 to 3 dB for each position further away from the cochlea at frequencies above 1.0 kHz. Positions I-4 at the vertex and forehead stimulation arcs show greater cochlear vibration response compared with position I-4 at the occiput arc: position I-4 at the vertex arc produces 3 to 7 dB greater vibration response for frequencies between 0.5 and 7.0 kHz, and position I-4 at the forehead arc produces 5 to 10 dB greater response between 0.7 and 7.0 kHz. The results measured in the x direction are similar to the total accelerance results for all three stimulation arcs with stimulation at positions 3 and 4. At these positions, vibration in the x direction dominates the vibration response and, consequently, the total x direction accelerance responses are similar. For the other positions, stimulation in the x direction shows generally worse transmission relative to position occiput arc I-4 than when the response is analyzed according to the total transmission (a_{tot}). In terms of transmission efficiency, the worst position to place a BC transducer is on the mid-sagittal plane. For frequencies above 1 kHz, the difference in vibration transmission between positions I-4 and the position 0 is 10 to 20 dB for the total accelerance transmission and 15 to 25 dB when the measurements are in the x direction.

F. Transcranial transmission

The term transcranial attenuation is often used as a measure for the difference in vibration level between the ipsilateral and the contralateral side of a human head. Here, we use the term transcranial transmission defined as the vibration at the contralateral cochlear promontory relative to the vibration at the ipsilateral cochlear promontory for a specific stimulation position. With this definition, the transcranial transmission is theoretically 1 for any stimulation applied on the sagittal plane (same vibration response at both cochleae). The transcranial transmissions for stimulation positions 1–4 at all three stimulation arcs are presented in Fig. 8. Similar to the presentation in Fig. 7, the analysis is conducted for measurements in the x direction (level and phase) and for the total vibration response (a_{tot}) according to Eq. (1).

Several general trends are found in the data displayed in

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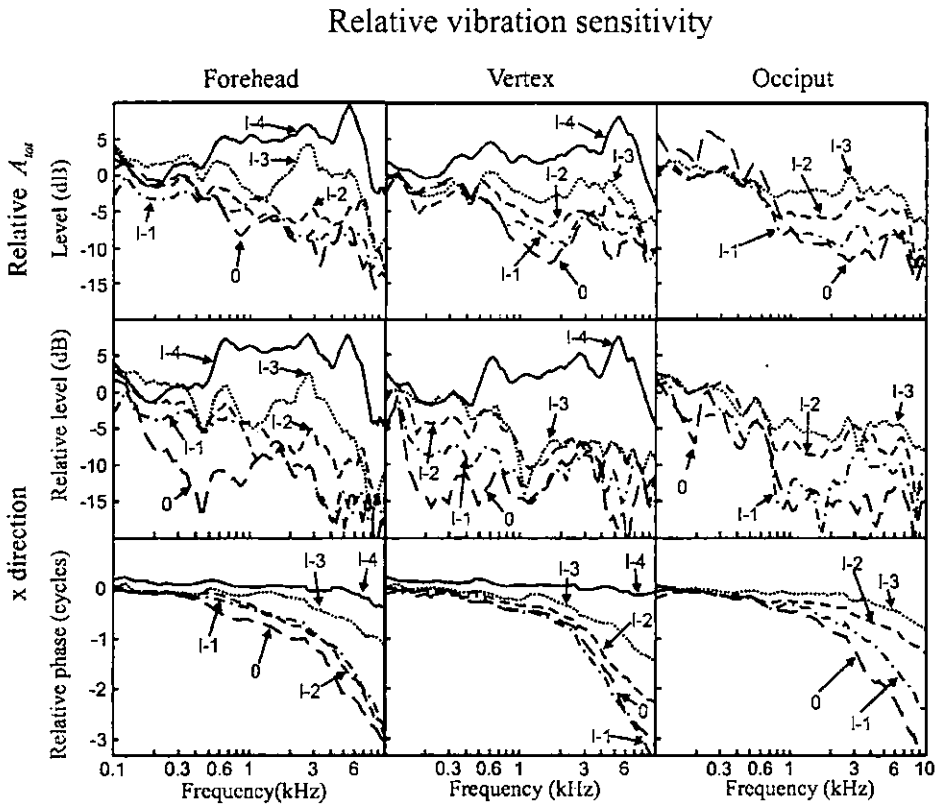

FIG. 7. The relative vibration of the cochlear promontory presented for the x direction as level and phase, and as the level for the total accelerance analysis (all directions quadratically summed, a_{tot}). The stimulation is at the ipsilateral side. All results are relative to the result from occiput arc I-4 and averaged for the six heads. The relative cochlear promontory vibration is displayed as position I-4—solid line, position I-3—dotted line, position I-2—dashed line, position I-1—dashed-dotted line, and position 0 (mid-sagittal plane)—long dashed line.

Fig. 9. At the low frequencies, below 500 Hz, where the skulls move primarily as a whole, 2 to 3 dB greater a_{tot} responses are found at the contralateral cochlear promontory compared with the ipsilateral cochlear promontory. For the x direction response, the transcranial transmission is close to 0 dB at the occiput and forehead stimulation arcs; at the vertex arc the transcranial transmission is approximately 5 dB at these low frequencies. For frequencies above 1 kHz, the transcranial transmission for positions 1–3 show similar level responses (both a_{tot} and x direction results): the levels

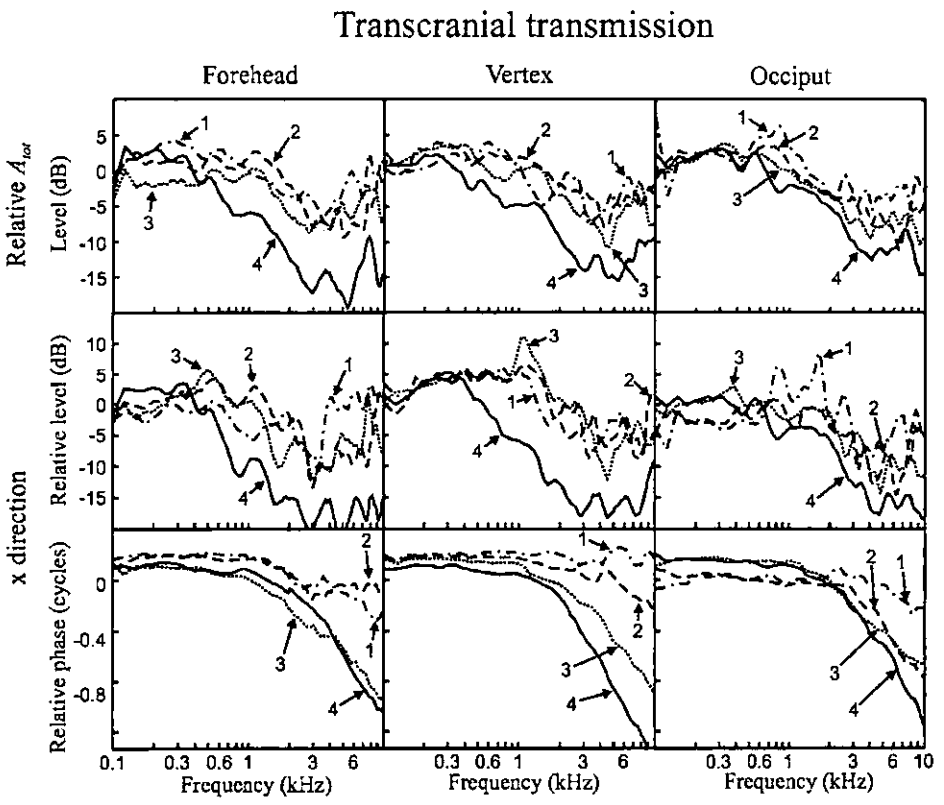

FIG. 8. The transcranial transmission is calculated as the acceleration response at the contralateral cochlear promontory divided by the acceleration response at the ipsilateral cochlear promontory for the same stimulation and position. The results are presented as the total accelerance level (quadratic summation of all three directions), and level and phase for the x direction. The presented transcranial transmission is averaged over the six heads. The results are displayed for the positions at each stimulation arc: position 4—solid line, position 3—dotted line, position 2—dashed line, and position 1—dashed dotted line.

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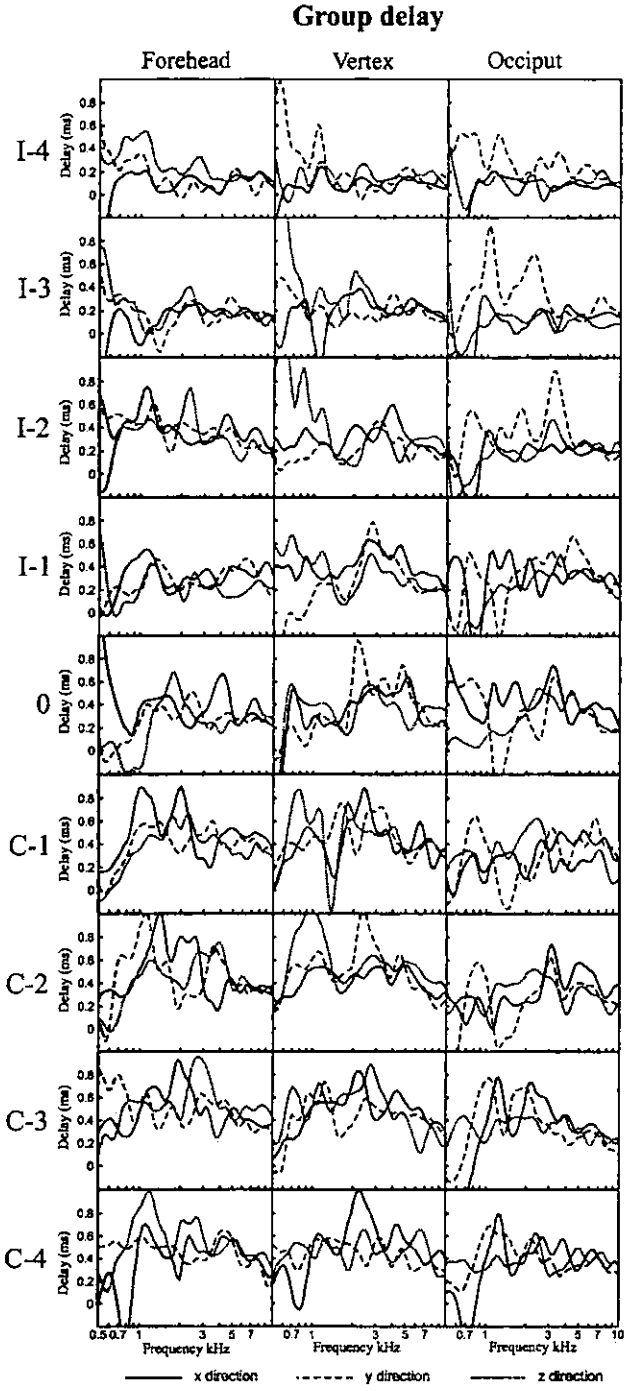

FIG. 9. The group delay calculated from the acceleration on the skull surface to the acceleration on the cochlear promontory. The delays are the average of the result from the six heads. The results are displayed for all positions at each stimulation arc and in the three measurement directions: x direction—solid line, y direction—dashed line, and z direction—dotted line.

decrease and become −5 to −10 dB around 5 kHz. At the highest frequencies investigated, above 6 kHz, the transcranial transmission increases slightly and generally becomes 0 to −5 dB.

When the stimulation is closer to the cochlea, at position 4, greater interaural differences are obtained. At frequencies above 500 Hz, the transcranial transmission decreases with frequency up to around 3 kHz, where the changes with frequency are irregular. The transcranial transmission at all positions 4 at frequencies above 3 kHz stays between −10 and −20 dB, with slightly greater interaural differences for the x direction measurements than for the a_{tot} analysis.

In the x direction, the relative phases in Fig. 8 show similar results at all three measurement arcs. At frequencies below 1 kHz, the relative phases for all stimulation positions are flat and, above 1 kHz, the relative phases fall off. The relative phase difference between the cochlear promontories is greatest when the stimulation is close to the ipsilateral cochlea. In Fig. 4, the accelerance phases with contralateral stimulation show similar results regardless of stimulation position, whereas the phases differ between the responses of the ipsilateral stimulation positions. As a result, the relative phase differences at high frequencies in the x direction transcranial transmission presented in Fig. 8 are mainly due to the accumulated phase in the ipsilateral transmission path. This can also be observed when comparing the relative phases presented in Figs. 7 and 8; although not exactly equal, the relative phases show similar results. It should be noted that the positions are switched; position 1 in Fig. 7 should be compared with position 4 in Fig. 8, position 2 in Fig. 7 with position 3 in Fig. 8, etc.

G. Wave velocity and time delay

The time delay from stimulation at the skull surface to a vibration of the cochlear promontory can be calculated from the phase of the frequency response function. For that analysis, the acceleration at the skull surface to the acceleration of the cochlear promontory (acceleration transfer function) was calculated. This was achieved by using the accelerance function together with the mechanical impedance function measured at the stimulation positions. Using the acceleration transfer function, the group time delay τ_{gd} was calculated from the phase according to

$$\tau_{gd} = -\frac{1}{2\pi}\frac{d\phi(f)}{df}, \tag{2}$$

where $\phi(f)$ is the phase of the acceleration transfer function in radians per second and f is the frequency in Hz. The results from the group delay calculation at each stimulation position are averaged for the six heads and presented in Fig. 9 for the frequencies 0.5 to 10 kHz. In this frequency range, the group delay varies with frequency. For some of the measurements, and at some frequencies, predominately the lower, the delay is negative. A negative time delay indicates a noncausal system which is unphysical. However, a negative group delay does not necessarily indicate a noncausal system; numerous causal systems with negative group delays exist (Mitchell and Chiao, 1998). It is only if the frequency response function has a relatively constant group delay over a frequency region that a signal with a bandwidth corresponding to that frequency range is delayed according to the group delay. If this prerequisite is not fulfilled, the delay of a signal is not easily related to the group delay. The group delays in Fig. 9 vary with frequency, and no simple time delay for the acceleration transmission in the skulls can be extracted. However, if

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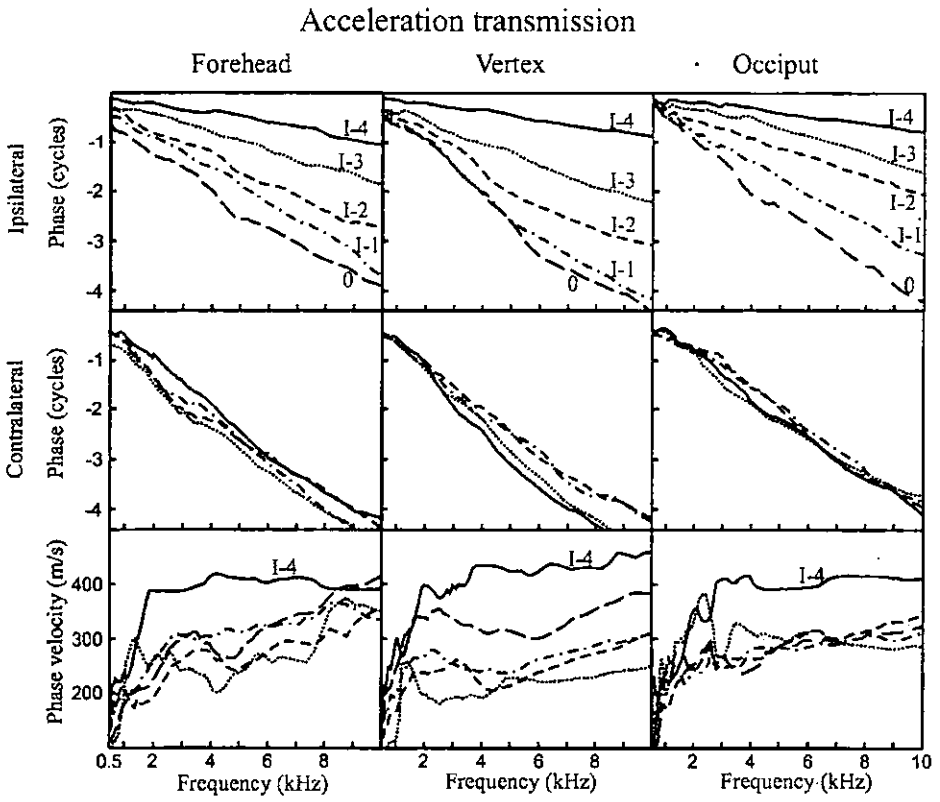

FIG. 10. The phases of acceleration at the skull bone surface to the acceleration at the ipsilateral and contralateral cochlear promontories are displayed with a linear frequency scale (0.5–10 kHz). The calculated phase velocities for the ipsilateral stimulation positions are also displayed. All data are from measurements in the x direction and averaged for all six heads. The phase velocity for position I-4 is calculated using the phase difference between the acceleration at the cochlear promontory and position I-4, whereas the phase velocities at positions I-3 to 0 are calculated using the phase differences between the accelerances at position I-4 and position I-3 to 0, respectively. Consequently, the phase velocity of position I-4 is an estimate of the wave speed in the skull-base whereas the others are estimates of the wave speed in the cranial bone.

the analysis is limited to frequencies between 1 and 10 kHz, some general trends can be found.

The overall result in Fig. 9 shows that on the ipsilateral side, the group delay increases with distance from the stimulation position to the cochlea. Close to the cochlea (position I-4), the group delay is approximately between 0 and 0.2 ms while it is closer to 0.4 ms when the stimulation is at the sagittal plane (typically between 0.2 and 0.6 ms). When the stimulation is on the contralateral side, the group delay stays primarily between 0.2 and 0.6 ms. Since the time delay is not constant but varies irregularly with frequency, dispersion of BC sound can be expected.

Another analysis of wave transmission and wave velocity of BC sound in the human head is presented in Fig. 10. Here, the average of phases and phase velocities of the acceleration transmission are presented for the stimulation positions. The data are displayed using a linear frequency scale between 0.5 and 10 kHz. The panels are divided into ipsilateral phase, contralateral phase, and ipsilateral phase velocity. When examining the phase data, the ipsilateral phases seem to decrease fairly linearly with frequency indicating a constant phase velocity. The phases from the four contralateral stimulation positions show similar phases. This means that the time delays from the contralateral positions are similar.

The phase velocities for the ipsilateral stimulation positions are calculated and presented in the panels at the bottom of Fig. 10. The phase velocity with stimulation at position I-4 is calculated according to

$$V_p = \frac{2\pi f d}{\phi_d(f)}, \tag{3}$$

where $\phi_d(f)$ is the phase difference of the acceleration between position I-4 and the cochlear promontory, f is the frequency, and d is the distance between position I-4 and the cochlear promontory. Position I-4 is on, or very close to, the petrous part of the temporal bone in the skull-base; the velocity estimate for position I-4 is for the wave propagation in that bone. The other positions are on the cranial bone surface where the bone thickness is thinner. Therefore, if the phase velocity is calculated similar to what was done for position I-4, the phase velocity is a mixture of the phase velocities in the thin cranial bone and the dense petrous bone. In order to separate between the phase velocity in the cranial bone and the petrous bone, position I-4 represents the phase velocity in the petrous bone and the positions 0 to I-3 are computed to produce an estimate of the phase velocity of the wave propagation in the cranial bone. This is achieved by calculating the phase difference of the accelerance function between position 0 to I-3 and position I-4. This phase difference (in radians) and the distance between the position and position I-4 forms the $\phi_d(f)$ and d used in Eq. (3) to calculate the phase velocity. Accordingly, the phase velocities in Fig. 10 are estimated for sound transmission in the petrous bone (position I-4) that represents the thicker skull-base and the thinner cranial bone (position 0 to I-3), separately. No estimate of the phase velocity is done for stimulation on the contralateral side. This is primarily due to the problem of estimating the correct wave transmission distance between the contralateral positions and the ipsilateral cochlear promontory.

The rapid increase in phase velocity at frequencies between 0.5 and 2 kHz seen in Fig. 10 is caused by the transition from the low-frequency mass-spring system of the skull to wave transmission motion of the skull at the higher frequencies. At the low frequencies, where the skull motion is dominated by the distributed mass and compliance, phase velocity and wave velocity have no meaning. The phase ve-

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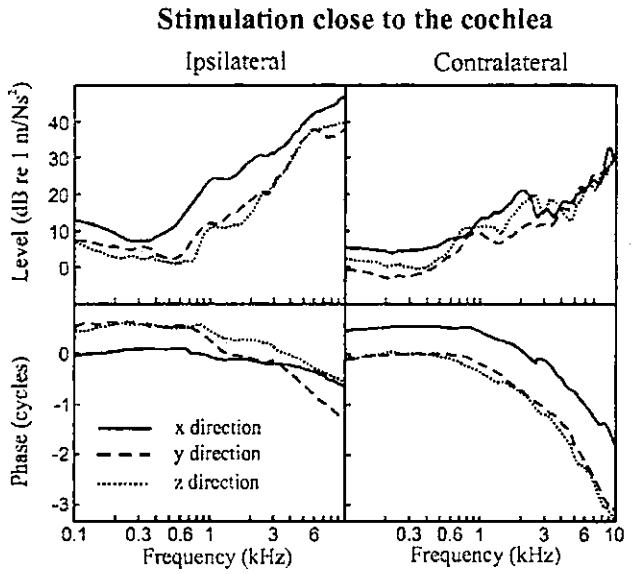

FIG. 11. Accelerances as level and phase measured in the three directions at the cochlear promontory when the stimulation is at the solid angle (intersection of the three semi-circular canals) close to the cochlea. The accelerances are displayed separately for ipsilateral and contralateral stimulation; the results are the average from the six heads. Results in the x direction are shown with a solid line, in the y direction with a dashed line, and in the z direction with a dotted line.

locity in Fig. 10 at these low frequencies is a result of the stationary phase difference of the motion between two positions on the skull; it does not represent the wave speed of the skull vibrations. At higher frequencies, above 2 kHz, the phase velocity gives an indication of the wave transmission mode and its velocity.

The phase velocity at frequencies above 2 kHz in the petrous bone (position 4) shows velocities close to 400 m/s, except on the vertex arc where the velocity increases slightly with frequency. The wave transmission at position 4 is almost solely in the petrous bone in the skull base, and the wave motion is believed to be predominantly longitudinal. At the other ipsilateral positions, the phase velocity was calculated between the stimulation positions and position I-4. In this way, and for frequencies above 2 kHz, the phase velocity in the cranial bone is estimated to increase from around 250 m/s at 2 kHz to 300 m/s at 10 kHz. Such an increase indicates a mixture of wave modes; these may include bending as well as longitudinal wave motion.

H. Stimulation close to the cochlea

After all the previously described measurements were finished, a bilateral mastoidectomy was conducted on the heads enabling stimulation directly on the otic capsule. The mean accelerance from the six heads with stimulation at the ipsilateral and contralateral cochlea is shown in Fig. 11. The stimulation axis is predominantly in the x direction; this can be seen in the 5 to 10 dB greater level in that direction with ipsilateral stimulation compared with the vibration in the perpendicular plane. Compared with stimulation on the skull surface at positions I-4, the ipsilateral vibration level is approximately 10 dB greater with stimulation close to the cochlea. Also the response with contralateral cochlear stimulation is greater compared with stimulation at the skull surface at positions C-4; at frequencies above 1 kHz, stimulation close to the cochlea gives about 5 dB greater levels.

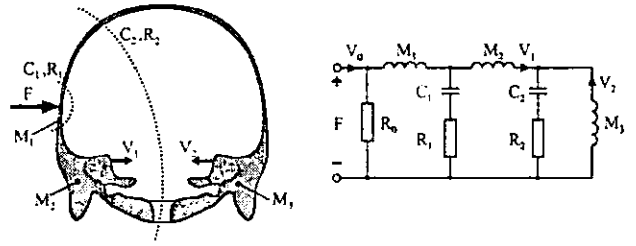

FIG. 12. A cross sectional view of the skull (left) and a corresponding lumped parameter impedance model of the vibration (right). The model is appropriate for the dynamic behavior of the skull at frequencies below the first skull resonance (approximately 1 kHz). The input force at the stimulation position is F, while V_1 and V_2 are the velocities at the ipsilateral and contralateral cochlea, respectively. The elements used in the model are masses (M), compliances (C), and dissipative elements (R).

I. Model of skull motion

In order to better conceptually grasp skull motion and the transition from low-frequency whole body motion to high-frequency wave transmission, a simplified one-dimensional mass-spring model of the skull was devised. This model, a lumped element impedance model, is in principle the same model proposed for low-frequency skull motion in a dry skull (Stenfelt *et al.*, 2000); the difference is an additional damping element (resistance R_0) in the present model, and the element values differ. A cross-sectional view of the skull bone going through the petrous bone is depicted in Fig. 12 (left) together with the lumped element impedance model (right). The velocities at the two cochleae when the stimulation is a force at the mastoid skull surface are shown in both the cross section and the impedance model. Although the model estimates the low-frequency velocity at the cochleae in one direction, the model does not provide the full motion of the cochlea.

The greatest limitation of the model is that the results are in one direction; from this study it is clear that the vibration at the cochlear promontory is in all three dimensions when the mastoid bone is excited. However, at low frequencies and with the stimulation at the mastoid in primarily the x direction, the response is greater in that direction. Another limitation is that, though the model topography is general, the values of the model elements depend on the position of the stimulation. For example, the element values in the model are different for vibration estimation with excitation at position I-4 and position I-3.

Although with limitations, the model can highlight some of the low-frequency phenomena seen in the vibration results. According to the model, the skull can be divided into three parts: (1) the area around the stimulation position that moves in phase (M_1), (2) part of the ipsilateral side comprising the ipsilateral petrous bone (M_2), and (3) the contralateral side including the contralateral petrous bone (M_3). These three areas are coupled with compliances (the inverse of a spring) including losses (C_1, R_1, and C_2, R_2). The three areas are not constant but change with frequency. Therefore, the

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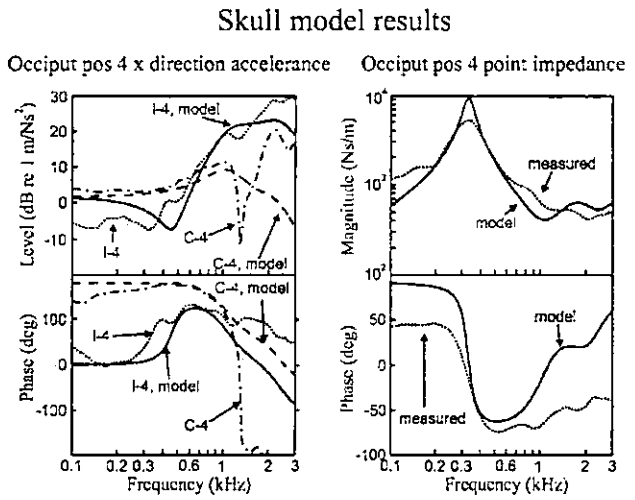

FIG. 13. Comparison of model and measured data. The x direction ipsilateral and contralateral accelerances with the stimulation at position occiput arc 4 are shown as level and phase (left). The impedance data for position occiput arc 4 are shown as level and phase (right). In the accelerance data, ipsilateral model results are shown with a solid line, contralateral model results with a dashed line, ipsilateral measured data with a dotted line, and contralateral measured data with a dash-dotted line. In the impedance data, the model data are shown with a solid line while the measured data are shown with a dotted line. The measured data are the same as the single head data presented in Fig. 3.

element values are a function of frequency. For example, the mass around the stimulation position (M_1) decreases with frequency since a smaller part of this mass vibrates in phase as the frequency increases. However, since the greatest effect of the individual elements are found when they interact with each other (producing resonances or antiresonances), we use constant values in the present model to represent the elements at the frequencies around these resonances and antiresonances.

The model was supplied with element values to fit the results from occiput arc I-4 in Fig. 3. More details about the element values and fitting procedure can be found in the Appendix. Since some characteristics of the vibration response are lost when the data are averaged, the model results were compared with data from a single head. The results can be seen in Fig. 13. With a slight adjustment of the element values, similar comparisons can be conducted with any stimulation position in any of the heads. The model results are compared with the level and phase data of the x-direction accelerance and mechanical impedance from position occiput arc I-4. The measured data presented in Fig. 13 are the same as presented in Fig. 3.

In the accelerance level panel, an indication of a skull resonance is found at 1050 Hz. The model is therefore only valid at frequencies below this frequency. At the lowest frequencies, the response is a true rigid body motion where the ipsilateral and contralateral accelerances are of the same level with opposite phases. At higher frequencies, an antiresonance can be seen in the ipsilateral accelerance function with a resonance frequency near 450 Hz. The level of the contralateral accelerance is greater than the ipsilateral around this antiresonance frequency, and this is the reason for the low-frequency gain in the transcranial transmission (Fig. 8). The accelerance level with ipsilateral stimulation becomes greater than the contralateral at 700 Hz. The low-frequency mass behavior of the skull can be seen in the impedance panels as well. However, the measured impedance phase at the lowest frequencies indicates a large influence of damping, producing a phase of 45°. Although a loss element was included at the stimulation position in the model, such phase behavior of the model impedance was not achieved. It is the mechanical impedance phase that shows the greatest discrepancy between model and measured data. The impedance resonance appears at 310 Hz: above this frequency the impedance data are primarily compliance dominated except the phase data at the higher frequencies.

The resonance seen in the impedance data is in principle the same as the antiresonance found in the ipsilateral accelerance data. If the stimulation is applied directly on the petrous bone (e.g., Fig. 10), the ipsilateral accelerance is the inverse of the integrated mechanical impedance, and, consequently, the antiresonance in the accelerance function appears as a resonance in the impedance function. Since the impedance and ipsilateral accelerance are measured at two spatially different positions in Fig. 13, the vibration is measured at the stimulation position to calculate the impedance and on the ipsilateral cochlear promontory (M_2) for the accelerance, the resonance frequency differs. The general finding is that the frequency of this antiresonance increased with distance between the stimulation position and the ipsilateral cochlea.

For the phase response of the ipsilateral transmission in Fig. 12, the model was extended with a high-frequency part. At frequencies below 1 kHz, the phase response from the model in Fig. 12 was used, and at frequencies above 2 kHz a phase response derived with a constant time delay was used. The model changes gradually from the low-frequency model to the high-frequency model at frequencies between 1 and 2 kHz. The details of this phase model and transition between low- and high-frequency parts in the model are described in the Appendix. Using this model, with a time delay corresponding to a phase velocity of 450 m/s and a distance between stimulation position (occiput arc I-4) and cochlear promontory of 3.5 cm, Fig. 14 displays the results and a comparison with the skull measurements as phase, phase velocity, and group delay, similar to that presented in Figs. 9 and 10. As in Fig. 13, the model data are compared with occiput arc I-4 data from the skull shown in Fig. 3.

The results in Fig. 14 show that the model data were similar to the measured responses. The model phase increases at the lowest frequencies (500 Hz) and falls off at frequencies above 1 kHz. The measured phase shows a similar trend: increases at the lowest frequencies and decreases at frequencies above 1.2 kHz. However, the measured phase has a local minimum at 1 kHz and decreases at a slower rate for frequencies above 6 kHz. The model and measured phase velocities are also similar. The model phase velocity increases from around 100 m/s at 500 Hz to around 450 m/s at frequencies above 1 kHz (according to the model, the phase velocity is set to 450 m/s at frequencies above 2 kHz). Once again, the measured data have a local minimum at 1 kHz and stays between 400 and 550 m/s at frequencies above 1.2 kHz. Compared with the model data, the measured

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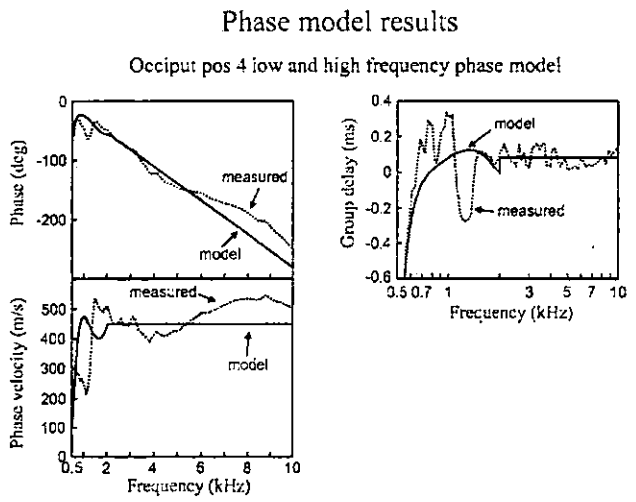

FIG. 14. Comparison of model and measured phase data. The phase and phase velocity is plotted at the left with a linear frequency scale (0.5–10 kHz), while the group delay is plotted at the right with a logarithmic frequency scale (0.5–10 kHz). The model data are shown with a solid line and the measured data are shown with a dotted line. The measured data are the same as the single head data presented in Fig. 3 using position occiput arc 1-4.

data have a somewhat lower velocity around 4 kHz and a higher velocity at frequencies above 6 kHz. The measured data indicate dispersion at both low and high frequencies.

The panel displaying the group delay indicates similarities between measured and model data. At the lowest frequencies, the delays are negative; this is seen at several positions in Fig. 9. The model data have a constant group delay of 0.078 ms at frequencies above 2 kHz (given by the model). The measured group delay is spread around this delay with a tendency of greater delays at around 3 to 4 kHz and lower delays at 5 to 8 kHz. The transition from the mixture of two phase models to the constant velocity model at 2 kHz is clearly visible in the group delay data. This is due to the computation of the group delay as the derivative of the phase versus frequency [Eq. (2)]. At both transitions between models, at 1 kHz where the model goes from a low-frequency model to a mixed model, and at 2 kHz where it goes from a mixed to a constant delay model, the derivative of the phase is noncontinuous. This noncontinuity gives rise to the abrupt rise in the group delay data of the model at 2 kHz.

IV. DISCUSSION

Nearly a thousand measurements were made of the cochlear promontory vibration using accelerometers and a LDV with stimulation at 29 positions in six intact human cadaver heads for the frequency range 0.1 to 10 kHz. Furthermore, the mechanical impedance was measured at the stimulation positions at the skull surface. This thorough investigation has given some insight to the mechanics of the skull, and the motion of the cochlear promontory when the stimulation is a vibration at the skull bone surface. Although there are several published studies of human skull mechanics, those studies are limited to the point impedance, vibration of the cranial vault, vibration response in one direction, and/or investigations in dry skulls.

Most measurements in this study are on the vibration of the cochlear promontory when the excitation is at the skull bone surface. For this to be interesting for BC hearing, the cochlear vibration should be related to a sensation level for BC sound. It is at present not absolutely clear which phenomena contribute, and to what extent they contribute, to a BC perception. It is generally assumed that a BC sensation is primarily caused by sound radiation into the external ear canal, inertial motion of the middle ear ossicles, inertial effects of the cochlear fluid, and alteration of the cochlear space (Tonndorf, 1966). Of these, the external ear canal component is not significant when the ear canal is open (Stenfelt *et al.*, 2003). All others are related to the vibration level of the cochlear promontory. Although it is not possible to translate a vibration level of the cochlear promontory to a hearing sensation level due to several unknown factors, such as the directional sensitivity and vibration modes of the cochlea, the vibration level of the cochlear promontory can be used as a rough approximation of the BC sensation level.

A. Mechanical point impedance of the skull

Several investigations of the skull point impedance have been reported in the literature, both with and without the skin covering the skull bone, using living and cadaver heads as well as severed dry skulls (Corliss and Coidan, 1955; Franke, 1956; Stalnaker and Folge, 1971; Gurdjian *et al.*, 1970; Flottorp and Solberg, 1976; Smith and Suggs, 1976; Håkansson *et al.*, 1986). Of these, the most thorough investigation is Håkansson *et al.* (1986), where the mechanical point impedance at an osseointegrated titanium implant, as well as at the skin in the parietal bone (about 55 mm behind the ear canal entrance), was investigated in seven living humans. Moreover, the mechanical impedance of a 175 mm^2 circular area of the average human skin covered mastoid was standardized in 1971 (IEC 373, 1971) for the calibration of BC transducers used in audiometry. However, it was difficult to design mechanical couplers that met this impedance, and the standard of the mechanical impedance for calibrating BC transducers was revised in 1990 to the mechanical impedance of the Brüel and Kjær type 4930 artificial mastoid (IEC 373, 1990).

The mechanical point impedance was measured at 27 positions at the skull surface in each of the six cadaver heads according to Fig. 1. The results from these measurements were pooled and averaged in Fig. 2. The impedance measurements obtained, although at several additional positions, are similar to the measurements of Håkansson *et al.* (1986) where the impedance was measured at a screw connection directly in the skull bone. When comparing the mean results from the study of Håkansson *et al.* with our occiput arc position 3 data, which is the closest position to that used in the Håkansson *et al.* study, similar results are found for both magnitude and phase. The greatest difference between the two investigations is found at the very high frequencies (8 to 10 kHz). At those frequencies, the impedance magni-

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tude in the Håkansson *et al.* study is 3 to 6 dB lower and the phase is up to 40° lower than in this study. This difference may be due to the rigid connection used in the present study: Håkansson *et al.* used a metal connection at the implant that produces a local compliance that could affect their high-frequency data.

Although most previous mechanical impedance studies have been made with the skin interposed between the skull and the impedance measurement device, it was here measured directly to the skull bone. The skin acts chiefly as a spring at the frequencies used; this spring is the first element in the impedance chain and it dominates the impedance response. Therefore, the skin may mask mechanical characteristics that could have been seen in the impedance measurements. Three general areas can be identified in the magnitude and phase curves presented in Fig. 2. At the lowest frequencies, below 150 to 400 Hz, the skull acts as a pure mass. This is where the skull moves truly as a rigid body and the skull motion is determined by translational and rotational whole body motions. Above this frequency range, the cranial bone starts flexing around the stimulation position, giving a stiffness-controlled impedance (cf. Sec III A). At frequencies of 3 kHz and above, losses start to influence the impedance; however, the impedance is still dominated by the stiffness of the bone around the stimulation position.

Except for the low-frequency impedance resonance, no resonances and antiresonances of the skull structure are identifiable from the impedance measurements. The reason is that the resonances of the skull structure are well damped, as has been noted in previous reports on the mechanical impedance. Accordingly, the structural responses of the skulls are hidden behind the local mass and stiffness behavior at and around the attachment position.

B. Vibration of the cochlea

In the literature on BC vibration of the skull, different measurement techniques, such as impulse hammers, accelerometers, holographic interferometry, and LDV, have been used to reveal the mode of vibration of the cranial vault when a BC sound is applied (von Békésy, 1932; Bárány, 1938; Kirikae, 1959; Khalil *et al.*, 1979; Ogura *et al.*, 1979; Kobayashi *et al.*, 1983; Dorheide and Hoyer, 1984; Håkansson *et al.*, 1994). These investigations have used live humans, cadavers, and dry skulls. The present study has focused on the vibration at the cochlear promontories when the stimulation is a vibration at the skull bone surface. Previous investigations of cochlear vibration during BC stimulation are limited to two studies. In the first, an accelerometer was attached to the petrous part of the mastoid bone in a sectioned dry skull when the stimulation was applied to the mastoid (Buchman *et al.*, 1991). In the other study, three perpendicular accelerometers were mounted at the petrous part of both mastoid bones in an intact dry skull that was internally coated with damping material. In that study, the excitation was applied at four positions on the mastoid and parietal bone, and one position on the forehead (Stenfelt *et al.*, 2000).

The present study is similar to the study by Stenfelt *et al.* (2000) in that the cochlear promontory vibration in three directions was measured while vibrating the skull surface. The difference is that a dry skull and five stimulation positions were used by Stenfelt *et al.* while intact cadaver heads and a large number of stimulation positions distributed over a substantial area of the skull bone were used in this investigation. One potential concern is that the cadaver heads used had been removed from the bodies. According to Stalnaker and Folge (1971), the head-neck junction is insignificant for frequencies above 0.4 kHz. It is therefore assumed that the effect of severing the heads in this study is negligible.

Two different methods to measure the vibration at the cochlear promontory were used: a triaxial accelerometer was glued to the cochlear promontory that measured the acceleration in three perpendicular directions, and the laser beam of a LDV was aimed at the cochlear promontory that measured the velocity in the direction of the laser beam. The measurement direction of the LDV was the same as the x direction of the accelerometer measurement. Similar vibration results were obtained with the triaxial accelerometer in the x direction as with the LDV. The average result from the six heads with the two measurement methods differed no more than 5 dB at any position or frequency; the difference was generally less than 2 dB. This indicates further that the slight drilling of the ear canal that was done in order to fit the triaxial accelerometer to the cochlear promontory did not greatly affect the vibration transmission, and the glue bond attaching the accelerometer to the cochlear promontory could be considered rigid.

The results from the individual heads show that there were several resonances and antiresonances present. They did not appear at the same frequencies in all three directions. Furthermore, they differed in frequency between the heads and their influence disappeared when the results from the six heads were averaged. The resonances were greatly damped and have therefore only a minor influence on BC sound. The antiresonances have greater impact and produced attenuation of up to 20 dB. However, since they were of narrow bandwidth and did not appear in the three directions at the same frequency, their influence on BC transmission is dependent on the directional sensitivity of the cochlea. This directional sensitivity of the cochlea is at present unknown. Most antiresonances were found when the stimulation was applied close to the midline of the skull, or when it was on the contralateral side (predominantly C-1 and C-2). This is believed to be an effect of wave transmission through the cranial vault when the stimulation is close to the sagittal plane (producing more antiresonances). When the stimulation was closer to the cochlea, the skull-base transmitted more of the energy with less influence from the structural response of the cranial vault.

From both the analysis of the cochlear promontory vibration in the individual heads and the averaged responses, it was clear that, as long as the stimulation was on the ipsilateral side, the closer the excitation position was to the cochlea, the greater the response level and the less phase accumulated (shorter time delays). However, when the excitation was applied on the contralateral side, no significant difference between the response from the stimulation positions

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were found, either in level or in phase. In general, the worst place to apply a BC stimulation, in terms of vibration level at the cochlear promontory, was on the mid-sagittal plane. The greatest vibration level at the cochlear promontory was obtained when the stimulation was applied directly at the cochlea; almost 10 dB greater levels were achieved compared with the occiput arc I-4 position.

At lower frequencies, the direction of stimulation dominated the response direction. At higher frequencies, no dominant direction was seen except when the stimulation position was close to the response position (stimulation at positions I-4 and otic capsule). The averaged responses in the three directions were normally within 5 to 10 dB of each other. The response pattern was similar whether the stimulation was applied at the forehead, vertex, or occiput part of the skull; it depended primarily on the distance between the stimulation and response positions. This finding was similar to that reported by Stenfelt *et al.* (2000), where the vibrations were found similar for the three perpendicular directions, except when the stimulation was close to the cochlea; then, the vibration in the stimulation direction dominated the vibration response.

When the quadratic summation of the accelerance results in the three perpendicular directions was performed [Eq. (1)], a result termed total accelerance response was obtained. It is an approximation of the vibration power transmitted to the cochlear promontory. This is a useful measure since it converts the vibration response in the three directions to a single number facilitating comparisons between results from different stimulation positions. Using this analysis, the transmission loss at the ipsilateral skull surface was 0.5 to 1.5 dB/cm for frequencies above 1 kHz (Fig. 7). Positions I-4 at the forehead and vertex arcs resulted in approximately 5 dB greater vibration level at the cochlear promontory for frequencies above 1 kHz, compared with position I-4 at the occiput arc. At this time, we have no explanation for this result.

In the international standard for calibration of BC transducers (ISO 389-3, 1994), an interim standard is proposed for the sensitivity difference between forehead and mastoid stimulation. This standard states that, for BC, stimulation at the forehead produces 8 to 14 dB worse thresholds than stimulation at the mastoid. This sensitivity difference corresponds well with the x direction results for frequencies below 3 kHz when the relative sensitivity between stimulation positions was analyzed (Fig. 8). Above 3 kHz, the measured x direction difference in vibration levels was greater than that stated in the standard and the a_{tot} results correspond better. This is another indication that cochlear promontory vibration data can be used to estimate the perception of BC sound, though the relationship between acceleration and perception is probably a function of the amplitude and phase of all directions of motion.

C. Transcranial transmission

The transcranial transmission measured in these skulls is an objective measure; it is the vibration measured at the contralateral cochlea divided by that at the ipsilateral cochlea. The inverse of this is referred to as the transcranial attenuation and is often used when BC transmission through the skull is estimated by psychoacoustic measurements. Nolan and Lyon (1981) reported the mean subjective transcranial attenuation to be approximately 10 dB for the frequencies 0.25 to 4 kHz in live humans; the range was from −10 to 40 dB. Hurley and Berger (1970) found the transcranial attenuation to be around 5 dB between 0.5 and 2 kHz, whereas Kirikae (1959) reported it to be 5 dB between 0.25 and 1 kHz and 10 to 15 dB at 2 kHz. In the transcranial vibration transmission that is presented in Fig. 8, the vibration at the contralateral side is generally 0 to 5 dB greater than at the ipsilateral side for frequencies below 1 kHz. This is not normally reported when the transcranial transmission is estimated by psychoacoustic measurements. At higher frequencies, the transcranial transmission is worse resulting in an attenuation of 10 to 20 dB at 10 kHz, depending on measurement direction and position.

In the study by Stenfelt *et al.* (2000), where the vibration was measured close to the cochlea in a dry skull, less attenuation was obtained: around 0 dB below 1 kHz that became 5 to 10 dB at 10 kHz. Since a dry skull was used in that study, less attenuation was expected. However, the transcranial transmission level differs between this study and the several studies that used a psychoacoustic approach. At low frequencies, where the skull moves primarily as a rigid body, the sensation level at both cochleae should be similar. There may, however, be other factors such as the directional sensitivity of the cochlea that influences the results when psychoacoustic measurements are used; e.g., if the cochlea is sensitive primarily in the y direction, other transcranial transmission functions than those presented in Fig. 8 would be appropriate. The vibration sensitivity of the cochlea (vibration of the cochlea to a perceived sensation) is probably a function of the vibration amplitude and phase in all three directions, as well as the vibration mode; it is therefore meaningless to try to find a single sensitivity direction.

D. Wave motion of bone conducted sound

Tonndorf (1966) initially proposed that the waves along the bones of the cranial vault propagate as flexural waves (bending waves). Later, this was revised, since no frequency dependence of the wave motion was found in their own study (Tonndorf and Jahn, 1981) or in others (Zwislocki, 1953; Franke, 1956). They suggested that the wave propagation of the cranial vault occurs as plate waves, which constitutes both longitudinal and transverse components. Although the special case of plate waves that was proposed by Tonndorf and Jahn (1981) does not have frequency-dependent propagation velocity, plate waves are dispersive in general; the phase (and group) velocity changes with frequency. The phase velocity for BC stimulation in this study showed dispersion (velocity changed with frequency) (Fig. 10), especially for the estimation of the propagation velocity in the cranial bone. When the wave transmission was primarily through the skull-base (position I-4), less dispersion was found at the higher frequencies. There was also a variation of

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the group delays for almost the whole frequency range, indicating dispersive wave transmission (Fig. 10).

The skull bone has a complicated structure; at the cranial vault it consists of two parallel thin structures of dense bone (lamina externa and lamina interna) with a scaffoldlike bone structure termed diploë in between. Fluid is present within this diploë, and the cranial bone is loaded on the outside by the skin and soft tissues, and on the inside by the brain and cerebrospinal fluid. All these factors influence the wave transmission of the vibration in the skull, and it can be assumed that several modes of wave transmission in the skull bone are present at the frequencies used here. By separating the analysis for the stimulation at position I-4 with the other positions, some indication of the nature of the wave transmission was found. At the skull-base, a higher phase velocity (around 400 m/s) was obtained than that obtained at the cranial vault (250 to 300 m/s). The velocity at the skull base appeared to be almost constant at the higher frequencies, whereas frequency dependence of the phase velocity at the cranial vault was found. This was likely a result of different wave propagations in the different areas of the skull: at the skull base in thicker bone, longitudinal wave transmission dominated whereas a mixture of modes, including bending wave motion, might exist in the cranial bones. Position occiput arc I-4 was at the skull-base, forehead arc I-4 was just outside the skull-base, whereas vertex arc I-4 was positioned in the cranial bone, about 30 mm above the ear canal opening. The slight frequency dependence seen in the phase velocity at vertex arc I-4 was believed to be caused by the transmission in the cranial bone at this position.

At the lowest frequency presented in Fig. 10, the phase velocity estimated was below 100 m/s. This result was due to the phase of the local compliance around the stimulation position. This stiffness behavior at the attachment position caused a phase alteration that appeared as a low phase velocity at those relatively low frequencies. The phase and group velocity of BC sound have been reported to be between 260 and 540 m/s (von Békésy, 1948; Zwislocki, 1953; Franke, 1956; Tonndorf and Jahn, 1981). Except for von Békésy, who did not investigate the low-frequency wave speed, low phase velocities at the lower frequencies were reported, similar to our findings. By devising a mass-spring model of the skull for the low frequencies and a wave propagation model with constant phase velocity at higher frequencies, the alteration from low phase velocities at low frequencies to higher velocities at frequencies above 2 kHz could be explained. Also, the finding of negative group delays at the low frequencies could be explained by this model. However, it should be noted that, due to the low-frequency characteristics of phase response, neither the phase velocities nor the group delays presented were easily converted to a time delay for BC transmission in the head.

The current study was based on mechanical point impedance measurements of the skull and cochlear vibration measurement when the excitation was at the skull surface. Although slightly different levels were found, the mechanical impedance showed similar behavior for all measurements. When a vibration excited the skull, even if in a single direction, the vibration at the cochlear promontory was in all space dimensions. It was only at the lower frequencies, below 0.5 to 1 kHz, and when the stimulation position was close to the cochlea, that the stimulation direction dominated the response direction. Otherwise, the cochlea vibrated in all space dimensions without any dominating direction. In terms of vibration level of the cochlear promontory, the best stimulation position was close to the cochlea and the worst stimulation position was on the sagittal plane. Also, the greatest difference, in both level and phase, between the cochleae was when the stimulation was close to the cochlea. Both the group and phase velocity of the skull bone wave propagation depended on the frequency: at low frequencies the skull acted as a mass-spring system with a low phase velocity. At higher frequencies, the speed of the wave propagation depended on the location on the skull: the skull-base showed a close to constant wave speed of around 400 m/s whereas the cranial bone produced phase velocities around 250 m/s at 2 kHz that became close to 300 m/s at 10 kHz.

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APPENDIX: SKULL MODEL DATA

The element values of the one-dimensional mass-spring model of the skull depicted in Fig. 12 were fitted to the results of stimulation at position 4 at the occiput arc in the skull data presented in Fig. 3. It was decided to fit the results to some key properties in the results. At low frequencies, the model result should be mass dominated with the total mass ($M_1+M_2+M_3$) close to that obtained in the impedance data. The sum of the two compliances (C_1 and C_2) together with the large mass (M_3) forms the resonance seen in the impedance data. The damping of this resonance is formed by the three resistive elements (R_0, R_1, and R_2). The antiresonance of the I-4 data is caused by the interaction of the masses M_2 and M_3 together with the compliance C_1. Finally, the first skull resonance (around 1.1 kHz) is primarily formed by the compliance C_2 together with the mass M_3. From this, the values were adjusted manually to visually fit the measured data. Accordingly, the values used for the model in Fig. 13 were M_1=0.05 kg, M_2=0.1 kg, M_3=0.7 kg, C_1=140 nm/N, C_2=170 nm/N, R_0=30 kNs/m, R_1=200 Ns/m, and R_2 =600 Ns/m.

It can be observed that the total mass of the skull model ($M_1+M_2+M_3$) is 0.85 kg, which is considerably less than the 3 kg for the head reported in Table I. This can be explained by the decoupling of the brain and soft tissues for the frequencies used here. The dry skull itself weighs slightly less than 1 kg. The decoupling of the brain and soft tissues can be one explanation for the deviation in magnitude and phase of the impedance at the lowest frequencies (below 200 Hz) in Fig. 12. At these frequencies, parts of the soft tissues and/or brain vibrate with the skull bone, thus increas-

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ing the effective mass. According to the impedance data at 100 Hz, the effective mass is 1.6 kg, which is about twice the mass seen at 200 Hz.

For the results presented in Fig. 14, a model of the phase between the velocities at the cochlear promontory and the stimulation position was devised. This model was divided into three frequency areas. At frequencies below 1 kHz, the low-frequency part of the phase was defined as the phase difference between V_1 and V_0 in the mass-spring model in Fig. 12, i.e., $\phi_{LF}=\angle V_1/V_0$. At the high frequencies, above 2 kHz, the phase was described by a constant time delay, i.e., $\phi_{HF}=\angle e^{-j\omega t_d}$. For the mid-frequencies, between 1 and 2 kHz, the phase was a function of the low- and high-frequency phase functions, i.e., $\phi_{MF}=\phi_{LF}+a(f)(\phi_{HF}-\phi_{LF})$. Here, the function $a(f)$ increased linearly from 0 at 1 kHz to 1 at 2 kHz. The delay t_d used to compute ϕ_{HF} in Fig. 14 was 0.078 ms. This was derived by assigning the phase velocity to be 450 m/s, and the distance between the stimulation position and the cochlear promontory for occiput arc I-4 in that skull was 3.5 cm.

[1]The mechanical point impedance is defined as the force divided by the velocity at the stimulation position.

[2]Antiresonance is here defined as a significantly low level response of narrow bandwidth in the frequency response function.

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The Postnatal Growth of the Temporal Bone and its Implications for Cochlear Implantation in Children

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The postnatal growth of the human temporal bone was examined by direct anatomical measurements on 60 cadaver specimens of all ages. The bones were dissected as one would perform cochlear implant surgery using a posterior tympanotomy approach. Nineteen anatomical/surgical landmarks with implications for cochlear implant surgery were identified on each bone and the distance between these points measured. The temporal bone was found to be a complex structure, phylogenetically, anatomically and functionally consisting of four different parts with independent postnatal development. The inner and middle ears were adult size at birth. The external auditory canal and most parts of the temporal bone were subject to significant lateral growth. The size of the pneumatised mastoid increased in all directions. In the facial recess, however, no postnatal growth was observed. Between birth and adulthood an average of 12 mm (SD 5 mm) of growth was seen directly between the sino-dural angle and the round window, the landmarks approximating the implantation site for the receiver-stimulator and the electrode entry point into the inner ear. However, if an electrode leadwire is fixed at a cortical fixation site such as the posterosuperior point of Macewen's triangle, the leadwire would be subject to approximately 20 mm of growth. These results indicate that a paediatric cochlear implant design incorporating an expandable leadwire to accommodate this growth should allow up to 25 mm of leadwire lengthening. The fossa incudis showed no growth relative to the round window and was found to be a convenient fixation site for the electrode array close to the cochlea. From an anatomical and surgical point of view, cochlear implantation in very young children is feasible, provided the electrode array is secured and the design accommodates for controlled leadwire lengthening. *Key words: developmental anatomy, temporal bone growth, skull growth, paediatric otology, cochlear implants.*

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INTRODUCTION

It is now clear that young profound to totally deafened children can receive considerable benefit from a multiple-channel cochlear implant (1, 2). Since the approval of the Cochlear 22 channel cochlear implant for use in children aged 2–17 years in 1990, an increasing number of pre- and postlingually deafened children are being implanted with this device. Clinical results indicate that the younger implantees benefit most from early implantation, facilitating early speech perception and speech development. Early auditory deprivation causes incomplete maturation and degenerative changes within the central auditory pathway (3–5). Electrical stimulation, in contrast, appears to be capable of preventing at least some of these changes (6). Implanting congenital or neonatally deafened children under the age of two may, therefore, have substantial advantages over implantation at a later age. First, however, some questions concerning reliability of hearing tests in infants, the chronic effects of electrical stimulation, the control of infection and the problem of postoperative temporal bone growth remain to be addressed. The present study deals with the question of skull growth.

The current concept of cochlear implantation consists of an externally worn speech processor with headset and an implantable receiver-stimulator. The Cochlear 22-channel device features a multichannel scala tympani electrode, a receiver/stimulator and a leadwire connecting the two (7). The intracochlear electrode is inserted into the scala tympani of the basal turn either through the round window membrane or via a cochleostomy just anteroinferior to the round window. The receiver stimulator however, has to be placed near the surface just under the scalp to permit the transfer of speech data and power via a transcutaneous radio-frequency link. The site for its placement is usually on the lateral surface of the squamous part of the temporal bone just posterosuperior to the mastoidectomy cavity. However, in order to ensure consistent speech perception results in the long-term, the intracochlear electrode array must be mechanically stable. In young children there is some uncertainty regarding the impact of skull and temporal bone growth on the implant. This growth may jeopardize the success of the device. A substantial increase in the distance between the point of electrode insertion, any potential electrode fixation site, and the location of the receiver-stimulator, may place stress on the leadwire, resulting in the displacement of the electrode from the cochlea and damage to the electrode leadwires. A reduction in the number of the functional electrodes—due either to the displacement of the array or leadwire damage—would jeopardize the long-term benefit of the cochlear implant (1, 2). Furthermore, the gradual dislodgement of the electrode array would result in a change of pitch perception for a given electrode pair. Finally, the repeated breakdown of the electrode entry seal could result in an increased risk in the spread of infection into the cochlea, as the seal takes several weeks to become an effective barrier to the spread of infection (8). This is of particular importance in young children who are prone to otitis media. For the prevention of these potential complications it is essential to establish procedures that will not allow the electrode to move after implantation.

To our knowledge there have been no reports describing the removal of an electrode array as a result of skull growth. However, as increasing numbers of younger children will be implanted in the future, precise knowledge about the rate at which postnatal growth occurs is essential for the development of safe surgical procedures in the paediatric group.

Abundant information about the growth of the human head during childhood has already been published (9–12). In general, the postnatal growth of the head is less dramatic than the growth of the body. The head of a newborn has approximately 60% of the length of an adult head. The body length of a newborn, in contrast, accounts for only some 28% of the expected length (11).

The inner ear has been described by various authors to be adult size even before term (11–15). However, less detailed information is available describing the postnatal development of the temporal bone and its related structures. Nokubi (16) and Dahm (17) have examined the postnatal growth of the temporal bone by direct anatomical measurements of its external features. They demonstrated significant differences in the development of the various regions of the temporal bone. These different parts varied considerably in their growth patterns, the extent of growth as well as the period of accelerated growth.

The pre- and postnatal development of the middle ear has been described by a number of investigators (18–23). Their histological and morphological studies showed relative maturity of the middle ear cleft and the ossicles at term. Only a moderate lateral postnatal extension of the posterior hypotympanum in conjunction with the proposed verticalization of the tympanic ring was noted by Proctor (19) and Spector (21).

The width of the facial recess as the access route for middle ear and cochlear implant surgery has been a matter of concern and has recently been the subject of a number of studies (24, 25). Their results indi-

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cated no statistically significant difference in the size of the facial recess between the various age groups ranging from newborns to adults.

Temporal bone growth with reference to cochlear implantation has, to our knowledge, only been the subject of three publications (14, 26, 27). Simms & Neely (27) examined the change of different surface landmarks to assess the growth of the temporal bone. The increase in the distances between the external auditory canal to the mastoid tip and several points along the suture lines at the periphery of the temporal bone was assessed using a surface projection method. They described a bimodal growth pattern with an accelerated development in the first four years of life. O'Donoghue et al. (26) used computerized axial tomography of temporal bones to examine various axes regarded relevant for cochlear implant surgery. They concluded that the greatest development occurred in the squamous and petrous portions of the temporal bone during the first two years of life. Moreover, they indicated the need for a 10–30 mm redundancy in the leadwire of a paediatric cochlear implant in order to accommodate head growth. In the most extensive study, Eby & Nadol (14) examined histological sections from 48 temporal bones, and plain X-rays from 253 skulls in order to assess the growth pattern of the temporal bone. Histologically, they noted no evidence of postnatal growth of the inner ear and minimal growth of the middle ear. Their radiological findings indicated growth of the mastoid in all three dimensions: length, width and depth, following two exponential curves. They concluded that at least a 25 mm leadwire expansion should be allowed to accommodate skull growth.

These previous studies have examined either external features of the temporal bone or used two dimensional techniques (surface projection, tomography and histology) to evaluate the postnatal growth pattern. However, temporal bones, dissected using surgical procedures required for cochlear implantation, are more suitable for evaluating growth between the structures relevant for cochlear implant surgery. Some of the landmarks relevant for cochlear implantation only become obvious after a cortical mastoidectomy and posterior tympanotomy are performed. In the undissected temporal bone these structures would not be available for anatomical measurements. After dissection the actual size of the routes for surgical access can be evaluated more accurately, the course of the prospective electrode array and leadwire can be assessed, and the extent of growth between potential fixation sites can be examined in detail.

To prevent electrode displacement, fixation of the leadwire close to the cochlea is desirable. A fixation site should be easily accessible and should not grow away from the cochlea during development. To define potential fixation sites, detailed information about the growth pattern of the temporal bone is needed. In addition, if an expandable leadwire is necessary to accommodate for post-operative skull growth, anatomical data will be needed to design a safe and effective paediatric cochlear implant. The aim of the present study is to provide this information.

Developmental anatomy of the human temporal bone

The general growth of a child is characterized by specific growth periods. Periods of accelerated growth are observed at the age of 0–1 y, 5–7 y and 12–15 y (11). However, these major growth periods are not necessarily linked with growth changes of the temporal bone. Although some major growth changes of the head can be observed in these periods, the temporal bone follows a different pattern. Each part of the temporal bone seems to develop during different periods at a different speed, according to their phylogenetical origin, their function, the surrounding tissues and the forces applied to them.

The temporal bone consists of the squamous, petrous, tympanic and styloid components. The mastoid, regarded by some authors to be a fifth part, however, originates phylogenetically from the inferior protrusions of the squamous and the petrous bone (28).

In the antenatal course of development of the temporal bone the two larger mesodermal components, the petrosa and the squama appear and embrace the first branchial pouch and cleft (29). The entodermal expansion of the first branchial pouch (foregut) will later result in the formation of the tympanic cavity. The ectodermal layer of the first branchial groove deepens to build the external auditory canal. The third part of the temporal bone, the tympanic bone, develops around the multilayered tympanic membrane, which separates the first pouch and groove.

The petrous and styloid parts of the temporal bone are both formed in cartilage. The petrous component contains the neural elements of the inner ear. At four weeks of gestational age ectodermal tissue, forming the otic placode, has invaginated and forms the otocyst. This anlage forms the membranous labyrinth and reaches adult size in the 20th week (28). The surrounding mesenchymal tissue is differentiating into primitive cartilage at 5 weeks, sparing the perilymphatic space and forming the bony otic capsule and petrous bone. At the 16th week intrachondral (enchondral) ossification starts at 14 different ossification centres and is completed only shortly before birth. The different ossification centres fuse without

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any intermediate zones of epiphyseal growth. The foetal trilaminar structure of this unique bone is kept throughout lifetime; no conversion towards haversian bone takes place.

The squamous bone is created by membranous ossification. It is not until the 8th week stage that one can first discern development of the squama of the temporal bone as commencing from one membranous ossification centre which extends into the zygomatic process (28). The majority of the squamous part of the temporal bone forms a vertical plate, which forms the lateral wall of the middle cranial fossa. On its lateral surface the temporalis muscle is attached and the zygomatic process projects anteriorly. It articulates with the sphenoid and maxillary bone anteriorly, the parietal bone superiorly, the tympanic part of the temporal bone laterally and the petrous part of the temporal bone posteriorly. Medially it forms together with the petrous part the tegmen tympani, the roof of the Eustachian tube, the attic and the antrum. It includes, on its posterosuperior circumference of the external ear canal, the spine of Henle or suprameatal spine. In the adult it forms the anterosuperior and lateral portion of the mastoid bone. The suture line towards the petrous part, the posterior petrosquamosal suture, is visible on the lateral surface of the temporal bone in the newborn, but disappears after the second year. Within the mastoid it can remain as a lamina and is known as Körner's septum. During skull growth, the squamous temporal bone moves laterally resulting in an increase in the cranial diameter (22, 26).

Between the petrous and squamous bones, expansion of the endochondral mucosal lining of the lateral portion of the tubo-tympanic recess results in the formation of the tympanic cavity. The medial portion persists in a less dilated condition, but becomes gradually elongated to form the pharyngotympanic tube (Eustachian). The formation of the tympanic cavity results in its epithelium gradually enveloping the ossicles, their tendons and ligaments and the chorda tympani nerve so that all these structures receive a more or less complete epithelial investment. Later expansion posteriorly to the tympanic cavity, gives rise to the tympanic antrum and, eventually, to the mastoid air cells. The upwards expansion of the tympanic cavity causes the chorda tympani nerve to be included into the tympanic membrane (29). The Ossicles (mesoderm) are cartilaginous up to the 15th week, ossify from the 16th week and are adult size by the 5th foetal month (22). Periosteal and endosteal bone formation takes place and is completed by the 25th week. The malleus and incus derive from the first branchial arch (Meckel's cartilage), and the stapes from the second branchial arch and parts of the otic capsule (13).

The external auditory meatus deepens by active proliferation of ectoderm forming a temporary epithelial plug which later breaks down. It represents the first ectodermal (branchial) groove. The tympanic bone has four ossification centres appearing at the 9–10th foetal week. They are situated at the periphery of the future tympanic membrane and form a bony, superiorly incomplete ring by the 16th week by membranous ossification. At term, the diameter of this ring is almost adult size (22). After birth, the tympanic bone grows laterally via two tubercles, the anterior and the posterior which eventually will fuse with each other to build the mostly transient foramen of Huschke. It usually closes up at the age of five years. At the same time the plane of the tympanic part (membrane) changes from almost horizontal in the 12th foetal week, to a more vertical plane. At birth the plane of the tympanic membrane is 25 degrees from the horizontal plane. In the adult it is at an angle of approximately 50–60 degrees (28). This trend is not fully completed at term.

The mastoid process is not recognizable in the first year of life (30). The pull of the sternocleidomastoid muscle and the progressing pneumatization are thought to be the major forces behind its development. According to Ars (22), the mastoid and antral air cells develop as an outgrowth of the antrum. The antral bone expands posteriorly and the ventrolateral wall continues to grow until puberty or beyond, to give rise to the bone of the mastoid. This is not completed until late teenage years.

MATERIALS AND METHODS

Sixty human temporal bones were used in this study. The ages ranged from 0.16–84 years with 52 of the 60 bones harvested coming from cadavers whose age at death was 18 years or less (Table I). Of the 60 bones, 37 (62%) were obtained from males and 23 (38%)

Table I. *Summary of temporal bones used in the present study based on age and sex*

	Age (years)	Female	Male	Total
1	0 < 1/2	5	5	10
2	1/2 < 1	1	4	5
3	1 < 2	2	1	3
4	2 < 4	2	4	6
5	4 < 6	3	3	6
6	6 < 8	1	5	6
7	8 < 10	3	2	5
8	10 < 14	1	2	3
9	14 < 18	3	5	8
10	> 18	2	6	8
Total		23	37	60

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from females; 36 bones (60%) were from the right side and 24 (40%) from the left.

The specimens were fixed and stored in neutral buffered formaldehyde. After removal of soft tissue, a mastoidectomy and posterior tympanotomy, according to the surgical procedure for cochlear implant surgery, was performed under an operating microscope (31). Care was taken to preserve the suprameatal spine and suprameatal (Macewen's) triangle, resulting in a small bony overhang over the mastoid exanteration. The mastoidectomy was extended along the sigmoid sinus posteriorly to the sino-dural angle, its junction with the tegmen of the mastoid cavity, and inferiorly to the digastric ridge. The tip of the short process of the incus and its attachment in the incudal recess (fossa incudis) was carefully exposed. The prominence of the lateral semicircular canal, the facial nerve and the chorda tympani were identified. The vertical and horizontal diameter of the tympanic membrane was then measured and the membrane, including the fibrocartilaginous ring was then carefully removed from the tympanic sulcus of the temporal bone, the manubrium and the malleus. The round window was then inspected, a false membrane—if present—was removed and the crista fenestra identified.

Nineteen anatomical and surgical sites were selected to provide information about the growth of the temporal bone in the anterior, posterior and lateral planes (Table II; Figs. 1–4).

1) *Round Window (RW):* The anteroinferior part of the orifice, approximating the site of the crista fenestra, was selected as the reference site. In cochlear implantation, the round window can be the electrode entry point into the scala tympani and is therefore an important landmark.

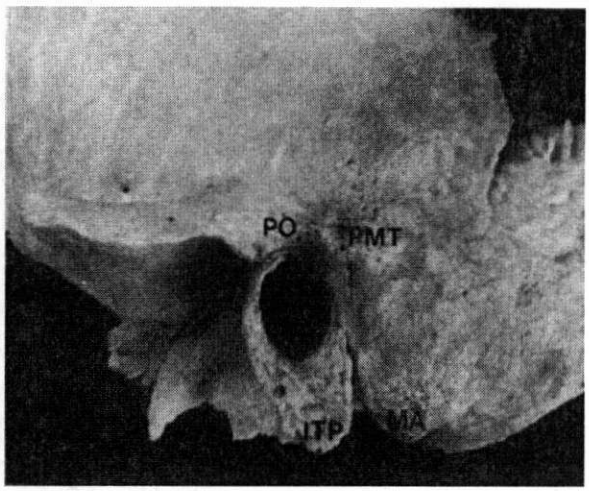

Fig. 1. Left temporal bone illustrating a number of anatomical sites on its lateral surface used in the present study. Inferolateral tympanic point (ITP); Mastoid tip (MA); Posterosuperior point of Macewen's triangle (PMT); Porion (PO).

Table II. *Anatomical and surgical reference points used in the present study*

Inner ear:
1) Round Window (RW): Crista fenestra.
2) Oval Window (OW): Anterior rim of the stapes footplate.
3) Lateral semicircular canal (LS): Most prominent point, as it presents after mastoidectomy.
4) Promontory (PR): Most lateral aspect.
5) Arcuate eminence (ARC): The most prominent point of the arcuate eminence.
6) Internal auditory canal (IAC): Posterior rim.
Middle ear:
7) Fossa incudis (FI): Tip of the short process of the incus.
8) Umbo (UMB): Tip of the manubrium of the malleus.
9) Tympanic spine (TSP): Greater (posterior) tympanic spine located at the medial end of the tympanomastoid fissure just posterior to the notch of Rivinus.
10) Tympanic sulcus (TSU): Point on sulcus adjacent to the posterior canaliculus for the chorda tympani.
External ear canal:
11) Inferolateral tympanic point (ITP): The most inferior point on the lateral surface of the tympanic bone.
12) Porion (PO): Superolateral aspect of the external auditory canal.
Lateral surface:
13) Posterosuperior point of Macewen's triangle (PMT): Posterosuperior point of the suprameatal (Macewen's) triangle.
14) Mastoid tip (MA): The most inferior point.
15) Stylomastoid foramen (STY): The external orifice.
Mastoidectomy cavity:
16) Sino-dural angle (SD): Most posterolateral point.
17) Sigmoid sinus (SIG): Where it produces most anteriorly.
18) Digastric ridge (DIR): Most caudal point.
19) Facial canal (FAC): The midline of its vertical course.

2) *Oval Window (OW):* The most anterior rim of the stapes footplate was selected as a landmark. It can be used as a reference for the inner and middle ears, as well as the ossicular chain.

3) *Lateral semicircular canal (LS):* The most prominent (lateral) part of the canal, as it presents after mastoidectomy, is an important surgical landmark, that represents the labyrinthine part of the inner ear. It is usually identified during cochlear implant surgery.

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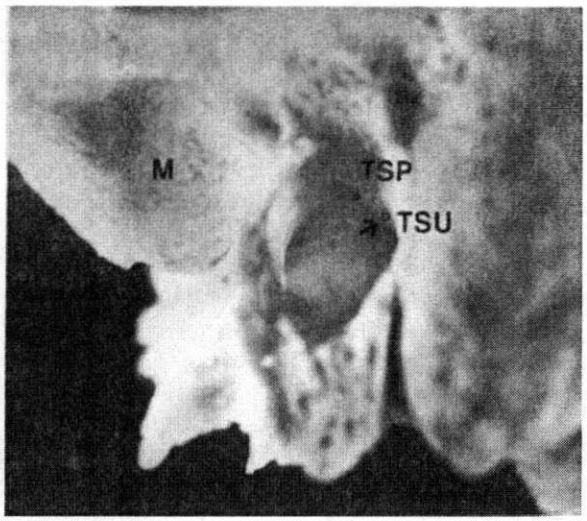

Fig. 2. Higher power view illustrating the tympanic ring and the tympanic part of the human temporal bone. Mandibular fossa (M); Greater tympanic spine (TSP); Tympanic sulcus (TSU). Note that open symbols with arrows indicate that the point is located underneath overlying bone.

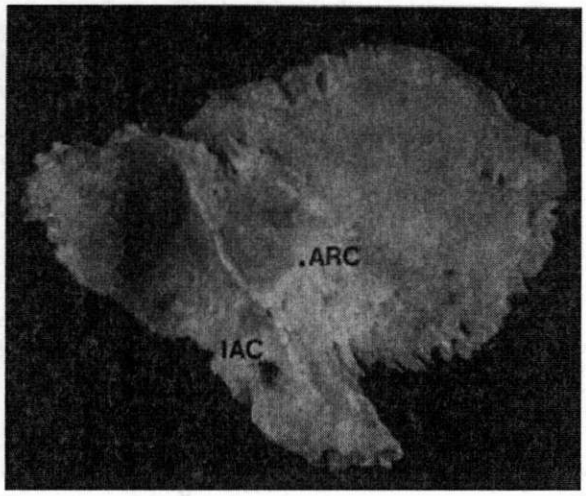

Fig. 3. The medial surface of a left temporal bone illustrating the arcuate eminence (ARC) and the internal auditory canal (IAC).

4) *Promontory (PR):* The most lateral aspect of the promontory, where crossed by the tympanic nerve (Jacobson's nerve) was chosen for our study. Although anatomically difficult to define, it is an important landmark detectable on X-rays. It represents the otic capsule around the first part of the basal turn of the cochlea. The site for an electrode insertion via a cochleostomy would be slightly posteroinferior to this point. Its location in relation to the tympanic membrane and ossicles is important in assessing postnatal middle ear development.

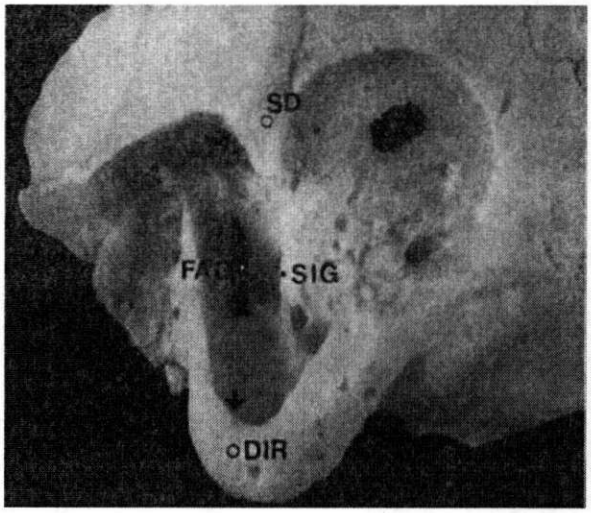

Fig. 4. A left temporal bone illustrating a mastoidectomy, posterior tympanotomy and a receiver-stimulator bed for cochlear implantation. Digastric ridge (DIR); Facial canal (FAC); Sino-dural angle (SD); and Sigmoid sinus (SIG).

5) *Arcuate eminence (ARC):* The most prominent (middle) part of the arcuate eminence on the floor of the middle cranial fossa represents the underlying superior semicircular canal and is useful for measurements of the inner ear.

6) *Internal auditory canal (IAC):* The most posterior point on the rim of the internal auditory canal was selected as a landmark as it is easily detectable. It is the most medial point of measurement in our study.

7) *Fossa incudis (FI):* We used a site where the tip of the short processes of the incus comes closest to the floor of the mastoid antrum. This is also the posteromedial part of the small bony buttress that is created by the posterior tympanotomy, and can be used as an electrode fixation site. It represents the most posterior part of the middle ear space and the ossicular chain, as well as the medial border of the mastoid cell system.

8) *Umbo (UMB):* The most lateral aspect of the tip of the manubrium of the malleus was identified. It is in the central part of the tympanic membrane and can therefore be used for evaluating the middle ear, the external ear canal and the ossicular chain.

9) *Tympanic spine (TSP):* At the medial end of the tympanomastoid fissure and just posterior to the notch of Rivinus, lies the greater (posterior) tympanic spine. It is close to the osseous annulus and where the mallear fold inserts into the squamous bone.

10) *Tympanic sulcus (TSU):* This is the site, where the chorda tympani is closest to and crosses under the posterior aspect of the tympanic annulus, as its entry point to the tympanic cavity. It is the anterolateral

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extreme border of the facial recess, a lateral border of the middle ear cavity and the medial border of the external ear canal. Its location limits the facial recess access route to the implantation site of the electrode array.

11) *Inferolateral tympanic point (ITP):* This is the most inferolateral point of the osseous external auditory canal. It is useful for assessing the lateral growth of the tympanic bone. In very young children the posterior tympanic tuberosity of the tympanic ring was used.

12) *Porion (PO):* The supramastoid crest (linea temporalis), where it is closest to the superior aspect of the external auditory canal (Frankfurt plane) was used as a landmark that is identifiable on X-rays.

13) *Posterosuperior point of Macewen's triangle (PMT):* The upper posterosuperior angle of the suprameatal (Macewen's) triangle was used because it is a surgical landmark. In cochlear implant surgery ties for the fixation of the leadwire are often placed near here.

14) *Mastoid tip (MA):* The most inferior point of the mastoid process was used for our measurements to demonstrate the lateroinferior growth of the mastoid.

15) *Stylomastoid foramen (STY):* The external orifice of the Fallopian canal, located in the adult behind the mastoid process, can provide information about the extension of the mastoid process and the development of the facial canal.

16) *Sino-dural angle (SD):* The most lateral point of the angle made between the sigmoid sinus and the roof of the mastoid cavity (Citelli's angle) was the site on the sino-dural angle used. It is the most posterior part of the pneumatised area of the mastoid and approximates the implantation site of the receiver/stimulator in cochlear implant surgery.

17) *Sigmoid sinus (SIG):* We selected a point that protrudes most anteriorly towards the posterior wall of the external auditory canal. If prominent, the sigmoid sinus can restrict access for creating a posterior tympanotomy and exposure of the round window.

18) *Digastric ridge (DR):* The most caudal point of the digastric ridge was selected as seen from inside the mastoid cavity after a complete mastoidectomy.

19) *Facial canal (FAC):* The centre of the vertical (mastoid) part of the Fallopian canal was selected, at a point where it is closest to the osseous tympanic annulus, and where the chorda tympani enters the middle ear cavity. The vertical section of the facial nerve limits the posteromedial border of the facial recess and consequently can restrict access to the round window.

The distances between these anatomical landmarks were measured using precision callipers and the aid of a microscope. The precision of the callipers allowed measurements in steps of a quarter of a millimetre. Repeated measurements by two examiners on the same bone showed good reproducibility. In several specimens some landmarks were destroyed on removal of the temporal bones, therefore some distance measurements have less than 60 samples.

The data were transferred to a database (Microsoft Excell) and evaluated statistically according to their age with a statistical program (CSS). The samples were broken down into 10 different age groups (<6 months; 6–12 months; 1–2 years; 2–4 years; 4–6 years; 6–8 years; 8–10 years; 10–14 years; 14–18 years and >18 years) and the mean and standard deviation (SD) calculated for each group. Evidence of statistically significant growth as a function of age was determined using multiple analysis of variance and the Newman-Keuls test.

RESULTS

General observations

The macroscopic appearance of temporal bones differ significantly with age. The most obvious difference was the absence of the mastoid process and the immaturity of the bony part of the external auditory canal in the temporal bones from children under one year of age. At the site of the later mastoid process, the lateral surface of the temporal bone simply curves to a more horizontal plane that merges with the skull base. The surface of the stylomastoid foramen lies superficially in the anteroinferior part, where it meets with the posteroinferior margin of the incomplete ring of the tympanic bone. The stylomastoid foramen and the facial nerve are consequently exposed on the inferolateral surface of the temporal bone in children under one year of age. In the specimens from older children, these structures are more protected and hidden between the developing mastoid process and the external auditory canal.

At term, the external auditory canal exists only as a shallow bony ring surrounding the relatively superficial tympanic membrane. In the older specimens a bony canal is present, and the tympanic membrane is less exposed. In children under one year of age the posterior petrosquamous suture was always detectable on the lateral surface of the mastoid part, and could be followed into the depth of the temporal bone during dissection. The suture runs in an oblique fashion from posterosuperior to anteroinferior across the mastoid part of the temporal bone starting just posterosuperior to the tympanic ring. During dissection the suture was found to descend through the mastoid, resulting in an anteriorly directed septum that was always found to be lateral to the facial

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canal. In the young it consists of a rather thick layer of dense bone and cartilage. In children older than two and in adults, a vestigium of this suture was occasionally seen as a thin bony plate, known as Körner's septum. A limited number of aerated cells were found even in the youngest temporal bones. The digastric ridge was not detectable in children under one year of age due to the virtual absence of the mastoid process.

The arcuate eminence, particularly in the older children and adults, was not always exactly representing the underlying superior semicircular canal due to the variable presence and extent of perilabyrinthine air cells.

The facial canal and the chorda tympani in the younger children were always found to be significantly more superficial in the inferior part of their intramastoid or vertical course.

As with previous studies, we first evaluated the growth pattern of the temporal bone detectable externally. Then the development of the various parts of the bone were examined in more detail by using the internal and external landmarks representing these parts. Finally, we analysed the growth changes with respect to cochlear implantation. While these growth changes are summarised in figure form throughout the text, a more detailed analysis of the growth changes is presented in Table form in the Appendix.

The general growth of the temporal bone: Measurement of external reference points

The general growth pattern of the temporal bone was evaluated by examining the change in the distances between some externally detectable landmarks. These landmarks include the porion, the mastoid tip, the internal auditory canal, the arcuate eminence, the sino-dural angle, the inferolateral tympanic point and the stylomastoid foramen (Table II).

The anteroinferior extension of the temporal bone can be assessed from the distance between the superior margin of the external auditory canal—the porion and the most posterolateral point of the sino-dural angle. A moderate increase in the anteroinferior extension of the temporal bone was observed with increasing age (Fig. 5). A statistically significant difference of 11.4 mm ($p < 0.05$) was detected between children under 6 months (mean: 21.6 mm, SD: 4.1 mm) and the adult group (>18 years; mean: 33.00 mm, SD: 7.37 mm). While this measure exhibited a relatively large variance, the youngest age group occasionally exhibited a statistically significant difference ($p < 0.05$) with older children (6–8 and 14–18 years). Children older than 6 months showed no statistically significant difference with the adult group.

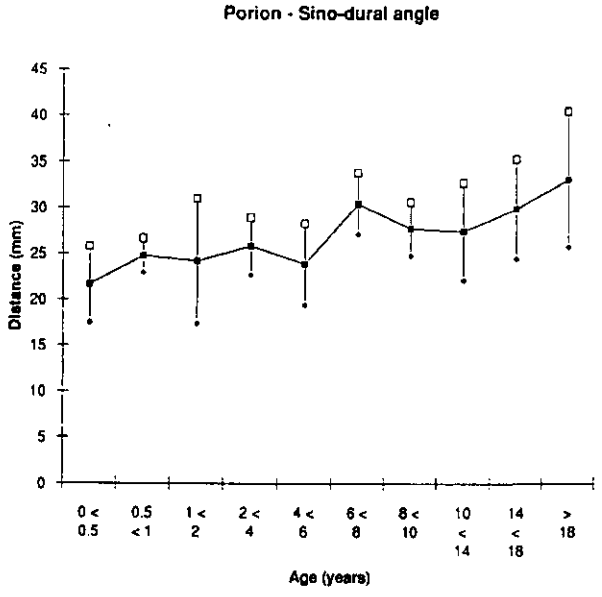

Fig. 5.

The depth of the temporal bone is expressed by the distance from the porion to the posterior rim of the internal auditory canal. Beside a rapid growth period between these anatomical points in the second year of life, the distance between these landmarks exhibited gradual and steady growth until adulthood (Fig. 6). A statistically significant difference ($p < 0.05$) in the distance between these points was only present for children under one year of age (mean: 22.5 mm, SD: 2.8 mm) when compared with both older children (>one year of age) and the adult group (mean: 30.75 mm, SD: 5.3 mm). The temporal bones of older children (>one year) showed no statistically significant difference with that of the adult group.

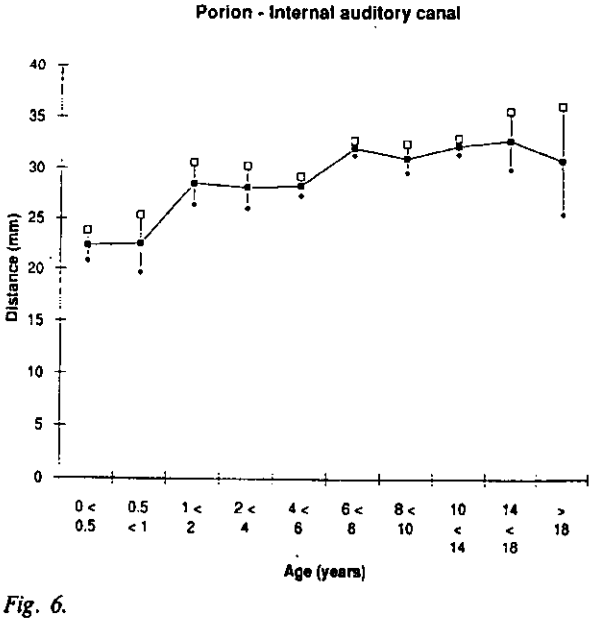

Fig. 6.

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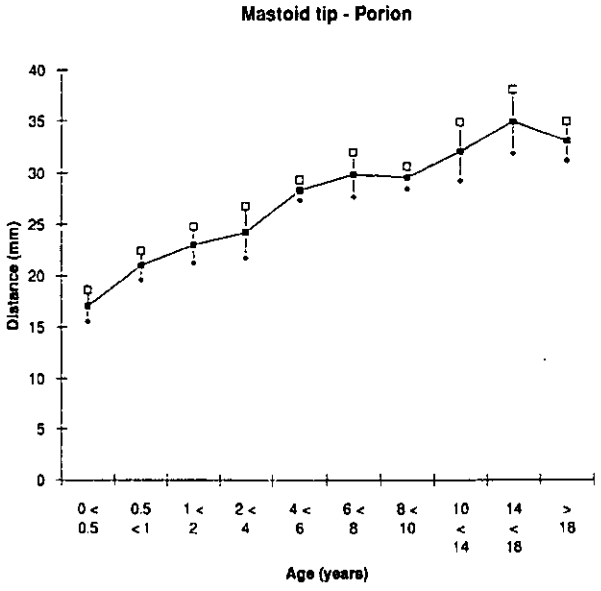

Fig. 7.

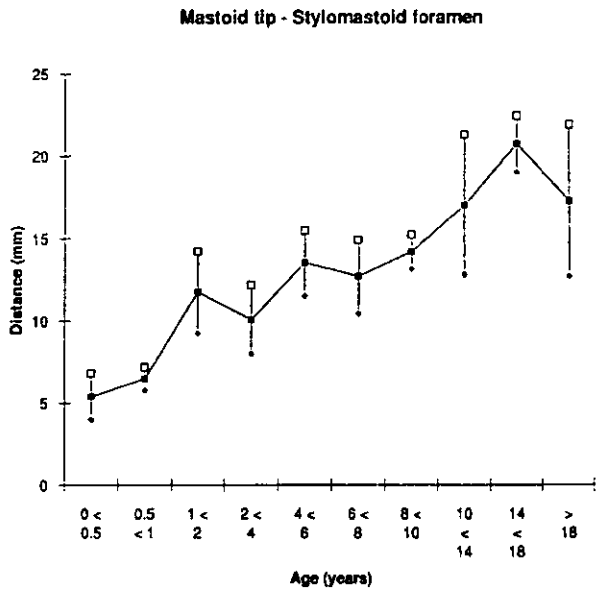

Fig. 8.

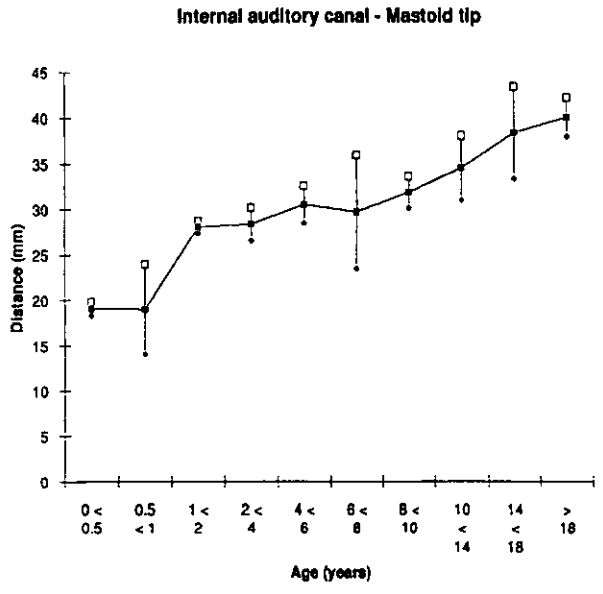

Fig. 9.

The distance from the porion to the tip of the mastoid process provides an indication of the superoinferior growth of the temporal bone along the lateral surface (Fig. 7). In the youngest children only a shallow bony elevation on the inferolateral part of the temporal bone posterior to the stylomastoid foramen could be identified as the beginning of the development of the mastoid process. Continuous growth with age was observed. The mean distance between these reference points was 17.1 mm (SD 1.5 mm) for children under 6 months, and 33 mm (SD 1.87 mm) in the adult group, representing growth of approximately 16 mm. This difference was highly statistically significant ($p < 0.0002$). After a period of rapid growth through the first 6 years of life, the growth rate is reduced until a final brief period of growth in adolescence.

The significant superoinferior extension of the temporal bone was also reflected in the growth between the mastoid tip and the stylomastoid foramen (Fig. 8). From 5.37 mm (SD 1.4 mm) in children under 6 months it developed to 17.25 mm (SD 4.59 mm) in adulthood. Again this growth is highly statistically significant ($p < 0.0002$) with the most rapid growth occurring in the first two years of life.

A similar growth pattern was seen between the mastoid tip and both the internal auditory canal (21 mm; Fig. 9), and the most prominent point of the arcuate eminence (26 mm). In both cases the extent of growth was statistically significant from newborn to adulthood. The growth profile showed rapid expansion in the first year of life, with the mastoid-internal auditory canal growing from 19.1 mm (SD 0.65 mm) to 28.0 mm (SD 0.71 mm), and the mastoid—arcuate eminence growing from 18.36 mm (SD 1.85 mm) to 28.0 mm (SD 1.2 mm). This period of rapid growth accounts for almost half the total growth observed between these anatomical sites.

The distance between the internal auditory canal and the arcuate eminence, in contrast, exhibited a slight but not significant increase with age ($p > 0.05$; Fig. 10).

The greatest change in distance was found between the sino-dural angle and the mastoid process (Fig. 11). In children under 6 months, 18.97 mm (SD 3.61 mm) was the average distance between these two anatomical points. The same landmarks were found

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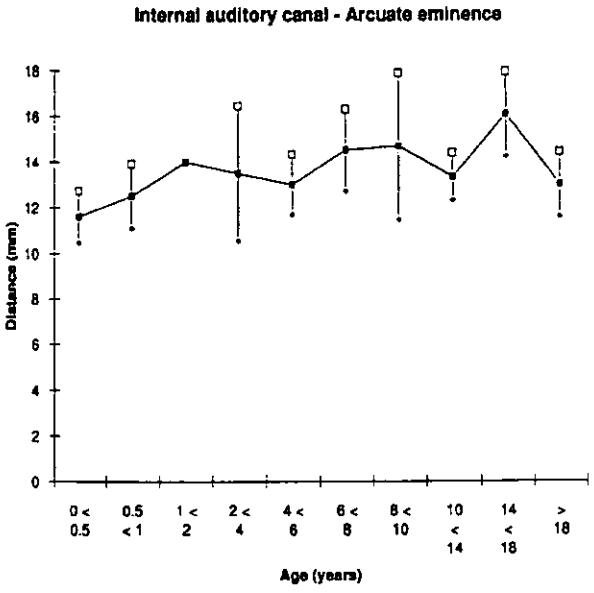

Fig. 10.

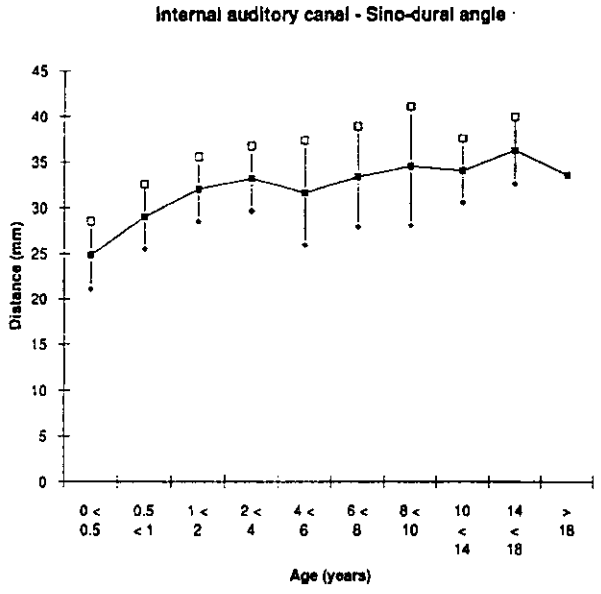

Fig. 12.

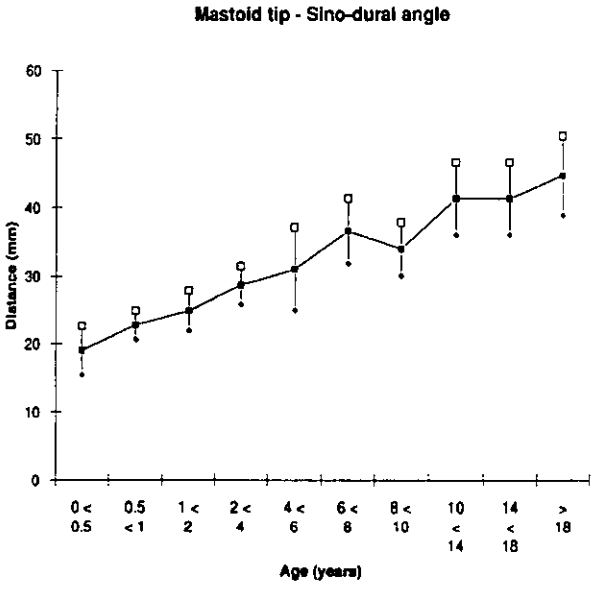

Fig. 11.

to be almost 26 mm further apart in the adult temporal bone (mean 44.57 mm, SD 5.8 mm) and was highly statistically significant $p < 0.0002$). Moreover, this growth occurred at a relatively even rate until adulthood, with all age groups below 10 years exhibiting a significant difference compared with the adult dimensions.

The extent of growth between the internal auditory canal and the most posterolateral point of the sino-dural angle, basically along the posteromedial edge of the temporal bone, was less extensive (Fig. 12). From 24.8 mm (SD 3.71 mm) in the youngest group, a period of faster growth was seen until two years of age (mean 32.0 mm, SD 3.53 mm), with a slower growth pattern then occurring until adulthood, where the distance was 33.5 mm (SD 0.0 mm).

As shown above, statistically significant growth can be observed between most of the prominent and externally detectable landmarks of the temporal bone. This growth, however, is not uniform, and concurrent with these changes in overall dimensions, a change in the shape and appearance of the temporal bone takes place. These dimensional changes would appear to result from differential patterns of growth in the various parts of the temporal bone.

Specific regional growth patterns of the human temporal bone

Various anatomical regions of the temporal bone were examined both separately, and in relationship to one another by examining growth between specific external and internal reference points.

(i) Inner ear and bony labyrinth

The round and oval windows, promontory and the lateral semicircular canal were the anatomical landmarks selected to represent the cochlea and labyrinth (Table II). The mean distance between the round and oval windows fell within a range of 4.1–4.5 mm with an average standard deviation of just 0.34 mm (Fig. 13). There was no evidence of significant growth between these points from birth through to adulthood. The promontory was an average of 3.88 mm (SD 0.43 mm) from the crista fenestra of the round window and again no evidence of growth between these points was observed (Fig. 14). The lateral semicircular canal, although further away and somewhat

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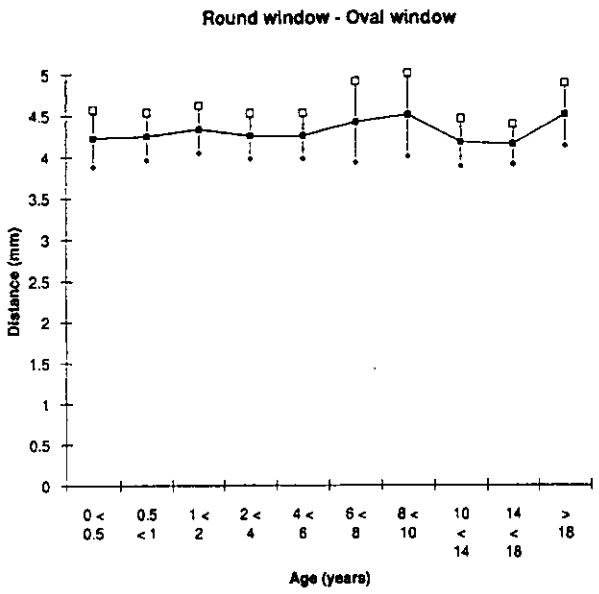

Fig. 13.

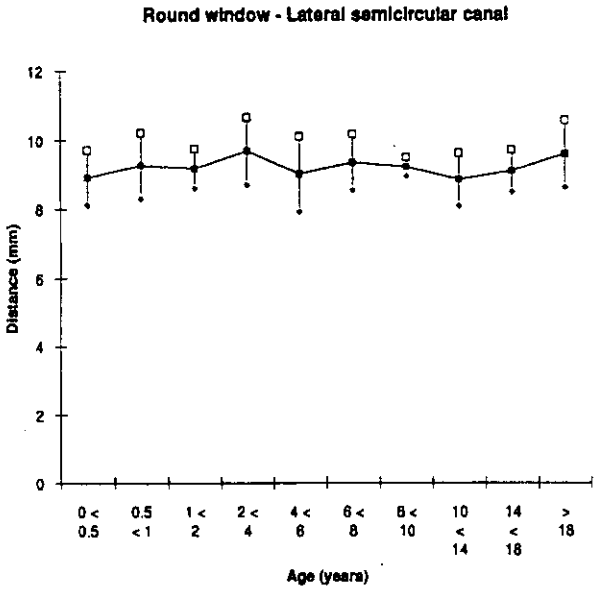

Fig. 15.

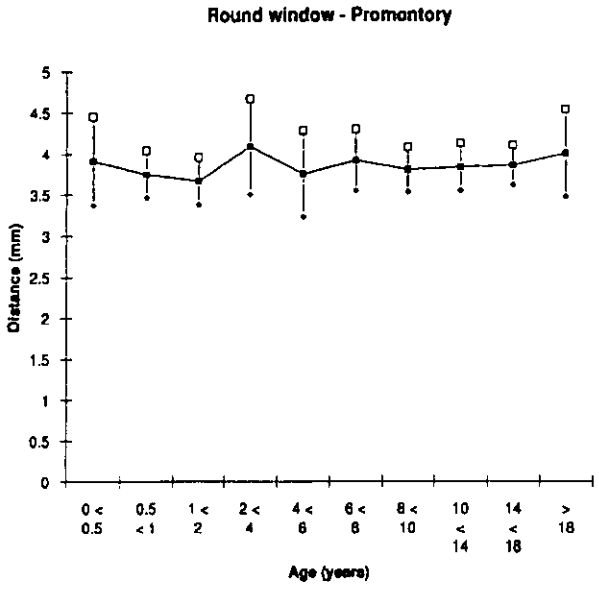

Fig. 14.

Fig. 16.

more difficult to define as the most lateral point on a curved surface, was in all age groups almost the same distance with a mean of 9.2 mm (SD 0.81 mm) from the round window (Fig. 15); 8.19 mm (SD 0.85 mm) from the oval window (Fig. 16); and 9.89 mm (SD 1.43 mm) from the promontory (Fig. 17). No significant change as a function of age was observed in any of these measurements.

The dimensions across the labyrinth to the prominence of the superior semicircular canal, and subjacent to the arcuate eminence, showed no statistical evidence of growth across age groups, although these data were subject to a somewhat larger variance. The mean distance between the arcuate eminence and the lateral semicircular canal was 9.69 mm (SD 1.23 mm; Fig. 18), and the arcuate eminence to the round window was 13.73 mm (SD 1.69 mm; Fig. 19).

However, some increase in length was noted between the internal auditory canal and the anatomical points representing the tympanic side of the inner ear; the round and oval windows and the promontory. The distance between the internal auditory canal and the round window varied from 8.25 mm (SD 0.63 mm) in children under 6 months of age, to 11.5 mm (SD 2.83 mm) at adulthood (Fig. 20). Due to the relatively large variance associated with these

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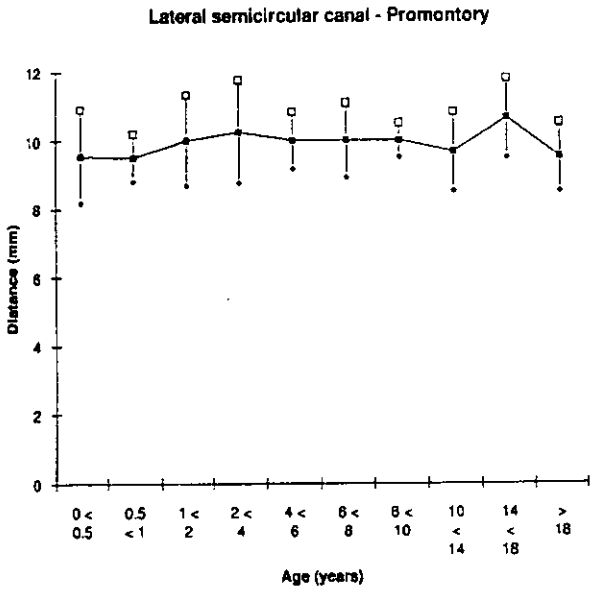

Fig. 17.

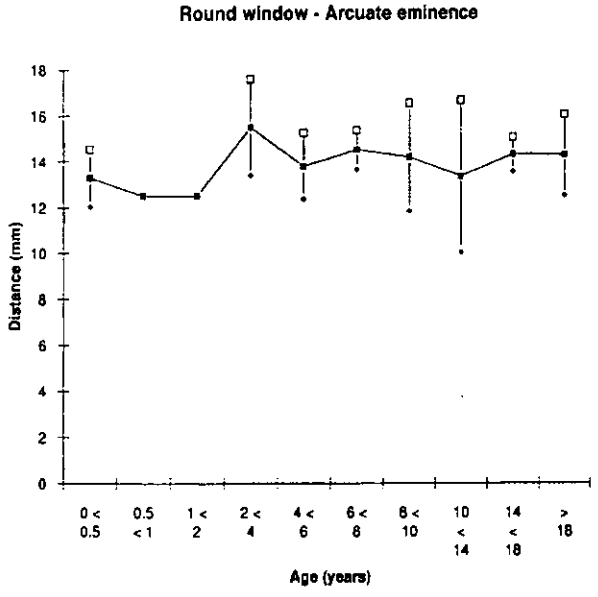

Fig. 19.

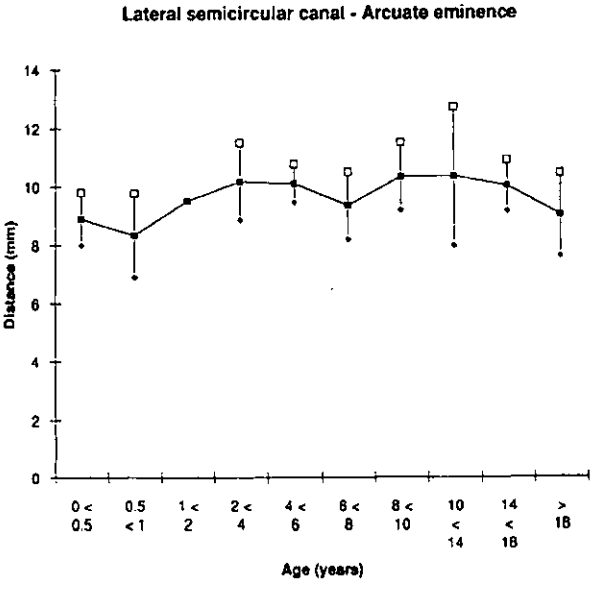

Fig. 18.

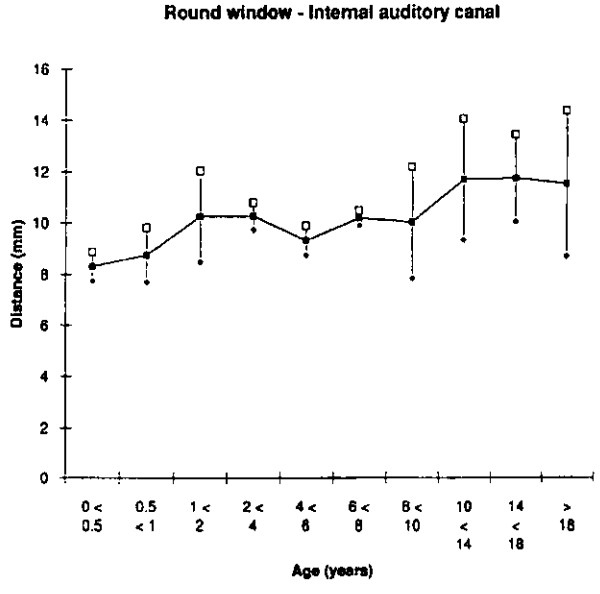

Fig. 20.

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data there was no evidence of statistically significant growth between age groups. However, two periods of rapid growth were apparent, one occurring in the first two years of life and the second during early adolescence. Similar patterns of growth were observed between the internal auditory canal and the promontory and oval window.

In summary, the present results indicate that the inner ear and labyrinth have the same dimensions at term as they will as an adult. The only exemption seems to be the area around the internal auditory canal, which exhibits limited growth after birth.

(ii) Ossicles

The umbo of the malleus, the tip of the short process of the incus, and the most anterior rim of the stapes footplate (oval window) were the reference points selected to examine growth among the three ossicles (Table II). There was no evidence of statistically significant growth observed between any of these three landmarks. The overall mean distance between the tip of the short process of the incus (FI) and the stapes footplate (OW) was 7.80 mm (SD 0.91 mm; Fig. 21); 7.87 mm (SD 0.83 mm); between the incus and the tip of the long process of the malleus

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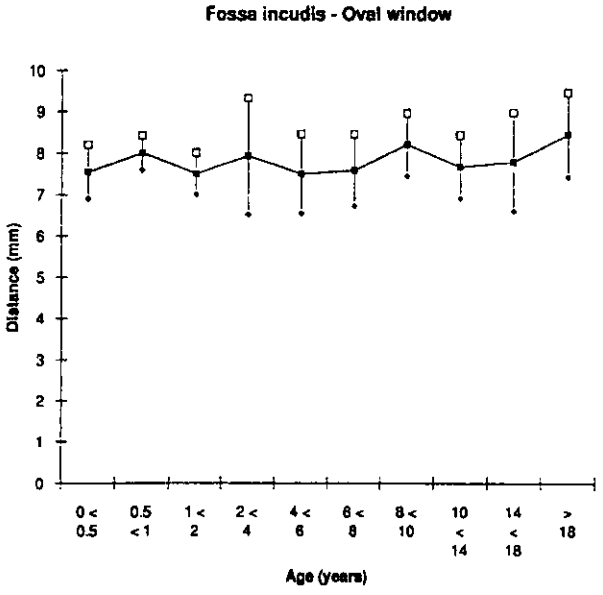

Fig. 21.

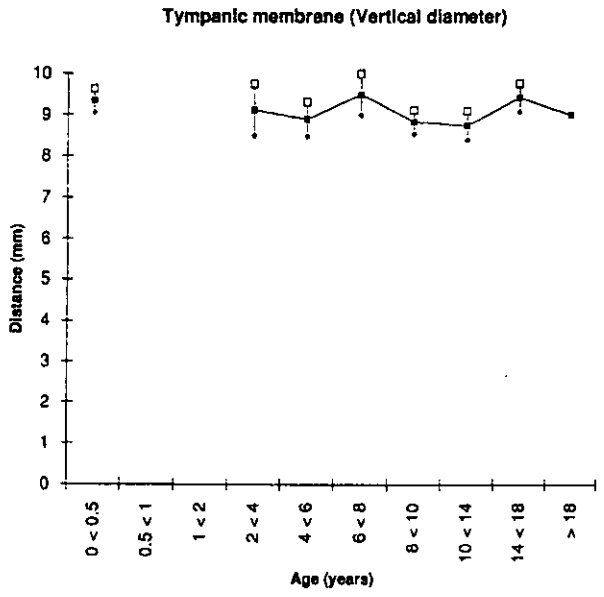

Fig. 23.

(UMB); and 4.47 mm (SD 0.71 mm) between the oval window and the malleus. All ossicles appeared to be adult size at term and showed no sign of postnatal growth.

(iii) Tympanic membrane

Direct measurement of the horizontal and vertical diameters of the tympanic membrane showed no evidence of postnatal growth (Figs. 22 and 23). The mean diameters were 9.14 mm (SD 0.59 mm) and 9.15 mm (SD 0.44 mm) respectively.

The tympanic spine and the tympanic sulcus adjacent to the posterior canaliculus for the chorda tympani, are landmarks of the osseous annulus, and the umbo approximates the centre of the tympanic membrane, where the tip of the manubrium mallei inserts. The distances between the umbo and both sites along the osseous annulus showed no significant change with age (all $p > 0.05$), indicating the morphological maturity of the tympanic membrane at term. The mean distance between the umbo and the tympanic spine—where the posterior ligament of the malleus inserts into the osseous annulus—was 5.89 mm (SD 0.43 mm) across all age groups, while the mean distance between the umbo and the tympanic sulcus was 5.95 mm (SD 0.53 mm). Finally, the distance between the tympanic sulcus and the tympanic spine also showed no evidence of significant growth. A mean distance across all age groups was 6.55 mm (SD 0.77 mm).

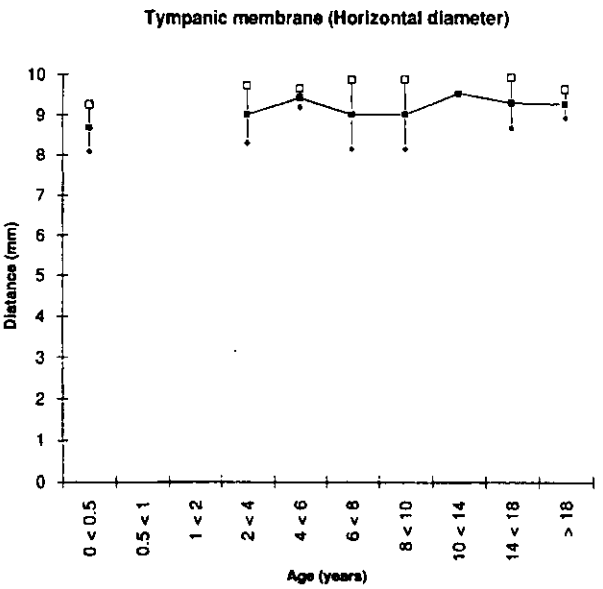

Fig. 22.

(iv) Middle ear

The space of the middle ear is expressed by the reference points of the tympanic membrane (tympanic sulcus and umbo) laterally, the round window, oval window and the promontory medially, and the short process of the incus (FI) posteriorly (Table II). Our results indicate no statistically significant growth between any of these landmarks during postnatal development. The umbo was an average 2.1 mm (SD 0.51 mm) from the promontory; 5.05 mm (SD 0.51 mm) from the round window (Fig. 24); and 4.47 mm (SD 0.71 mm) from the oval window. The tympanic spine was a mean distance of 9.34 mm (SD 1.0 mm) to the round window; 7.45 mm (SD 0.76 mm) to the promontory; and 5.02 mm (SD 1.0 mm) to the fossa incudis. The tympanic sulcus was 7.12 mm (SD 1.05 mm) from the round window

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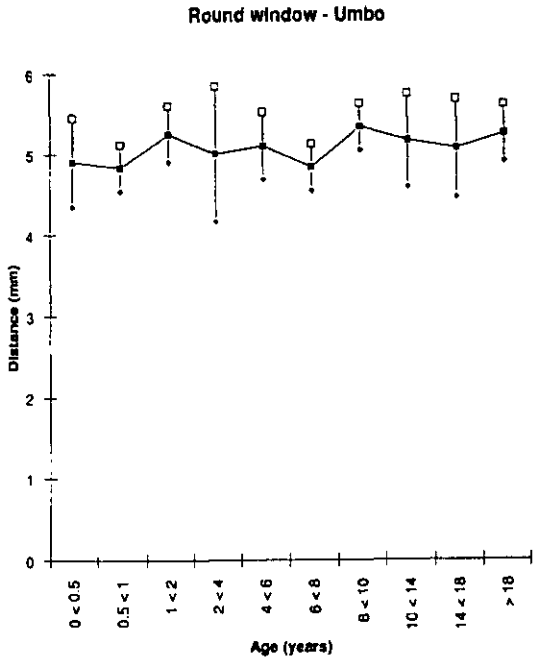

Fig. 24.

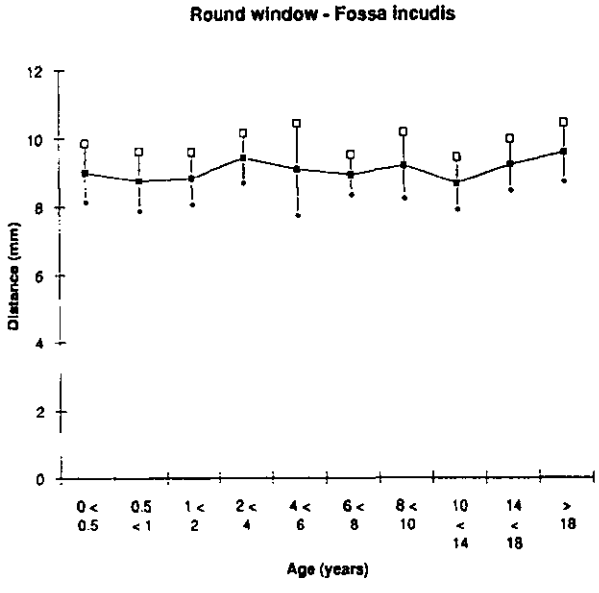

Fig. 25.

and 4.51 mm (SD 0.63 mm) from the fossa incudis. Finally, the fossa incudis was a mean distance of 9.12 mm (SD 0.85 mm) from the round window (Fig. 25) and 9.02 mm (SD 0.98 mm) from the promontory. As observed with the inner ear, the ossicles and the tympanic membrane, the middle ear showed no evidence of significant postnatal growth.

(v) External auditory canal

The lateral superficial border of the external auditory canal can be defined by the porion superiorly, the inferolateral tympanic point inferiorly and the upper posterior point of Macewen's triangle posteriorly (Table II). The deep medial part is again represented by the tympanic membrane (TSP, TSU and UMB). The width of the orifice of the external auditory canal was expressed by the porion, the posterosuperior point of the suprameatal triangle, and the inferolateral tympanic point. Although Macewen's triangle and the porion are not part of the tympanic bone, they have a close relationship to, and are at the level of, the lateral orifice of the external auditory canal. The inferolateral tympanic point of the tympanic bone shows a significant increase in its distance to the porion ($p < 0.01$) and the posterosuperior point of Macewen's triangle (PMT; $p < 0.02$) from birth to adulthood. The distance between the inferolateral tympanic point and the porion increased 4.55 mm (18.45 mm, SD 2.37 mm to 23.0 mm, SD 2.74 mm) and the inferolateral tympanic point to the posterosuperior point of Macewen's triangle increased 9.8 mm (14.8 mm SD 3.5 mm to 24.56 mm SD 3.78 mm) over this period. Between the same age groups, the distance from the porion to the posterosuperior point of Macewen's triangle increased 3.92 mm from 5.95 mm (SD 2.9 mm) to 9.87 mm (SD 1.66 mm). This growth was also statistically significant ($p < 0.05$).

The depth or lateral extension of the external auditory canal along its roof can be evaluated by measuring the distance between the porion and the tympanic spine. Our results indicate that this dimension more than doubles its original length from birth to adulthood (<6 months 7.36 mm SD 1.6 mm to 15.5 mm SD 1.73 mm in the adult group; Fig. 26), and the extent of this growth is highly statistically significant

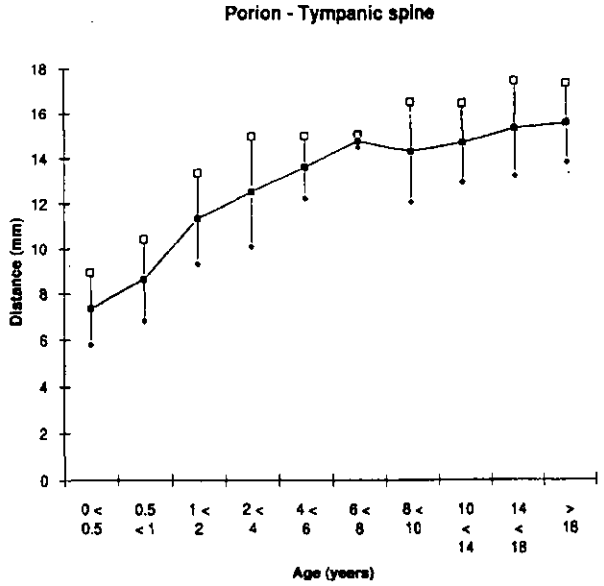

Fig. 26.

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($p < 0.0002$). The majority of this growth occurs in the first 2–4 years of life. For example, 1–2 year old children have already completed almost half of the expected increase (11.3 mm; SD 2.02 mm), and exhibit a significant difference compared to the <6 month group ($p < 0.004$). Similar patterns of growth were experienced when measuring from the porion to either the round or oval windows. The porion to the round window measured 16.2 mm (SD 2.2 mm) in the youngest group and 24.5 mm (SD 1.71 mm) in adults, while the portion to the oval window was 14.1 mm (SD 2.02 mm) in children under 6 months and 22.81 mm (SD 1.87 mm) in adults. Again, about half the growth took place before two years of age.

The posterolateral border of the external auditory canal, approximated by the posterosuperior point in Macewen's triangle, showed a 9.6 mm increase in the distance from the tympanic spine during maturation (8.58 mm SD 1.55 mm at <6 months to 18.19 mm SD 1.53 mm at adulthood). In addition, the posterior point of Macewen's triangle to the tympanic sulcus showed a 7.83 mm increase (8.17 mm SD 2.93 mm at <6 months to 16.0 mm SD 1.41 mm as adults). The inferior part of the external auditory canal also showed signs of lateral growth (Fig. 27). The distance between the inferolateral tympanic point of the tympanic bone and the tympanic spine increases significantly ($p < 0.0005$) from birth (12.05 mm SD 2.53 mm) to adulthood (20.19 mm SD 3.79 mm). In this case the majority of the growth appeared to take place during adolescence. In addition, a 10.88 mm increase in the distance between the umbo and the inferolateral tympanic point was noted ($p < 0.0005$). The range was 5.87 mm (SD 0.63 mm) in the youngest group to 16.75 mm (SD 1.77 mm) in the oldest age group (Fig. 28). Unlike the growth between the inferolateral tympanic point and the tympanic spine, the majority of growth between the umbo and the inferolateral tympanic point occurred during the first six years of life. In the youngest group of children only a small bony protuberance of the developing osseous ear canal was present which was used as the landmark. This is reflected in a minimum distance of 5.87 mm between the inferolateral tympanic point and the umbo and approximates the radius of the tympanic membrane as found in our measurements of the tympanic membrane (see above). During the first year of life the proturberances of the tympanic ring grow outwards and join one another to form an anteroinferiorly situated transient opening (Huschke's foramen), which in our study could be identified in seven of the 20 temporal bones between one and six years of age.

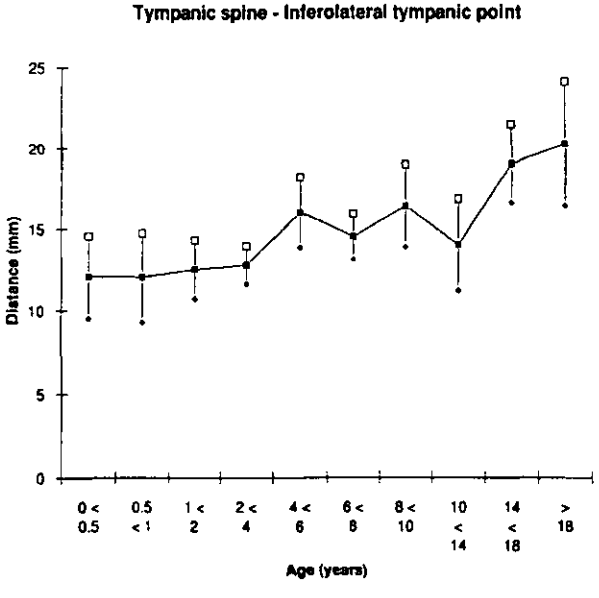

Fig. 27.

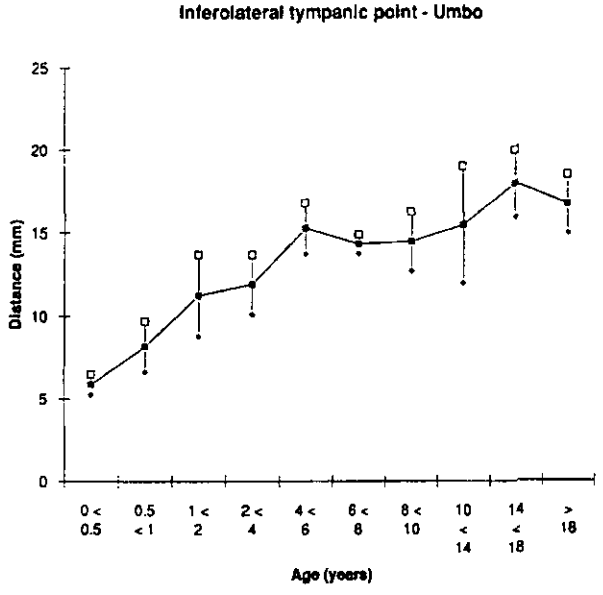

Fig. 28.

In all measurements involving the inferolateral tympanic point, a rapid period of lateral growth was observed through the first five years of life (e.g. Fig. 28). A second period of growth was also usually observed during adolescence to complete the development.

In summary the external auditory canal is subject to dramatic postnatal development. At term only an incomplete tympanic ring is present. This rapidly extends laterally during childhood and adolescence, creating a bony canal of approximately 16 mm depth. The inferior part of the external orifice undergoes some inferior migration resulting in a somewhat funnel shaped external opening that is directed slightly inferiorly.

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(vi) Mastoid

The limits of the mastoid portion of the temporal bone can be described by the mastoid tip, the sino-dural angle, the digastric ridge, the stylomastoid foramen and the posterosuperior point of Macewen's triangle. The inferior limits are expressed by the lateral semicircular canal, the fossa incudis and the sigmoid sinus (Table II).

The posterior extension of the mastoid, expressed by the distance between the posterosuperior point of Macewen's triangle and the sino-dural angle, undergoes significant growth during the maturation period (18.34 mm SD 3.9 mm in the <6 month group to 27.36 mm SD 7.42 mm in adults; $p < 0.01$). This growth tended to increase gradually throughout childhood with a brief period of rapid growth late in adolescence (Fig. 29). In addition, these data showed considerable variance at most age groups.

Growth superoinferiorly can be expressed by the change in distance between the posterosuperior point of Macewen's triangle or the sino-dural angle superiorly, and the tip of the mastoid process inferiorly. The human temporal bone undergoes significant growth in this direction. Our data indicate that the temporal bone grows an average 19.23 mm between the mastoid tip and the posterosuperior point of Macewen's triangle from birth (12.33 mm; SD 3.32 mm) to adulthood (31.56 mm SD 3.07 mm; Fig. 30); this amount of growth was highly statistically significant ($p < 0.0002$). Moreover, while the most extensive growth occurred in the first year of life, extensive growth was also observed in the 4-8 and 14–18 year age groups. The sino-dural angle to mastoid tip distance also underwent a considerable increase; a mean difference of 25.6 mm was recorded between the youngest (18.97 mm; SD 3.61 mm) and oldest (44.57 mm; SD 5.79 mm) age groups. Although an accelerated growth pattern was observed during the first two years of life, mastoid tip development continued to occur throughout childhood and adolescence.

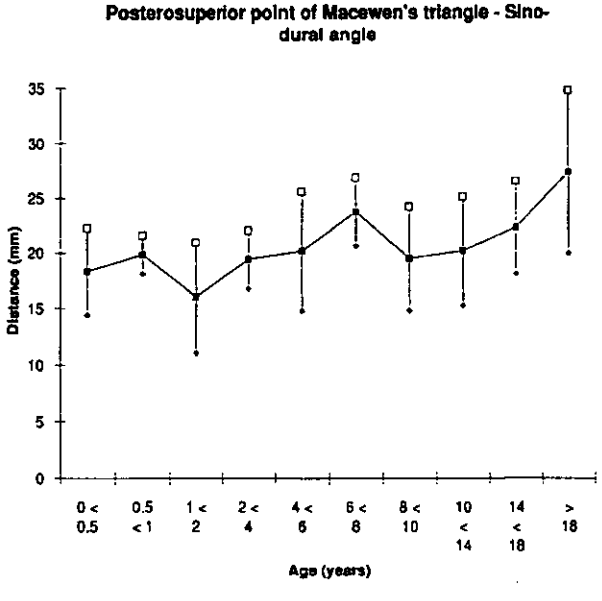

Fig. 29.

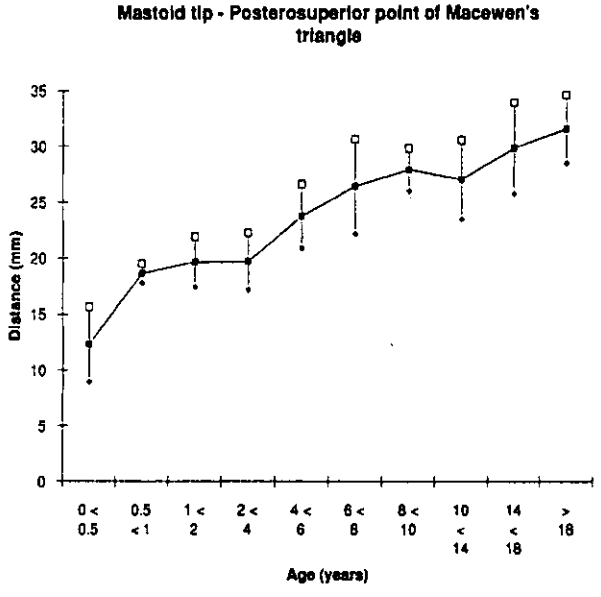

Fig. 30.

The development of the mastoid tip from, and its relationship with the inner ear, is probably best expressed by its distance to the fossa incudis and the lateral semicircular canal. These two landmarks represent the medial and anteromedial borders of the mastoid part of the temporal bone. The increases noted were again highly statistically significant. The total growth between the mastoid tip and the fossa incudis was an average 23.6 mm (10.76 mm SD 1.64 mm, <6 months to 34.31 mm SD 2.89 mm, >18 years; $p < 0.0002$). Again, this growth occurred throughout both childhood and adolescence (Fig. 31). A similar pattern of growth was observed between the mastoid tip and the lateral semicircular canal, with a total mean extension of 23.8 mm (10.69 mm SD 1.86 mm, <6 months to 34.5 mm SD 2.42 mm, >18 years).

The digastric ridge could only be detected in temporal bones older than 6 months of age due to the absence of a real mastoid process in the younger children. However, from 6–12 months to adulthood, the distance to the medial surface of the mastoid tip increased 9.75 mm (SD 1.06 mm). The most caudal point on the digastric ridge, however, is not in a fixed position and undergoes an inferior displacement during growth. This was demonstrated by assessing its relationship to the fossa incudis and the lateral semi-

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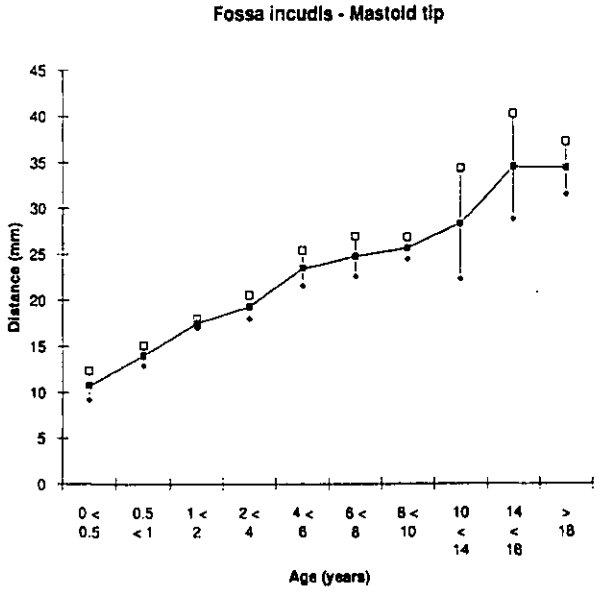

Fig. 31.

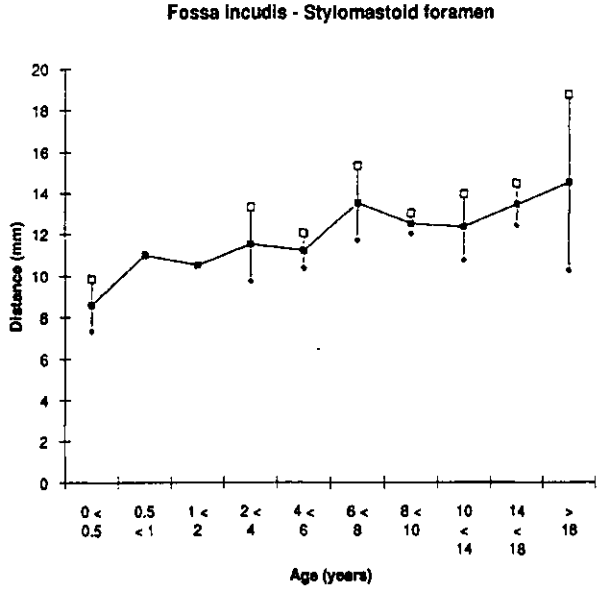

Fig. 33.

circular canal. Between the second 6 months of life (11.5 mm) and adulthood (21.75 mm), the distance between the digastric ridge and the fossa incudis increased an average 10.25 mm (SD 2.47; Fig. 32). Exactly the same amount of growth was noted between the digastric ridge and the lateral semicircular canal. The stylomastoid foramen, in contrast, showed less inferior migration with age than the digastric ridge. Mean increases of 5.9 and 6.4 mm were recorded between the stylomastoid foramen and the fossa incudis (Fig. 33), and the stylomastoid foramen and the lateral semicircular canal respectively. While the majority of growth occurred within the first year of life, growth continued at a reduced rate through to adulthood.

The lateral extension or depth of the mastoid section of the temporal bone can be expressed by the distance between the posterosuperior point of Macewen's triangle and the lateral semicircular canal (Fig. 34), and the posterosuperior point of Macewen's triangle and the fossa incudis (Fig. 35). A statistically significant 10.42 mm (PMT-LS; $p < 0.0002$) and 10.17 mm (PMT-FI; $p < 0.0002$) of lateral growth of the mastoid was noted. In both cases, the majority of the growth occurred in the first two years of life, although additional growth

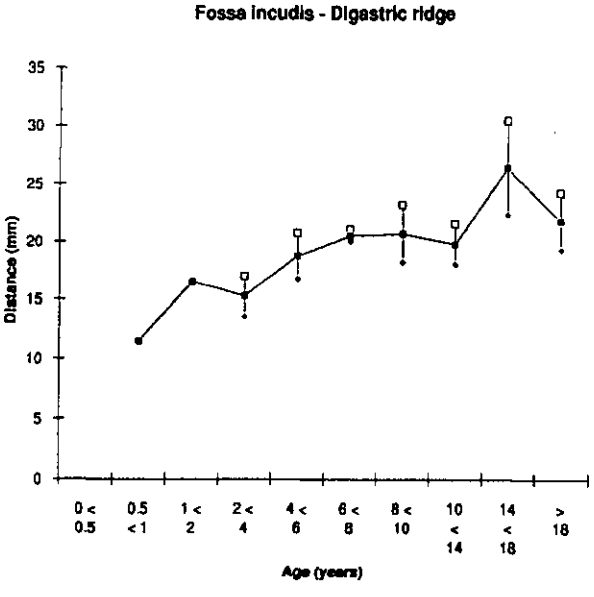

Fig. 32.

Fig. 34.

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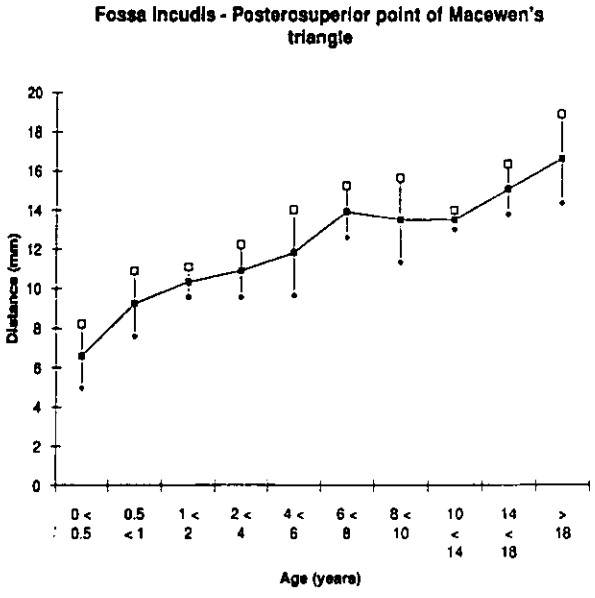

Fig. 35.

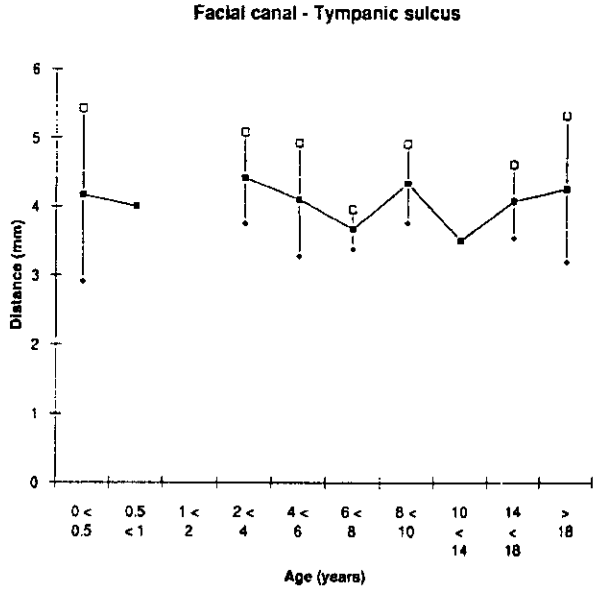

Fig. 36.

periods occurred in the 4–8 and 14–18 year age groups.

In summary, the mastoid part of the temporal bone presents with considerable postnatal growth along all three dimensions. Its surface grows laterally from medially neighbouring structures of the inner ear and the cranial fossa. It lengthens in the anteroinferior direction and displays maximum growth superoinferiorly with the development of the mastoid process.

(vii) Facial recess

The maximum possible access to the posterior sinus tympani resulting from a simple posterior tympanotomy is outlined by the facial canal medially, the tympanic sulcus laterally and the bony buttress that constitutes the floor of the fossa incudis superiorly.

A measure of the width of the posterior tympanotomy for access to the round window is the distance from the facial canal at the midline of its vertical course, to the tympanic sulcus adjacent to the posterior canaliculus for the chorda tympani. No change with age was noted between these two landmarks (Fig. 36). The mean diameter across all age groups was 4.11 mm (SD 0.67 mm; $p = 0.83$). In addition, we found no significant change in the distance between the fossa incudis on the one side and the tympanic sulcus or the facial canal on the other side. Here the mean values across all ages were 4.51 mm (SD 0.64 mm) and 5.35 mm (SD 1.19 mm) respectively. It should be noted, however, that the thickness of the bony buttress underlying the fossa incudis, forming the superior border of the posterior tympanotomy, is included in these measurements. An increased access to the facial recess and posterior tympanum can be achieved by sacrificing the chorda tympani and creating an extended posterior tympanotomy.

In summary, the facial recess appears to be adult size at term and is therefore not subject to significant postnatal development.

(viii) Facial canal

The site we choose as the landmark representing the facial canal is situated deep and caudal to the suprameatal (Macewen's) triangle. In the newborn it was found to be an average 8.4 mm (SD 3.2 mm) beneath the posterosuperior point of Macewen's triangle. In the adult, in contrast, bone of an average thickness of 15.5 mm (SD 1.41 mm) covered the facial canal, indicating a relative medial displacement of the canal some 7 mm (Fig. 37). The majority of this growth occurred during the first year of life with a secondary growth phase occurring at 8–10 years of age. In contrast, the distance between the facial canal and the neighbouring lateral semicircular canal or the tympanic sulcus remained virtually constant. The same was true for its distance to the round window. Across all age groups the facial canal to round window distance varied between 7.3–8.0 mm (SD 0.85 mm).

The length of the vertical intramastoid part of the facial canal was assessed approximately by the increase in distance between the exit point of the facial nerve at the stylomastoid foramen and the lateral semicircular canal—the point closest to the knee of the facial canal where it turns horizontally into its tympanic part. A statistically significant growth of 5.9 mm was noted between the newborn (8.4 mm; SD

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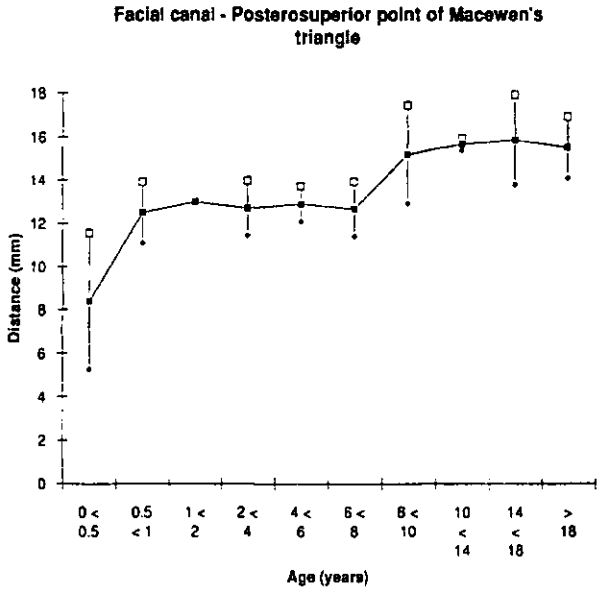

Fig. 37.

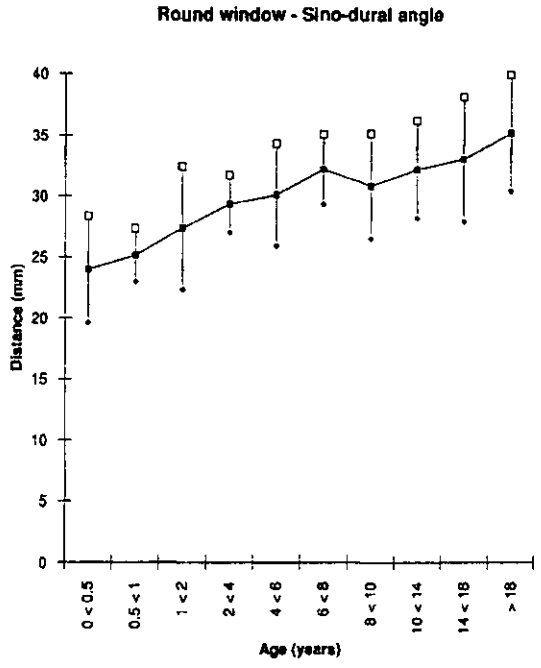

Fig. 38.

1.88 mm) and the oldest children (14.35 mm; SD 1.99 mm).

Growth between surgical landmarks relevant for cochlear implantation

The course of the cochlear implant leadwire and electrode array within the temporal bone winds from the implantation site of the receiver-stimulator subjacent to the sino-dural angle, via variable fixation points and the facial recess, to the implantation site at or near the round window. It passes through the different parts of the temporal bone and the length of its course can be assessed by choosing a combination of anatomical landmarks. Growth between the relevant anatomical landmarks will indicate the expected growth changes likely to occur along the leadwire. To provide this information, the growth between the electrode entry point and the receiver-stimulator must be assessed.

In the present study the most posterolateral point of the sino-dural angle was chosen as the anatomical landmark closest to the prospective implanation site of the receiver-stimulator package. The direct distance between the sino-dural angle and the round window increased significantly ($p < 0.0002$) from 23.5 mm (SD 4.36 mm) in the group under 6 months, to 35.14 mm (SD 4.77 mm) in the adult group (Fig. 38). An average growth of 11.6 mm was observed between these two landmarks. In the 1–2 year age group the average distance was 27.33 mm (SD 5.03 mm) indicating that approximately one third of the postnatal development occurs during the first two years of life. The same pattern could be seen in the distance from the sino-dural angle to the promontory. In the youngest group this distance was 25.45 mm (SD 4.14 mm) compared with 36.71 mm (SD 5.44 mm) in the adult group—a significant difference of 11.3 mm ($p < 0.0005$). Moreover, the distance between these points had grown 3.25 mm—one third of its total growth—by 2 years of age (28.7 mm SD 5.6 mm).

The course of the leadwire in a cochlear implant patient, however, does not follow the shortest distance between the electrode entry point and the sino-dural angle. The leadwire passes through the facial recess (TSU, FI, FAC) and its course can therefore be divided into at least two anatomical sections. Our results indicate that almost all growth occurs between the sino-dural angle and the facial recess. For example, a mean difference of 11.5 mm was seen between the sino-dural angle and the fossa incudis across age groups (<6 months, 17.85 mm SD 3.87 mm; >18 years, 29.36 mm SD 5.18 mm; Fig. 39). This difference was highly significant ($p < 0.0002$). A rapid and significant growth phase in the first four years of 5.1 mm, was followed by more gradual growth rate through to adulthood. The distance from the fossa incudis to the round window, in contrast, remains virtually constant (Fig. 25). In the present study a non-significant ($p = 0.759$) increase of 0.6 mm could be detected between the youngest (9.0 mm; SD 0.91 mm) and the oldest (9.56 mm; SD 0.86 mm) age groups. In addition, no significant growth ($p = 0.87$) was observed between the fossa incudis and the promontory from newborn (8.84 mm; SD 1.29 mm) to adults (9.31 mm; SD 0.88 mm). The same pattern

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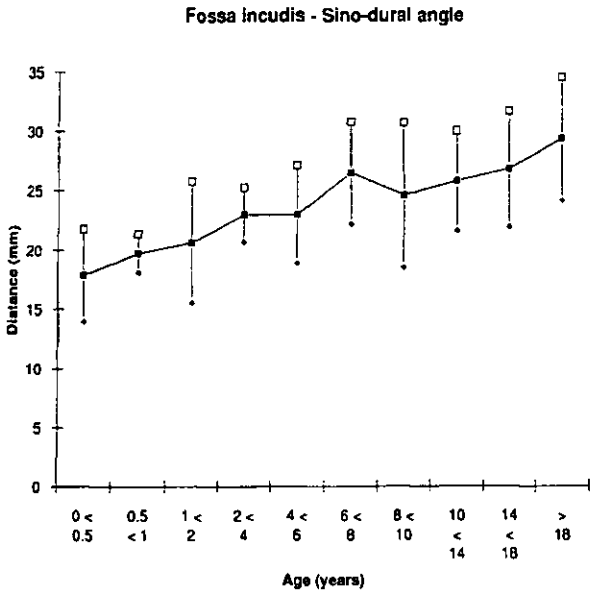

Fig. 39.

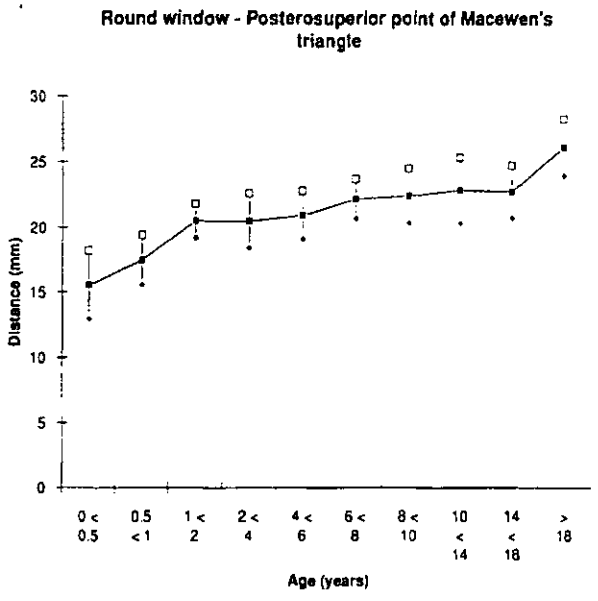

Fig. 40.

applies for the distance between the round window, and the facial canal and the tympanic sulcus, the two other representative points within the facial recess. The mean distance of the facial canal to the round window was 7.7 mm (SD 0.85 mm) across all age groups. The tympanic sulcus was an average 7.12 mm (SD 1.05 mm) away from the round window.

In addition, it has been recommended to secure the leadwire in order to stabilize it and to prevent electrode slippage post implantation (31, 32). Fixation points are usually situated at the periphery of the mastoid exenteration. Anteriorly, the posterior wall of the bony external auditory canal has been used. More superficially the superior (PMT) or the inferior (MA) margin of the mastoidectomy have also been used for this purpose. The posterosuperior point of Macewen's triangle, which approximates a site where a Dacron tie is often used for the fixation of the leadwire, shows significant signs of postnatal development along two different axes, the mediolateral and the posteroanterior. In the latter case the distance from the sino-dural angle to the posterosuperior point of Macewen's triangle shows statistically significant growth of 9.0 mm ($p < 0.01$) between the <6 month group (18.34 mm, SD 3.9 mm) and adults (27.36 mm, SD 7.42 mm; Fig. 29). Between all older age groups (i.e. >6 months), however, growth was not significant. Even more growth is observed in the mediolateral direction. From the round window to the posterosuperior point of Macewen's triangle, an average of 11.0 mm of growth was recorded from the youngest (15.15 mm, SD 2.4 mm) to the oldest group (26.12 mm, SD 2.18 mm; Fig. 40). Again, this growth was statistically significant ($p < 0.0002$). It is important to note that almost half of this growth was observed during the first two years of life. Virtually the same amount of growth—10.2 mm—was noted between the posterosuperior point of Macewen's triangle and the underlying fossa incudis (Fig. 35), and is in accordance with the previously noted invariability of the distance between the fossa incudis and the round window (Fig. 25).

The overall growth of a line drawn along a leadwire positioned from the sino-dural angle to the posterosuperior point of Macewen's triangle and finally to the round window, indicates an average change in distance of 20.0 mm from the <6 month old child (33.8 mm; SD 4.50 mm) to the adult group (53.8 mm; SD 8.56 mm; Fig. 41). This distance is greater than the expected growth measured directly between the sino-dural angle and the round window (Fig. 38). Moreover, this growth occurs throughout both childhood and adolescence at a relatively uniform rate.

The largest growth changes, however, occurred in the mastoid. The distance from the mastoid tip to the round window exhibited a total mean increase of 21.3 mm; from 11.8 mm (SD 1.77 mm) in the youngest group; 19.67 mm (SD 0.29 mm) in the 1–2 year olds; and finally 33.13 mm (SD 2.37 mm) in the adult group. The distance from the mastoid tip to the sino-dural angle exhibits even greater growth; 18.96 mm (SD 3.61 mm) in the youngest age group; 24.83 mm (SD 2.93 mm) in the 1–2 year olds; to 44.57 mm (SD 5.79 mm) in adults. The extensive postnatal growth of the mastoid tip indicates that this region of the mastoid should be avoided when routing the leadwire during cochlear implantation.

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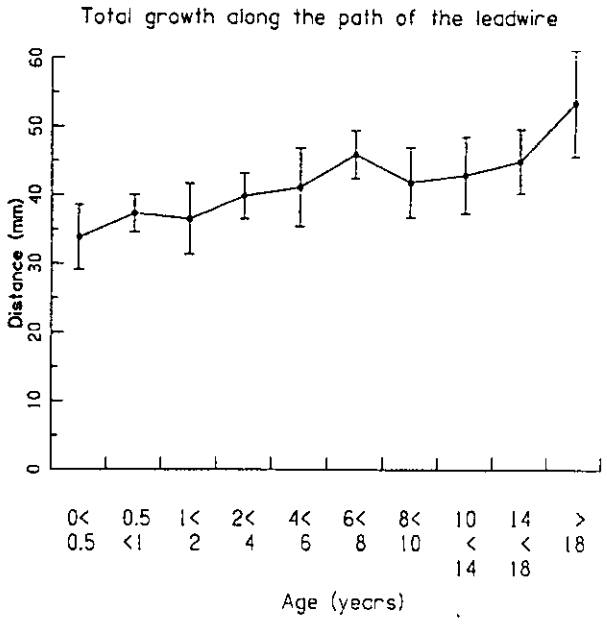

Fig. 41.

A bulging sigmoid sinus can hinder the access to the facial recess and complicate cochlear implant surgery. The proximity of the most prominent part of the sigmoid sinus was assessed by measurements of its distance to the landmarks of the facial recess: the facial nerve, the tympanic annulus and the fossa incudis. We saw no evidence of statistically significant growth as a function of age, although considerable variance was noted. A mean distance of 13.28 mm (SD 2.26 mm) was observed between the tympanic annulus and the sigmoid sinus. A range of values from 8.50–19.00 mm were measured for the distance between the fossa incudis and the sigmoid sinus. The closest structure to the sigmoid sinus was the facial canal. A mean distance of 9.84 mm (SD 2.34 mm) was recorded between these points.

The relationship of the sigmoid sinus to the structures relevant for cochlear implant surgery reveal no significant changes across age groups. Moreover, not one of the dissected temporal bones presented with a sigmoid sinus that was protruding to an extent that would have made cochlear implantation impossible.

Finally, the surgical procedure of cochlear implantation was found to be feasible in all sixty temporal bones regardless of age.

DISCUSSION

The present results describe direct anatomical measurements performed on 60 cadaver specimens in order to evaluate the growth pattern of the human temporal bone. The population of specimens was considered to be representative and no selection in terms of ethnic background or sex was used. A considerable variation in size between the individuals in each age group was, therefore, to be expected and only growth greater than this variance was noted.

The present results showed that the temporal bone is subject to considerable postnatal change in its overall size as well as in its shape. Our findings associated with the inner ear confirmed the well known fact of its adult size at term (11–15). The internal auditory canal is subject to postnatal lengthening of more than 3 mm at its posterior (lateral) rim. The petrous apex has been described as undergoing significant medial growth postnatally and results subsequently in the lengthening of the internal auditory canal (14).

In the middle ear we were able to confirm previous reports about the maturity of the ossicles and the tympanic cavity (18, 20). We did not include in our study measurements of the inferior part of the tympanic ring and therefore, cannot comment on any widening of the posterior hypotympanum as described by both Proctor (18) and Spector (20).

Our measurements of the facial recess indicate that it is adult in size at birth. With an average width between the tympanic sulcus and the facial canal of 4.1 mm, the present result is in the same magnitude as reported by previous authors (24, 25, 33, 34). In addition, we demonstrated that the border of the facial recess, represented in our study by the facial canal, the tympanic sulcus and the fossa incudis, shows no sign of growth away from the round window.

The present findings indicated a substantial centrifugal growth of the lateral parts of the temporal bone. All structures situated lateral to the middle ear, the facial canal and the tympanic membrane, showed significant outward growth resulting in a relative inward shift of the inner and middle ear structures. The lateralization of the surface is most obvious in the development of the external auditory canal. A small incomplete ring at term, it develops into a clearly formed canal of more than 8 mm in depth. This growth is most pronounced during the first two years of life (Fig. 26), but is found to continue through to young adulthood. The mastoid part of the temporal bone was found to undergo the same amount of lateral growth as the external auditory canal. An increase of approximately 10 mm in the thickness of the mastoid bone overlying the fossa incudis, lateral semicircular canal and the facial canal was observed between the newborn and the adult.

In addition to the lateral extension, there is considerable growth of the mastoid in the superoinferior and anteroposterior directions. The mastoid tip shows extensive growth of approximately 20 mm su-

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peroinferiorly during development. The extension of the mastoid part in the anteroinferior direction was found to be approximately 9 mm along the surface from the posterosuperior point of Macewen's triangle to the sino-dural angle. Across the mastoid, the growth in the distance from the fossa incudis or lateral semicircular canal to the sino-dural angle was approximately 12 mm.

These are important findings for cochlear implant surgery because they indicate that the inferior and lateral extension of the mastoid can have a significant effect on electrode leadwire positioning. Any placement or fixation of a leadwire near the bony external auditory canal of a growing child would be exposed to an increased risk of displacement of the electrode array due to subsequent post-operative growth. A canal route or fixation of the electrode array at the posterior canal wall has been described and is used in adult patients (31). Beside the increased risk of canal skin erosion as reported by Webb (31), we consider this approach unsuitable for use in children.

Fixation of the electrode leadwire at the inferior margin of the mastoidectomy cavity in children is not recommended due to the extensive growth changes in the mastoid tip region. In children under one year of age, the mastoid process is absent and any fixation of the electrode leadwire near the prospective site of mastoid tip development may be subject to maximal expansion during maturation. Fixation of the leadwire at the anterosuperior margin of the mastoidectomy cavity would also result in a significant increase in the risk of electrode displacement because it is influenced by both the lateral and the posterior growth of the temporal bone. An electrode leadwire, secured at the posterosuperior point of Macewen's triangle in a newborn, would be subject to approximately 20 mm of growth if routed between the sino-dural angle and the fossa incudis. Along a leadwire that has no cortical fixation proximal to the receiver-stimulator, however, only an 11–12 mm lengthening would be expected. These data indicate that the risk of displacement or damage of the electrode and leadwire, as a result of skull growth, can be effectively reduced by avoiding any cortical fixation site other than at the site of the receiver-stimulator.

It is important that the leadwire be effectively fixed at a site close to the cochlea in order to maintain the electrode array within the scala tympani. This fixation point must not be associated with regions undergoing post-operative development. Virtually no growth relative to the cochlea was found within the middle or inner ears or the facial recess. However, these regions do not provide suitable or easily accessible fixation sites along the course of the leadwire. The facial recess, in contrast, is exposed during the surgical procedure and the electrode array fed through. Distally, the mastoid is subject to extensive growth and would not be suitable for fixation. The anterolateral border of the facial recess consists of the posterior wall of the external auditory canal and the tympanic ring. These structures, due to their extensive postnatal development, are also not suitable for fixation. The facial recess is limited inferomedially by the facial canal. This is a very unlikely fixation point because of the imminent risk of facial nerve damage. At the superior border of the facial recess is a small buttress of bone, located just underneath the tip of the short process of the incus; the fossa incudis. This buttress is suitable for the placement of a suture or a similar fixation method (31) as it does not exhibit postnatal growth relative to the cochlea, it is in line with the usual course of the leadwire, and is easily accessible during the surgical procedure.

To accommodate the growth of the temporal bone after cochlear implantation it may be necessary to design a leadwire system that is capable of expanding as proposed by a number of investigators (35, 36). Having outlined the optimum fixation sites for the internal and cortical fixation, we can now assess in detail the requirements for such a leadwire system. A leadwire, that is implanted during the first six months after birth, will, until it reaches adult size, be subject to an average extension of approximately 12 mm inside the temporal bone. Between the sino-dural angle and the round window, the smallest distance in the youngest group was 19 mm (mean 23.95 mm; SD 4.38 mm), and the longest distance in the adult group 43 mm (mean 35.14 mm; SD 4.76 mm). A leadwire lengthening system should match these minimum and maximum sizes of the mastoid and be, therefore, capable of up to 25 mm of extension.

One of the most important factors influencing the amount of expected leadwire lengthening is the position of the receiver-stimulator package. If the package is placed mainly over the sino-dural angle or pneumatized part of the mastoid, we can expect average growth in the order of 12 mm. The placement of the majority of the receiver-stimulator package into the parietal or occipital bone could result in greater displacement of the package relative to the cochlea. This should, if possible, be avoided by the implant surgeon. Thus, for anatomical reasons the package should be placed preferably within the borders of the temporal bone. To allow enough room for the microphone or spectacle frames, however, a distance of at least 10 mm should be kept from the postauricular sulcus (31).

The question of the effects of an implant on normal skull growth patterns has been addressed in recent animal experiments that suggest that the presence of

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a cochlear implant in the region of the temporal bone does not interfere with the normal development of the head. A long-term implantation study on subhuman primates revealed no radiological signs of skull asymmetry or abnormal suture growth (37, 38).

The present results describe the general growth pattern of the temporal bone and the significant growth changes detected in the various parts of it. In addition, the results provide the otologic surgeon with concrete information about the size and location of a variety of surgical and anatomical landmarks. Their mean value and variance in each group, as well as the expected changes thereafter can help the surgeon to plan surgery on a young child. They should, if possible, avoid the region of the prospective or developing mastoid process, be aware of a shallow facial canal, place the receiver/stimulator bed as far anterior as possible but as far posteriorly as necessary, avoid a cortical fixation site for the array, allow for some redundant leadwire if not a lengthening system, and use a site for fixation of the array as close to the cochlea as possible.

CONCLUSION

1. The temporal bone is a complex structure, phylogenetically, anatomically and functionally consisting of different entities. As a result, its postnatal development is not uniform nor symmetrical.

2. The inner and middle ears—including the ossicles and the tympanic membrane—are well developed at term.

3. The most dramatic growth was noted in the mastoid region with a considerable increase in size in the inferior, posterior and lateral directions. This trend is not complete until the late teens.

4. All parts contributing to the lateral surface of the temporal bone are subject to centrifugal growth, resulting in gradual lateralization of these structures. This is best expressed in the extensive lateral growth of the tympanic bone resulting in the relative inward movement of the facial canal, the tympanic membrane and the inner and middle ears.

5. The direct distance between the prospective implantation site of the receiver-stimulator and the round window or implantation site increases on average 12 mm (SD 5 mm) between birth and adulthood.

6. The implanted electrode array may be subject to substantially greater growth changes depending on its internal and cortical fixation sites and the implantation site of the receiver-stimulator package. Therefore, a paediatric cochlear implant should accommodate up to 25 mm of leadwire lengthening.

7. The fossa incudis is a convenient fixation site for the electrode array close to the cochlea. No growth away from the cochlea occurs at this site. Securing the electrode leadwire here could absorb the tensile stress that is forced upon the leadwire by the posterolateral growth of the distally placed receiver-stimulator package.

8. The surgical procedure required for cochlear implantation—including mastoidectomy, posterior tympanotomy, adequate exposure of the electrode insertion site and electrode placement—is feasible in very young children.

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APPENDIX

Summary of postnatal temporal bone growth (all dimensions in millimeters)

Arcuate eminence—Facial canal

Age:	n:	Mean:	SD:
0 < 0.5	4	11.4	1.2
0.5 < 1	4	12.7	0.8
1 < 2	1	13.0	–
2 < 4	6	14.5	2.1
4 < 6	5	13.9	2.1
6 < 8	3	14.8	2.5
8 < 10	3	14.5	0.9
10 < 14	3	15.0	3.8
14 < 18	7	14.9	1.7
> 18	3	15.0	0.0

Arcuate eminence—Internal auditory canal

Age:	n:	Mean:	SD:
0 < 0.5	4	11.6	1.1
0.5 < 1	3	12.5	1.4
1 < 2	1	14.0	–
2 < 4	6	13.5	3.0
4 < 6	5	13.0	1.3
6 < 8	3	14.5	1.8
8 < 10	3	14.7	3.2
10 < 14	3	13.3	1.0
14 < 18	7	16.1	1.9
> 18	3	13.0	1.4

Arcuate eminence—Lateral semicircular canal

Age:	n:	Mean:	SD:
0 < 0.5	4	8.9	0.9
0.5 < 1	4	8.3	1.4
1 < 2	1	9.5	–
2 < 4	6	10.2	1.3
4 < 6	5	10.1	0.7
6 < 8	3	9.3	1.2
8 < 10	3	10.3	1.2
10 < 14	3	10.3	2.4
14 < 18	7	10.0	0.9
> 18	3	9.0	1.4

Arcuate eminence—Mastoid tip

Age:	n:	Mean:	SD:
0 < 0.5	4	18.4	1.9
0.5 < 1	4	22.3	2.9
1 < 2	1	28.0	–
2 < 4	6	29.3	1.2
4 < 6	5	33.4	1.5
6 < 8	3	34.3	2.0
8 < 10	3	34.0	0.9
10 < 14	2	39.3	3.9
14 < 18	6	43.3	3.7
> 18	3	43.8	3.2

Arcuate eminence—Round Window

Age:	n:	Mean:	SD:
0 < 0.5	4	13.3	1.3
0.5 < 1	4	12.5	0.0
1 < 2	1	12.5	–
2 < 4	6	15.5	2.1
4 < 6	5	13.8	1.4
6 < 8	3	14.5	0.9
8 < 10	3	14.2	2.4
10 < 14	3	13.3	3.3
14 < 18	7	14.3	0.8
> 18	3	14.3	1.8

Arcuate eminence—Tympanic spine

Age:	n:	Mean:	SD:
0 < 0.5	4	12.8	0.9
0.5 < 1	4	13.0	1.7
1 < 2	2	15.8	1.8
2 < 4	6	13.9	2.3
4 < 6	5	13.3	2.1
6 < 8	3	13.7	1.3
8 < 10	3	14.5	3.8
10 < 14	3	14.7	2.9
14 < 18	7	13.4	1.5
> 18	3	13.0	1.4

Digastric ridge—Facial canal

Age:	n:	Mean:	SD:
0 < 0.5	0	–	–
0.5 < 1	1	9.0	–
1 < 2	1	13.0	–
2 < 4	6	11.1	2.4
4 < 6	5	14.5	1.7
6 < 8	3	15.7	2.8
8 < 10	3	15.5	2.8
10 < 14	2	15.0	3.5
14 < 18	7	19.6	2.6
> 18	3	18.0	2.1

Digastric ridge—Fossa incudis

Age:	n:	Mean:	SD:
0 < 0.5	0	–	–
0.5 < 1	1	11.5	–
1 < 2	1	16.5	–
2 < 4	6	15.3	1.7
4 < 6	5	18.7	2.0
6 < 8	3	20.5	0.5
8 < 10	3	20.7	2.5
10 < 14	2	19.8	1.8
14 < 18	7	26.4	4.1
> 18	3	21.8	2.5

Digastric ridge—Lateral semicircular canal

Age:	n:	Mean:	SD:
0 < 0.5	0	–	–
0.5 < 1	1	14.0	–
1 < 2	1	16.0	–
2 < 4	6	15.2	2.7
4 < 6	5	18.8	2.2
6 < 8	3	21.2	1.3
8 < 10	3	19.8	2.3
10 < 14	2	18.8	3.2
14 < 18	7	25.8	3.8
> 18	3	24.3	3.9

Digastric ridge—Mastoid tip

Age:	n:	Mean:	SD:
0 < 0.5	0	–	–
0.5 < 1	1	4.0	–
1 < 2	1	5.5	–
2 < 4	6	5.9	1.9
4 < 6	5	6.9	1.8
6 < 8	3	8.0	1.8
8 < 10	3	6.8	1.3
10 < 14	2	11.5	2.1

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14 < 18	6	12.8	2.2
> 18	3	13.8	1.1

Digastric ridge—Round Window

Age:	*n*:	Mean:	SD:
0 < 0.5	0	–	–
0.5 < 1	1	12.0	–
1 < 2	1	16.5	–
2 < 4	6	15.4	2.3
4 < 6	5	19.1	2.6
6 < 8	3	20.8	2.3
8 < 10	3	19.3	2.5
10 < 14	2	18.8	2.5
14 < 18	7	26.1	4.1
> 18	3	21.5	2.1

Digastric ridge—Sigmoid sinus

Age:	*n*:	Mean:	SD:
0 < 0.5	0	–	–
0.5 < 1	1	7.5	–
1 < 2	1	11.0	–
2 < 4	6	10.7	2.4
4 < 6	5	11.7	1.4
6 < 8	3	12.3	0.3
8 < 10	3	12.8	3.3
10 < 14	2	14.8	0.4
14 < 18	7	16.6	2.8
> 18	3	12.3	2.5

Digastric ridge—Stylomastoid foramen

Age:	*n*:	Mean:	SD:
0 < 0.5	0	–	–
0.5 < 1	1	6.5	–
1 < 2	1	8.0	–
2 < 4	6	6.9	1.6
4 < 6	5	9.3	2.5
6 < 8	3	9.5	2.6
8 < 10	3	10.3	3.6
10 < 14	2	8.8	1.8
14 < 18	7	12.6	3.0
> 18	3	13.3	5.3

Digastric ridge—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	0	–	–
0.5 < 1	1	9.5	–
1 < 2	0	–	–
2 < 4	6	12.9	1.9
4 < 6	5	16.7	2.8
6 < 8	3	17.2	1.5
8 < 10	3	17.2	2.3
10 < 14	1	18.5	–
14 < 18	7	22.9	3.8
> 18	3	17.3	1.8

Facial canal—Fossa incudis

Age:	*n*:	Mean:	SD:
0 < 0.5	4	4.9	0.4
0.5 < 1	4	5.0	0.9
1 < 2	2	4.3	0.4
2 < 4	6	5.1	0.9
4 < 6	5	4.5	0.5
6 < 8	3	5.0	1.8
8 < 10	3	5.7	0.8
10 < 14	3	5.5	1.5
14 < 18	7	6.5	1.4
> 18	3	6.8	1.1

Facial canal—Internal auditory canal

Age:	*n*:	Mean:	SD:
0 < 0.5	4	13.8	0.4
0.5 < 1	3	15.3	1.1
1 < 2	2	16.3	0.4
2 < 4	6	16.4	1.0
4 < 6	5	15.8	1.3
6 < 8	3	17.7	1.8
8 < 10	3	15.7	0.8
10 < 14	3	15.8	3.2
14 < 18	7	16.8	1.3
> 18	3	15.3	2.5

Facial canal—Lateral semicircular canal

Age:	*n*:	Mean:	SD:
0 < 0.5	4	4.1	0.7
0.5 < 1	4	5.2	0.8
1 < 2	2	4.5	0.0
2 < 4	6	4.8	1.3
4 < 6	5	5.0	1.3
6 < 8	3	5.8	1.9
8 < 10	3	4.5	1.3
10 < 14	3	5.2	0.8
14 < 18	7	5.9	0.8
> 18	3	6.0	1.4

Facial canal—Mastoid tip

Age:	*n*:	Mean:	SD:
0 < 0.5	4	6.7	1.3
0.5 < 1	4	9.5	2.6
1 < 2	2	15.5	1.4
2 < 4	6	15.8	1.3
4 < 6	5	19.3	2.0
6 < 8	3	20.2	3.2
8 < 10	3	20.7	0.8
10 < 14	2	24.0	5.7
14 < 18	6	28.8	3.2
> 18	3	27.3	0.4

Facial canal—Porion

Age:	*n*:	Mean:	SD:
0 < 0.5	4	13.8	0.9
0.5 < 1	4	15.5	0.5
1 < 2	2	17.0	0.0
2 < 4	4	16.1	1.7
4 < 6	4	16.4	1.9
6 < 8	2	17.5	0.7
8 < 10	2	17.3	0.4
10 < 14	3	18.2	1.0
14 < 18	5	18.8	2.6
> 18	3	19.5	2.8

Facial canal—Posterosuperior point of Macewen's triangle

Age:	*n*:	Mean:	SD:
0 < 0.5	4	8.4	3.2
0.5 < 1	3	12.5	1.4
1 < 2	1	13.0	–
2 < 4	5	12.7	1.3
4 < 6	5	12.9	0.8
6 < 8	3	12.7	1.3
8 < 10	3	15.2	2.3
10 < 14	3	15.7	0.3
14 < 18	7	15.9	2.1
> 18	3	15.5	1.4

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Facial canal—Round Window

Age:	n:	Mean:	SD:
0 < 0.5	4	7.6	0.8
0.5 < 1	4	8.0	0.5
1 < 2	2	7.8	0.4
2 < 4	6	7.8	1.3
4 < 6	5	7.8	1.1
6 < 8	3	7.7	1.2
8 < 10	3	7.3	1.5
10 < 14	3	7.8	0.6
14 < 18	7	7.6	0.6
> 18	3	8.0	0.7

Facial canal—Sigmoid sinus

Age:	n:	Mean:	SD:
0 < 0.5	3	8.1	1.5
0.5 < 1	4	7.8	2.0
1 < 2	2	8.3	2.5
2 < 4	6	10.3	2.5
4 < 6	5	11.2	1.8
6 < 8	3	11.2	1.0
8 < 10	3	10.7	4.6
10 < 14	3	10.3	3.6
14 < 18	7	9.6	1.7
> 18	3	10.0	0.0

Facial canal—Sino-dural angle

Age:	n:	Mean:	SD:
0 < 0.5	4	18.2	4.6
0.5 < 1	4	19.5	2.6
1 < 2	2	23.0	2.1
2 < 4	6	22.3	2.7
4 < 6	5	23.4	4.8
6 < 8	3	28.3	4.2
8 < 10	3	24.7	7.8
10 < 14	3	26.2	4.6
14 < 18	5	26.5	5.1
> 18	2	24.0	0.0

Facial canal—Stylomastoid foramen

Age:	n:	Mean:	SD
0 < 0.5	4	4.5	1.1
0.5 < 1	3	6.8	1.8
1 < 2	2	7.0	1.4
2 < 4	6	7.1	1.9
4 < 6	5	7.3	1.6
6 < 8	3	8.8	1.6
8 < 10	3	8.5	0.5
10 < 14	3	8.3	1.3
14 < 18	7	8.7	2.3
> 18	3	8.5	4.2

Facial canal—Tympanic sulcus

Age:	n:	Mean:	SD
0 < 0.5	3	4.2	1.3
0.5 < 1	1	4.0	–
1 < 2	0	–	–
2 < 4	6	4.4	0.7
4 < 6	5	4.1	0.8
6 < 8	3	3.7	0.3
8 < 10	3	4.3	0.6
10 < 14	2	3.5	0.0
14 < 18	7	4.1	0.5
> 18	3	4.3	1.1

Facial canal—Umbo

Age:	n:	Mean:	SD:
0 < 0.5	4	8.4	1.0
0.5 < 1	4	8.2	0.3
1 < 2	2	8.3	0.4
2 < 4	6	8.8	1.1
4 < 6	5	8.4	1.0
6 < 8	3	8.5	0.5
8 < 10	3	8.8	1.0
10 < 14	3	8.5	0.5
14 < 18	7	8.6	1.0
> 18	3	8.3	0.4

Fossa incudis—Inferolateral tympanic point

Age:	n:	Mean:	SD:
0 < 0.5	10	13.5	2.7
0.5 < 1	5	13.1	3.8
1 < 2	3	12.8	2.4
2 < 4	6	11.9	1.4
4 < 6	6	14.2	3.3
6 < 8	6	15.9	2.5
8 < 10	5	16.6	3.5
10 < 14	3	16.2	2.6
14 < 18	7	18.3	2.3
> 18	8	21.2	3.4

Fossa incudis—Internal auditory canal

Age:	n:	Mean:	SD:
0 < 0.5	4	14.6	1.1
0.5 < 1	3	15.5	2.1
1 < 2	2	16.3	1.1
2 < 4	6	16.9	0.9
4 < 6	5	16.4	1.0
6 < 8	3	17.8	1.6
8 < 10	3	15.8	2.0
10 < 14	3	18.0	2.6
14 < 18	7	18.4	1.3
> 18	3	15.8	3.2

Fossa incudis—Lateral semicircular canal

Age:	n:	Mean:	SD:
0 < 0.5	10	3.0	1.0
0.5 < 1	5	3.1	0.8
1 < 2	3	3.2	0.8
2 < 4	6	3.7	1.1
4 < 6	6	3.8	0.8
6 < 8	6	3.6	1.2
8 < 10	5	3.8	1.3
10 < 14	3	3.3	1.0
14 < 18	7	3.9	0.7
> 18	8	3.2	0.8

Fossa incudis—Mastoid tip

Age:	n:	Mean:	SD:
0 < 0.5	9	10.8	1.6
0.5 < 1	5	14.0	1.1
1 < 2	3	17.5	0.5
2 < 4	6	19.3	1.3
4 < 6	6	23.4	1.9
6 < 8	6	24.8	2.2
8 < 10	5	25.6	1.2
10 < 14	2	28.3	6.0
14 < 18	6	34.4	5.7
> 18	8	34.3	2.9

Fossa incudis—Porion

Age:	n:	Mean:	SD:
0 < 0.5	10	8.4	2.2
0.5 < 1	5	10.6	1.5

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1 < 2	3	12.0	1.8
2 < 4	4	11.6	1.3
4 < 6	5	13.3	1.9
6 < 8	5	14.0	1.5
8 < 10	4	13.8	1.8
10 < 14	3	14.8	1.6
14 < 18	5	15.1	1.6
> 18	8	15.9	1.2

Fossa incudis—Posterosuperior point of Macewen's triangle

Age:	*n*:	Mean:	SD:
0 < 0.5	10	6.4	1.5
0.5 < 1	5	9.2	1.7
1 < 2	3	10.3	0.8
2 < 4	5	10.9	1.3
4 < 6	6	11.8	2.2
6 < 8	6	13.9	1.3
8 < 10	5	13.5	2.2
10 < 14	3	13.5	0.5
14 < 18	7	15.1	1.3
> 18	8	16.6	2.3

Fossa incudis—Promontory

Age:	*n*:	Mean:	SD:
0 < 0.5	10	8.8	1.3
0.5 < 1	5	8.9	1.0
1 < 2	3	8.5	0.5
2 < 4	6	9.5	1.3
4 < 6	6	9.2	1.2
6 < 8	6	8.6	0.7
8 < 10	5	9.2	0.4
10 < 14	3	8.8	0.6
14 < 18	7	9.1	0.7
> 18	8	9.3	0.9

Fossa incudis—Round Window

Age:	*n*:	Mean:	SD:
0 < 0.5	10	9.0	0.9
0.5 < 1	5	8.8	0.9
1 < 2	3	8.8	0.8
2 < 4	6	9.4	0.7
4 < 6	6	9.1	1.4
6 < 8	6	8.9	0.6
8 < 10	5	9.2	1.0
10 < 14	3	8.7	0.8
14 < 18	7	9.2	0.8
> 18	8	9.6	0.9

Fossa incudis—Sigmoid sinus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	11.4	1.5
0.5 < 1	4	10.2	1.5
1 < 2	2	10.8	1.1
2 < 4	6	12.9	2.2
4 < 6	5	12.7	2.8
6 < 8	3	14.2	1.0
8 < 10	3	14.3	4.2
10 < 14	3	13.5	4.4
14 < 18	7	14.4	2.3
> 18	3	14.3	1.8

Fossa incudis—Sino-dural angle

Age:	*n*:	Mean:	SD:
0 < 0.5	10	17.9	3.9
0.5 < 1	5	19.8	1.7
1 < 2	3	20.7	5.1
2 < 4	6	23.0	2.3
4 < 6	6	23.0	4.1
6 < 8	6	26.5	4.3
8 < 10	5	24.6	6.1
10 < 14	3	25.8	4.2
14 < 18	5	26.8	4.9
> 18	7	29.4	5.2

Fossa incudis—Stylomastoid foramen

Age:	*n*:	Mean:	SD
0 < 0.5	4	8.6	1.2
0.5 < 1	3	11.0	0.0
1 < 2	2	10.5	0.0
2 < 4	6	11.5	1.8
4 < 6	5	11.2	0.8
6 < 8	3	13.5	1.8
8 < 10	3	12.5	0.5
10 < 14	3	12.3	1.6
14 < 18	7	13.4	1.0
> 18	3	14.5	4.2

Fossa incudis—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	10	4.6	0.8
0.5 < 1	5	5.5	0.7
1 < 2	3	4.3	0.6
2 < 4	6	5.4	1.4
4 < 6	6	4.8	1.2
6 < 8	5	4.7	1.3
8 < 10	5	5.4	0.5
10 < 14	3	4.8	0.3
14 < 18	7	5.9	0.6
> 18	8	4.8	1.2

Fossa incudis—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	5.0	0.5
0.5 < 1	1	5.0	–
1 < 2	0	–	–
2 < 4	6	4.8	0.9
4 < 6	5	4.6	0.7
6 < 8	3	4.2	0.8
8 < 10	3	4.3	0.3
10 < 14	2	4.3	0.4
14 < 18	7	4.3	0.6
> 18	3	4.5	0.7

Fossa incudis—Umbo

Age:	*n*:	Mean:	SD:
0 < 0.5	4	8.3	0.8
0.5 < 1	4	8.3	0.3
1 < 2	2	7.8	0.4
2 < 4	6	8.2	1.0
4 < 6	5	7.7	1.3
6 < 8	3	7.5	0.9
8 < 10	3	7.3	0.3
10 < 14	3	7.3	1.0
14 < 18	7	7.7	0.3
> 18	3	8.5	1.4

Inferolateral tympanic point—Internal auditory canal

Age:	*n*:	Mean:	SD:
0 < 0.5	4	15.6	1.1
0.5 < 1	2	18.0	4.2
1 < 2	2	22.8	1.8
2 < 4	6	22.7	2.3
4 < 6	5	24.9	1.8
6 < 8	3	26.0	1.3
8 < 10	3	25.3	2.3

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10 < 14	2	26.3	2.5
14 < 18	7	30.2	2.6
> 18	3	26.5	4.9

Inferolateral tympanic point—Mastoid tip

Age:	n:	Mean:	SD:
0 < 0.5	9	13.1	3.3
0.5 < 1	4	9.8	1.7
1 < 2	3	11.2	2.8
2 < 4	6	11.3	2.1
4 < 6	6	11.0	1.6
6 < 8	6	12.4	2.8
8 < 10	5	14.9	3.7
10 < 14	1	19.0	–
14 < 18	6	17.8	4.7
> 18	8	14.5	3.9

Inferolateral tympanic point—Porion

Age:	n:	Mean:	SD:
0 < 0.5	10	18.5	2.4
0.5 < 1	4	18.4	2.9
1 < 2	3	19.5	2.8
2 < 4	4	17.0	0.7
4 < 6	5	19.8	2.6
6 < 8	5	21.1	3.2
8 < 10	4	21.0	3.3
10 < 14	2	18.3	3.9
14 < 18	5	18.3	1.9
> 18	8	23.0	2.7

Inferolateral tympanic point—Posterosuperior point of Macewen's triangle

Age:	n:	Mean:	SD:
0 < 0.5	10	14.8	3.5
0.5 < 1	5	16.4	1.9
1 < 2	3	18.2	5.0
2 < 4	5	15.6	3.7
4 < 6	6	15.8	4.6
6 < 8	6	19.2	6.0
8 < 10	5	20.3	6.3
10 < 14	3	19.3	7.3
14 < 18	7	15.9	3.4
> 18	8	24.6	3.8

Inferolateral tympanic point—Promontory

Age:	n:	Mean:	SD:
0 < 0.5	10	7.5	1.5
0.5 < 1	4	10.8	4.4
1 < 2	3	11.5	2.3
2 < 4	6	13.0	1.9
4 < 6	6	16.4	2.2
6 < 8	6	15.6	1.2
8 < 10	5	16.0	1.2
10 < 14	2	17.0	2.8
14 < 18	7	19.7	2.4
> 18	8	20.4	3.2

Inferolateral tympanic point—Round Window

Age:	n:	Mean:	SD:
0 < 0.5	10	9.0	1.7
0.5 < 1	5	10.4	2.5
1 < 2	3	11.7	1.3
2 < 4	6	13.4	1.5
4 < 6	6	16.9	2.4
6 < 8	6	17.8	1.6
8 < 10	5	16.7	1.6
10 < 14	3	16.3	1.9
14 < 18	7	19.7	2.5
> 18	8	21.3	3.7

Inferolateral tympanic point—Sino-dural angle

Age:	n:	Mean:	SD:
0 < 0.5	10	30.0	5.1
0.5 < 1	4	29.9	5.2
1 < 2	3	28.7	3.5
2 < 4	6	31.3	1.2
4 < 6	6	28.0	5.0
6 < 8	6	32.8	5.0
8 < 10	5	35.5	4.7
10 < 14	2	31.8	1.8
14 < 18	5	33.2	5.9
> 18	7	41.5	7.0

Inferolateral tympanic point—Tympanic spine

Age:	n:	Mean:	SD:
0 < 0.5	10	12.1	2.5
0.5 < 1	4	12.0	2.7
1 < 2	3	12.5	1.8
2 < 4	6	12.8	1.2
4 < 6	6	16.0	2.2
6 < 8	5	14.5	1.4
8 < 10	5	16.4	2.5
10 < 14	2	14.0	2.8
14 < 18	7	19.0	2.4
> 18	8	20.2	3.8

Inferolateral tympanic point—Tympanic sulcus

Age:	n:	Mean:	SD:
0 < 0.5	3	6.8	1.0
0.5 < 1	1	7.0	–
1 < 2	0	–	–
2 < 4	6	9.1	1.1
4 < 6	5	10.9	1.5
6 < 8	3	10.7	0.8
8 < 10	3	10.8	1.0
10 < 14	2	12.3	3.2
14 < 18	7	14.5	2.3
> 18	3	13.0	3.5

Inferolateral tympanic point—Umbo

Age:	n:	Mean:	SD:
0 < 0.5	4	5.9	0.6
0.5 < 1	3	8.2	1.5
1 < 2	2	11.3	2.5
2 < 4	6	11.9	1.8
4 < 6	5	15.3	1.6
6 < 8	3	14.3	0.6
8 < 10	3	14.5	1.8
10 < 14	2	15.5	3.5
14 < 18	7	18.0	2.0
> 18	3	16.8	1.8

Internal auditory canal—Lateral semicircular canal

Age:	n:	Mean:	SD:
0 < 0.5	4	13.4	1.0
0.5 < 1	3	13.3	1.1
1 < 2	2	15.8	0.4
2 < 4	6	15.9	1.3
4 < 6	5	14.7	0.6
6 < 8	3	16.0	2.5
8 < 10	3	15.5	2.8
10 < 14	3	16.3	1.9
14 < 18	7	16.2	1.4
> 18	3	13.8	1.1

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Internal auditory canal—Mastoid tip

Age:	*n*:	Mean:	SD:
0 < 0.5	4	19.1	0.7
0.5 < 1	3	19.0	4.9
1 < 2	2	28.0	0.7
2 < 4	6	28.3	1.8
4 < 6	5	30.5	2.1
6 < 8	3	29.7	6.3
8 < 10	3	31.8	1.8
10 < 14	2	34.5	3.5
14 < 18	6	38.3	5.0
> 18	3	40.0	2.1

Internal auditory canal—Oval Window

Age:	*n*:	Mean:	SD:
0 < 0.5	4	8.3	0.8
0.5 < 1	3	9.5	0.7
1 < 2	2	11.3	1.1
2 < 4	6	9.9	0.7
4 < 6	5	10.1	0.7
6 < 8	3	10.0	1.3
8 < 10	3	11.7	2.8
10 < 14	3	12.0	0.5
14 < 18	7	11.9	1.4
> 18	3	10.3	1.8

Internal auditory canal—Porion

Age:	*n*:	Mean:	SD:
0 < 0.5	4	22.3	1.5
0.5 < 1	3	22.5	2.8
1 < 2	2	28.5	2.1
2 < 4	4	28.1	2.1
4 < 6	4	28.3	1.0
6 < 8	2	32.0	0.7
8 < 10	2	31.0	1.4
10 < 14	3	32.2	0.8
14 < 18	5	32.7	2.9
> 18	3	30.8	5.3

Internal auditory canal—Posterosuperior point of Macewen's triangle

Age:	*n*:	Mean:	SD:
0 < 0.5	4	21.7	3.5
0.5 < 1	2	26.0	0.0
1 < 2	1	26.5	–
2 < 4	5	27.4	1.2
4 < 6	5	27.2	1.0
6 < 8	3	29.0	1.8
8 < 10	3	29.2	2.8
10 < 14	3	30.2	1.3
14 < 18	7	32.9	2.7
> 18	3	29.5	2.8

Internal auditory canal—Promontory

Age:	*n*:	Mean:	SD:
0 < 0.5	4	10.5	0.9
0.5 < 1	3	11.5	0.7
1 < 2	2	12.8	0.4
2 < 4	6	12.2	0.9
4 < 6	5	11.5	0.6
6 < 8	3	12.2	1.2
8 < 10	3	12.8	2.6
10 < 14	3	14.0	1.3
14 < 18	7	12.7	0.7
> 18	3	10.8	1.8

Internal auditory canal—Round Window

Age:	*n*:	Mean:	SD:
0 < 0.5	4	8.3	0.6
0.5 < 1	3	8.8	1.1
1 < 2	2	10.3	1.8
2 < 4	6	10.3	0.5
4 < 6	5	9.3	0.6
6 < 8	3	10.2	0.3
8 < 10	3	10.0	2.2
10 < 14	3	11.7	2.4
14 < 18	7	11.7	1.7
> 18	3	11.5	2.8

Internal auditory canal—Sino-dural angle

Age:	*n*:	Mean:	SD:
0 < 0.5	4	24.8	3.7
0.5 < 1	3	29.0	3.5
1 < 2	2	32.0	3.5
2 < 4	6	33.2	3.6
4 < 6	5	31.6	5.7
6 < 8	3	33.3	5.5
8 < 10	3	34.5	6.5
10 < 14	3	34.0	3.5
14 < 18	5	36.2	3.7
> 18	2	33.5	0.0

Internal auditory canal—Stylomastoid foramen

Age:	*n*:	Mean:	SD:
0 < 0.5	4	15.0	1.6
0.5 < 1	2	17.0	0.0
1 < 2	2	19.5	2.1
2 < 4	6	19.0	1.5
4 < 6	5	17.2	1.3
6 < 8	3	20.7	2.0
8 < 10	3	18.7	2.5
10 < 14	3	19.8	2.8
14 < 18	7	20.4	1.6
> 18	3	20.5	6.4

Internal auditory canal—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	4	15.3	1.2
0.5 < 1	3	16.5	0.7
1 < 2	2	17.3	0.4
2 < 4	6	16.5	1.1
4 < 6	5	16.1	0.4
6 < 8	3	15.7	3.6
8 < 10	3	16.3	2.5
10 < 14	3	16.3	4.5
14 < 18	7	17.2	3.5
> 18	3	16.8	1.1

Internal auditory canal—Tympanic sulcus

Age:	*n*:	Mean:	SD
0 < 0.5	3	13.5	3.1
0.5 < 1	1	15.5	–
1 < 2	0	–	–
2 < 4	6	15.7	1.2
4 < 6	5	15.3	0.4
6 < 8	3	16.5	1.5
8 < 10	3	16.2	2.0
10 < 14	2	16.0	0.7
14 < 18	7	16.9	3.3
> 18	3	14.5	1.4

Lateral semicircular canal—Mastoid tip

Age:	*n*:	Mean:	SD:
0 < 0.5	9	10.7	1.9
0.5 < 1	5	14.4	2.0

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1 < 2	3	18.8	0.8
2 < 4	6	19.8	1.6
4 < 6	6	24.3	2.3
6 < 8	6	26.4	2.8
8 < 10	5	24.9	1.0
10 < 14	2	28.8	5.3
14 < 18	6	34.1	7.4
> 18	8	34.5	2.4

Lateral semicircular canal—Oval Window

Age:	n:	Mean:	SD:
0 < 0.5	10	7.8	0.8
0.5 < 1	5	8.0	0.7
1 < 2	3	8.2	0.8
2 < 4	6	8.5	1.1
4 < 6	6	8.3	0.8
6 < 8	6	8.2	1.4
8 < 10	5	8.3	0.5
10 < 14	3	8.3	1.0
14 < 18	7	8.2	0.6
> 18	8	8.4	0.8

Lateral semicircular canal—Posterosuperior point of Macewen's triangle

Age:	n:	Mean:	SD:
0 < 0.5	10	8.0	1.9
0.5 < 1	5	10.9	2.0
1 < 2	3	13.2	1.6
2 < 4	5	12.4	1.5
4 < 6	6	13.8	2.5
6 < 8	6	15.1	2.2
8 < 10	5	14.6	1.6
10 < 14	3	14.7	0.8
14 < 18	7	16.6	1.5
> 18	8	18.4	2.2

Lateral semicircular canal—Promontory

Age:	n:	Mean:	SD:
0 < 0.5	10	9.5	1.4
0.5 < 1	5	9.5	0.7
1 < 2	3	10.0	1.3
2 < 4	6	10.3	1.5
4 < 6	6	10.0	0.8
6 < 8	6	10.0	1.1
8 < 10	5	10.0	0.5
10 < 14	3	9.7	1.2
14 < 18	7	10.6	1.1
> 18	8	9.5	1.0

Lateral semicircular canal—Round Window

Age:	n:	Mean:	SD:
0 < 0.5	10	8.9	0.8
0.5 < 1	5	9.3	1.0
1 < 2	3	9.2	0.6
2 < 4	6	9.7	1.0
4 < 6	6	9.0	1.1
6 < 8	6	9.3	0.8
8 < 10	5	9.2	0.3
10 < 14	3	8.8	0.8
14 < 18	7	9.1	0.6
> 18	8	9.6	1.0

Lateral semicircular canal—Sigmoid sinus

Age:	n:	Mean:	SD:
0 < 0.5	3	9.4	2.7
0.5 < 1	4	9.0	0.5
1 < 2	2	9.8	1.1
2 < 4	6	12.1	2.8
4 < 6	5	12.8	1.2
6 < 8	3	13.7	1.6
8 < 10	3	12.3	3.2
10 < 14	3	11.3	2.0
14 < 18	7	12.4	1.4
> 18	3	13.3	1.8

Lateral semicircular canal—Stylomastoid foramen

Age:	n:	Mean:	SD:
0 < 0.5	4	8.4	1.9
0.5 < 1	3	11.8	2.5
1 < 2	2	11.0	0.7
2 < 4	6	11.0	2.3
4 < 6	5	11.9	1.9
6 < 8	3	14.5	0.5
8 < 10	3	12.7	1.0
10 < 14	3	12.8	0.6
14 < 18	7	14.4	2.0
> 18	3	14.8	6.7

Lateral semicircular canal—Tympanic spine

Age:	n:	Mean:	SD:
0 < 0.5	10	6.6	1.1
0.5 < 1	5	7.4	1.3
1 < 2	3	7.0	1.7
2 < 4	6	7.6	1.4
4 < 6	6	8.3	1.8
6 < 8	5	8.1	1.7
8 < 10	5	7.8	1.3
10 < 14	3	7.7	1.6
14 < 18	7	8.6	0.8
> 18	8	7.0	1.4

Lateral semicircular canal—Tympanic sulcus

Age:	n:	Mean:	SD:
0 < 0.5	3	6.0	0.5
0.5 < 1	1	7.0	–
1 < 2	0	–	–
2 < 4	6	6.7	0.5
4 < 6	5	6.8	0.7
6 < 8	3	6.3	0.3
8 < 10	3	6.8	0.6
10 < 14	2	5.5	0.7
14 < 18	7	7.1	0.4
> 18	3	6.8	2.5

Mastoid tip—Porion

Age:	n:	Mean:	SD:
0 < 0.5	9	17.1	1.5
0.5 < 1	5	21.0	1.4
1 < 2	3	23.0	1.8
2 < 4	4	24.3	2.5
4 < 6	5	28.3	1.0
6 < 8	5	29.8	2.1
8 < 10	4	29.5	1.1
10 < 14	2	32.0	2.8
14 < 18	4	34.9	3.1
> 18	8	32.9	1.9

Mastoid tip–Posterosuperior point of Macewen's triangle

Age:	n:	Mean:	SD:
0 < 0.5	9	12.3	3.3
0.5 < 1	5	18.6	0.9
1 < 2	3	19.7	2.3
2 < 4	5	19.7	2.6
4 < 6	6	23.8	2.8
6 < 8	6	26.4	4.2
8 < 10	5	27.9	1.9

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10 < 14	2	27.0	3.5
14 < 18	6	29.8	4.1
> 18	8	31.6	3.1

Mastoid tip—Round Window

Age:	*n*:	Mean:	SD:
0 < 0.5	9	11.8	1.8
0.5 < 1	5	14.1	1.4
1 < 2	3	19.7	0.3
2 < 4	6	19.8	1.9
4 < 6	6	24.4	2.4
6 < 8	6	24.5	1.8
8 < 10	5	24.5	0.9
10 < 14	2	27.0	5.7
14 < 18	6	32.2	3.4
> 18	8	33.1	2.4

Mastoid tip—Sino-dural angle

Age:	*n*:	Mean:	SD:
0 < 0.5	9	19.0	3.6
0.5 < 1	5	22.8	2.1
1 < 2	3	24.8	2.9
2 < 4	6	28.6	2.8
4 < 6	6	31.0	6.1
6 < 8	6	36.6	4.8
8 < 10	5	33.9	3.9
10 < 14	2	41.3	5.3
14 < 18	4	41.3	5.2
> 18	7	44.6	5.8

Mastoid tip—Stylomastoid foramen

Age:	*n*:	Mean:	SD:
0 < 0.5	4	5.4	1.4
0.5 < 1	3	6.5	0.7
1 < 2	2	11.8	2.5
2 < 4	6	10.1	2.1
4 < 6	5	13.5	2.0
6 < 8	3	12.7	2.3
8 < 10	3	14.2	1.0
10 < 14	2	17.0	4.2
14 < 18	6	20.7	1.7
> 18	3	17.3	4.6

Mastoid tip—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	10	13.2	2.0
0.5 < 1	4	13.4	3.1
1 < 2	3	18.3	3.8
2 < 4	6	15.2	4.6
4 < 6	6	17.5	4.9
6 < 8	5	19.3	5.8
8 < 10	5	16.4	2.5
10 < 14	2	14.0	2.8
14 < 18	7	19.0	2.4
> 18	8	20.2	3.8

Mastoid tip—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	8.2	1.9
0.5 < 1	1	11.5	–
1 < 2	0	–	–
2 < 4	6	16.4	1.2
4 < 6	5	20.1	1.4
6 < 8	3	20.8	1.6
8 < 10	3	21.3	1.5
10 < 14	1	30.0	–
14 < 18	6	29.3	4.4
> 18	3	27.5	0.0

Oval Window—Porion

Age:	*n*:	Mean:	SD:
0 < 0.5	10	14.1	2.0
0.5 < 1	5	15.3	2.0
1 < 2	3	17.8	1.8
2 < 4	4	19.5	2.0
4 < 6	5	20.1	1.6
6 < 8	5	21.4	0.5
8 < 10	4	20.4	1.6
10 < 14	3	21.7	1.8
14 < 18	5	21.7	2.0
> 18	8	22.8	1.9

Oval Window—Posterosuperior point of Macewen's triangle

Age:	*n*:	Mean:	SD:
0 < 0.5	10	14.1	2.6
0.5 < 1	5	16.4	1.9
1 < 2	3	18.8	1.9
2 < 4	5	17.9	3.3
4 < 6	6	20.1	2.1
6 < 8	6	21.7	1.7
8 < 10	5	21.2	1.9
10 < 14	3	22.0	0.0
14 < 18	7	22.2	2.0
> 18	8	24.9	2.4

Oval Window—Round Window

Age:	*n*:	Mean:	SD:
0 < 0.5	10	4.2	0.3
0.5 < 1	5	4.3	0.3
1 < 2	3	4.3	0.3
2 < 4	6	4.3	0.3
4 < 6	6	4.3	0.3
6 < 8	6	4.4	0.5
8 < 10	5	4.5	0.5
10 < 14	3	4.2	0.3
14 < 18	7	4.1	0.2
> 18	8	4.5	0.4

Oval Window—Umbo

Age:	*n*:	Mean:	SD:
0 < 0.5	4	4.5	0.7
0.5 < 1	4	4.7	0.3
1 < 2	2	4.5	0.7
2 < 4	6	4.3	1.0
4 < 6	5	4.4	0.4
6 < 8	3	5.0	0.9
8 < 10	3	4.7	0.6
10 < 14	3	4.5	0.9
14 < 18	7	4.5	0.8
> 18	3	4.3	1.1

Porion—Posterosuperior point of Macewen's triangle

Age:	*n*:	Mean:	SD:
0 < 0.5	10	6.0	2.9
0.5 < 1	5	6.0	1.7
1 < 2	3	6.5	2.2
2 < 4	4	8.1	1.9
4 < 6	5	8.4	1.6
6 < 8	5	8.1	2.4
8 < 10	4	7.3	1.3
10 < 14	3	10.5	1.3
14 < 18	5	10.3	1.5
> 18	8	9.9	1.7

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Porion—Round Window

Age:	*n*:	Mean:	SD:
0 < 0.5	10	16.2	2.2
0.5 < 1	5	17.8	2.2
1 < 2	3	20.7	1.5
2 < 4	4	21.0	2.1
4 < 6	5	21.9	0.9
6 < 8	5	22.6	0.9
8 < 10	5	22.1	1.7
10 < 14	3	23.5	1.5
14 < 18	5	23.3	2.2
> 18	8	24.5	1.7

Porion—Sino-dural angle

Age:	*n*:	Mean:	SD:
0 < 0.5	10	21.6	4.1
0.5 < 1	5	24.8	1.8
1 < 2	3	24.2	6.8
2 < 4	4	25.8	3.1
4 < 6	5	23.8	4.4
6 < 8	5	30.4	3.4
8 < 10	4	27.6	2.9
10 < 14	3	27.3	5.3
14 < 18	5	29.8	5.4
> 18	7	33.0	7.4

Porion—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	10	7.4	1.6
0.5 < 1	5	8.6	1.8
1 < 2	3	11.3	2.0
2 < 4	4	12.5	2.4
4 < 6	5	13.6	1.4
6 < 8	4	14.8	0.3
8 < 10	4	14.3	2.2
10 < 14	3	14.7	1.8
14 < 18	5	15.3	2.1
> 18	8	15.5	1.7

Porion—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	12.9	0.8
0.5 < 1	1	14.0	–
1 < 2	0	–	–
2 < 4	4	14.4	2.5
4 < 6	4	15.1	1.4
6 < 8	2	15.8	1.8
8 < 10	2	17.0	0.0
10 < 14	2	17.3	1.1
14 < 18	5	16.1	1.9
> 18	3	17.3	3.2

Posterosuperior point of Macewen's triangle—Promontory

Age:	*n*:	Mean:	SD:
0 < 0.5	10	14.1	2.7
0.5 < 1	5	16.8	2.2
1 < 2	3	19.0	2.2
2 < 4	5	19.6	1.8
4 < 6	6	21.0	1.6
6 < 8	6	21.5	1.5
8 < 10	5	22.2	1.6
10 < 14	3	21.5	1.7
14 < 18	7	22.6	2.5
> 18	8	24.5	1.8

Posterosuperior point of Macewen's triangle—Round Window

Age:	*n*:	Mean:	SD:
0 < 0.5	10	15.2	2.4
0.5 < 1	5	17.5	1.9
1 < 2	3	20.5	1.3
2 < 4	5	20.5	2.1
4 < 6	6	20.9	1.8
6 < 8	6	22.2	1.5
8 < 10	5	22.4	2.1
10 < 14	3	22.8	2.5
14 < 18	7	22.7	2.0
> 18	8	26.1	2.2

Posterosuperior point of Macewen's triangle—Sino-dural angle

Age:	*n*:	Mean:	SD:
0 < 0.5	10	18.3	3.9
0.5 < 1	4	19.8	1.8
1 < 2	2	16.0	4.9
2 < 4	5	19.4	2.6
4 < 6	6	20.2	5.4
6 < 8	6	23.8	3.1
8 < 10	5	19.5	4.7
10 < 14	3	20.2	4.9
14 < 18	5	22.3	4.2
> 18	7	27.4	7.4

Posterosuperior point of Macewen's triangle—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	10	8.6	1.6
0.5 < 1	5	9.9	1.9
1 < 2	3	13.3	1.4
2 < 4	5	14.9	3.7
4 < 6	6	15.3	2.0
6 < 8	5	16.3	1.1
8 < 10	3	16.8	1.9
10 < 14	3	17.2	1.5
14 < 18	7	17.7	2.4
> 18	8	18.2	1.5

Posterosuperior point of Macewen's triangle—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	8.2	2.9
0.5 < 1	1	10.5	–
1 < 2	0	–	–
2 < 4	5	13.4	0.7
4 < 6	5	13.4	1.2
6 < 8	3	13.8	1.0
8 < 10	3	16.3	2.0
10 < 14	2	15.8	0.4
14 < 18	7	15.8	2.3
> 18	3	16.0	1.4

Promontory—Round Window

Age:	*n*:	Mean:	SD:
0 < 0.5	10	3.9	0.5
0.5 < 1	5	3.8	0.3
1 < 2	3	3.7	0.3
2 < 4	6	4.1	0.6
4 < 6	6	3.8	0.5
6 < 8	6	3.9	0.4
8 < 10	5	3.8	0.3
10 < 14	3	3.8	0.3
14 < 18	7	3.9	0.2
> 18	8	4.0	0.5

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Promontory—Sino-dural angle

Age:	*n*:	Mean:	SD:
0 < 0.5	10	25.5	4.1
0.5 < 1	5	27.1	2.4
1 < 2	3	28.7	5.6
2 < 4	6	30.5	2.0
4 < 6	6	29.6	2.4
6 < 8	6	33.8	3.8
8 < 10	5	32.2	5.9
10 < 14	3	34.5	5.3
14 < 18	5	35.5	4.9
> 18	7	36.7	5.4

Promontory—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	10	7.3	0.9
0.5 < 1	5	7.5	0.9
1 < 2	3	7.5	0.5
2 < 4	6	7.3	1.4
4 < 6	6	7.6	0.4
6 < 8	5	7.5	0.4
8 < 10	5	7.6	0.9
10 < 14	3	7.7	0.3
14 < 18	7	7.3	0.7
> 18	8	7.5	0.8

Promontory—Umbo

Age:	*n*:	Mean:	SD:
0 < 0.5	4	2.1	0.4
0.5 < 1	4	2.0	0.0
1 < 2	2	2.0	0.0
2 < 4	6	2.3	0.3
4 < 6	5	2.1	0.2
6 < 8	3	1.8	0.3
8 < 10	3	1.9	0.4
10 < 14	3	2.2	0.3
14 < 18	7	2.2	0.3
> 18	3	2.3	0.4

Round Window—Sigmoid sinus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	14.4	2.8
0.5 < 1	4	14.3	1.0
1 < 2	2	14.5	2.1
2 < 4	6	17.8	2.0
4 < 6	5	17.6	1.6
6 < 8	3	18.8	2.5
8 < 10	3	16.8	4.1
10 < 14	3	16.2	3.3
14 < 18	7	16.4	2.2
> 18	3	17.8	0.4

Round Window—Sino-dural angle

Age:	*n*:	Mean:	SD:
0 < 0.5	10	24.0	4.4
0.5 < 1	5	25.1	2.1
1 < 2	3	27.3	5.0
2 < 4	6	29.3	2.4
4 < 6	6	30.1	4.2
6 < 8	6	32.2	2.9
8 < 10	5	30.8	4.3
10 < 14	3	32.2	4.0
14 < 18	5	33.0	5.1
> 18	7	35.1	4.8

Round Window—Stylomastoid foramen

Age:	*n*:	Mean:	SD:
0 < 0.5	4	7.6	0.8
0.5 < 1	3	8.5	0.7
1 < 2	2	8.5	1.4
2 < 4	6	9.4	1.2
4 < 6	5	9.0	1.7
6 < 8	3	10.5	1.3
8 < 10	3	9.7	2.1
10 < 14	3	9.8	2.4
14 < 18	7	10.7	1.8
> 18	3	12.0	3.5

Round Window—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	10	9.5	0.9
0.5 < 1	5	9.4	0.5
1 < 2	3	9.2	1.3
2 < 4	6	8.8	1.2
4 < 6	6	9.3	0.8
6 < 8	5	9.4	1.5
8 < 10	5	8.8	1.4
10 < 14	3	9.5	0.0
14 < 18	7	9.3	1.2
> 18	8	9.9	0.8

Round Window—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	6.5	0.9
0.5 < 1	1	6.5	–
1 < 2	0	–	–
2 < 4	6	6.5	1.4
4 < 6	5	7.4	0.7
6 < 8	3	7.3	0.3
8 < 10	3	8.2	1.2
10 < 14	2	7.5	0.7
14 < 18	7	7.3	1.1
> 18	3	6.8	1.1

Round Window—Umbo

Age:	*n*:	Mean:	SD:
0 < 0.5	4	4.9	0.5
0.5 < 1	4	4.8	0.3
1 < 2	2	5.3	0.4
2 < 4	6	5.0	0.8
4 < 6	5	5.1	0.4
6 < 8	3	4.8	0.3
8 < 10	3	5.3	0.3
10 < 14	3	5.2	0.6
14 < 18	7	5.1	0.6
> 18	3	5.3	0.4

Sigmoid sinus—Sino-dural angle

Age:	*n*:	Mean:	SD:
0 < 0.5	3	13.5	3.3
0.5 < 1	4	13.8	3.4
1 < 2	2	21.0	4.9
2 < 4	6	15.3	2.4
4 < 6	5	16.2	4.3
6 < 8	3	21.0	2.2
8 < 10	3	18.3	5.7
10 < 14	3	19.3	3.2
14 < 18	5	20.0	4.0
> 18	2	18.0	0.0

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Sigmoid sinus—Stylomastoid foramen

Age:	*n*:	Mean:	SD:
0 < 0.5	3	10.4	1.9
0.5 < 1	3	11.5	0.7
1 < 2	2	10.3	2.5
2 < 4	6	12.3	2.3
4 < 6	5	12.9	2.0
6 < 8	3	13.5	0.0
8 < 10	3	12.7	3.4
10 < 14	3	14.2	3.8
14 < 18	7	12.6	2.3
> 18	3	10.8	0.4

Sigmoid sinus—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	12.0	2.8
0.5 < 1	1	9.5	–
1 < 2	0	–	–
2 < 4	6	13.8	2.6
4 < 6	5	14.1	1.5
6 < 8	3	14.0	1.0
8 < 10	3	14.2	4.2
10 < 14	2	11.3	0.4
14 < 18	7	13.5	2.0
> 18	3	12.5	1.4

Sino-dural angle—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	10	23.0	4.6
0.5 < 1	5	24.8	2.2
1 < 2	3	26.0	6.1
2 < 4	6	27.5	3.0
4 < 6	6	28.4	5.0
6 < 8	5	31.2	5.8
8 < 10	5	29.4	6.1
10 < 14	3	31.0	4.4
14 < 18	5	33.1	4.7
> 18	7	34.1	5.9

Sino-dural angle—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	23.3	5.5
0.5 < 1	1	25.0	–
1 < 2	0	–	–
2 < 4	6	26.3	2.4
4 < 6	5	26.7	4.9
6 < 8	3	31.5	3.1
8 < 10	3	28.7	8.6
10 < 14	2	27.8	5.3
14 < 18	5	29.3	4.9
> 18	2	26.5	0.0

Stylomastoid foramen—Tympanic spine

Age:	*n*:	Mean:	SD:
0 < 0.5	4	10.6	1.0
0.5 < 1	3	12.3	0.4
1 < 2	2	12.3	1.8
2 < 4	6	13.1	1.4
4 < 6	5	13.1	1.1
6 < 8	3	14.8	1.8
8 < 10	3	12.7	0.6
10 < 14	3	13.2	1.3
14 < 18	7	14.5	1.6
> 18	3	16.8	4.6

Stylomastoid foramen—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	4.8	0.8
0.5 < 1	1	6.0	–
1 < 2	0	–	–
2 < 4	6	7.0	1.4
4 < 6	5	7.8	0.8
6 < 8	3	9.3	0.3
8 < 10	3	7.8	0.3
10 < 14	2	9.0	2.1
14 < 18	7	9.3	2.2
> 18	3	10.8	3.9

Tympanic membrane: Horizontal plane

Age:	*n*:	Mean:	SD:
0 < 0.5	3	8.7	0.6
0.5 < 1	0	–	–
1 < 2	0	–	–
2 < 4	4	9.0	0.7
4 < 6	5	9.4	0.2
6 < 8	3	9.0	0.9
8 < 10	3	9.0	0.9
10 < 14	1	9.5	–
14 < 18	7	9.3	0.6
> 18	3	9.3	0.4

Tympanic membrane: Vertical plane

Age:	*n*:	Mean:	SD:
0 < 0.5	3	9.3	0.3
0.5 < 1	0	–	–
1 < 2	0	–	–
2 < 4	4	9.1	0.6
4 < 6	5	8.9	0.4
6 < 8	3	9.5	0.5
8 < 10	3	8.8	0.3
10 < 14	2	8.8	0.4
14 < 18	7	9.4	0.3
> 18	3	9.0	0.0

Tympanic spine—Tympanic sulcus

Age:	*n*:	Mean:	SD:
0 < 0.5	3	6.8	1.0
0.5 < 1	1	6.5	–
1 < 2	0	–	–
2 < 4	6	6.3	0.9
4 < 6	5	6.8	0.4
6 < 8	3	6.0	0.5
8 < 10	3	6.0	0.9
10 < 14	2	6.0	0.7
14 < 18	7	6.9	0.7
> 18	3	7.3	1.1

Tympanic spine—Umbo

Age:	*n*:	Mean:	SD:
0 < 0.5	4	6.2	0.6
0.5 < 1	4	6.0	0.5
1 < 2	2	6.5	0.0
2 < 4	6	5.9	0.4
4 < 6	5	5.8	0.3
6 < 8	3	6.0	0.0
8 < 10	3	5.5	0.0
10 < 14	3	5.8	0.3
14 < 18	7	5.6	0.4
> 18	3	6.3	0.4

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Tympanic sulcus—Umbo

Age:	*n*:	Mean:	SD:
0 < 0.5	3	6.3	0.6
0.5 < 1	1	5.5	–
1 < 2	0	–	–
2 < 4	6	5.7	0.6
4 < 6	5	6.1	0.4
6 < 8	3	6.0	0.5
8 < 10	3	5.8	0.6
10 < 14	2	6.3	0.4
14 < 18	7	6.0	0.6
> 18	3	5.8	0.4

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APPENDIX 5

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APPENDIX 6

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Acceleration Perturbations of Daily Living

A Comparison to 'Whiplash'

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Study Design. This study measured repeated human head accelerations (*g*) during daily activities.

Objectives. Perturbations of daily living were compared to similar data from low velocity rear-end motor vehicle accidents.

Summary of Background Data. Past assumptions suggest that motor vehicle accident severity does not correlate with the degree of sustained injury. Early engineering studies indicated that occupant disturbance in a low velocity motor vehicle accident is minor.

Methods. Eight volunteers were perturbed with 13 daily activities. Helmets on the heads of volunteers were instrumented with tri-planar accelerometers with output sampling of 500 Hz, sensitivity of 0.02 *g*, and a range of ±20 *g*.

Results. There was wide inter-subject response for various perturbations. Plopping backward into a chair caused maximum peak acceleration horizontally at 5.6 *g* and vertically at 8.5 *g*, with force vector of 10.1 *g* at 54.9°. Mean impulse duration was 0.19 sec. There was no hint of injury in any subject.

Conclusions. Perturbations of daily living compared similarly to the jostling expected in low velocity "whiplash"-type motor vehicle accidents. [Key words: acceleration, change of velocity, equivalent barrier speed, gravitation, perturbations, whiplash] **Spine 1994;19: 1285–1290**

In the analysis of motor vehicle accidents, a key question is whether a particular accident exposed an occupant to a force that could cause bodily injury. McNab noted that the severity of an impact cannot predict the degree of injury in a person involved in a motor vehicle accident.[4] Certainly, in major accidents, even among people in the same vehicle, the level of injury can vary greatly, from no injury to death. This underlines the importance of accepting exceptions, but denies the presence of a possible injury threshold based on the application of measurable forces. The question is whether there is a force above which injury is probable and below which no injury is guaranteed.

Early studies attempted to measure some of the forces sustained by the neck during certain perturbations. Mertz and Patrick proposed a threshold limit for the human neck in terms of torque during extension as it occurred about the occipital condyles.[5,6] Their studies of a human volunteer, dummies, and cadavers used load cells to measure the force application and motion parameters of neck acceleration during static and dynamic neck extension tests. They used a sled device with a rigid seat-back and no head restraining device. The force was applied in the extension direction. Based on the results of one human subject, they proposed a number of "limits" above which neck injury (not defined) could occur to a 50th percentile adult man. For a human subject, in a 16.1 km/hr simulated rear-end impact that causes a sled change of velocity (ΔV) of 14.5 km/hr, the calculated torque at the occipital condyles was 16.6 Nm, and the head acceleration was about 4.5 *g*. The authors found a mean peak acceleration of 7.2 *g* (range, 2.9–14.0 *g*) with a mean pulse duration of 77 ms (range, 38–114 ms). They proposed that 60° was the extension limit and 47 Nm was the dynamic torque limit (arbitrarily twice the measured static torque limit). The subject did not wish to undergo more severe dynamics tests above this level of impact "for fear of neck injury."

Although Mertz and Patrick considered motion about the occipital condyles as the key axis, other segments of the neck also participate in extension-flexion motion.[1] Mertz and Patrick did not mention any clinical or radiographic evidence of injuries in their subject. These complex motion analysis studies were an early attempt to search for the elusive neck injury threshold in humans, but cannot be easily duplicated for activities of daily living, nor in a clinical setting.

Severy et al used accelerometers to assess the "*g*"forces at the head of human volunteers and anthropomorphic dummies in rear-end motor vehicle accident simulations. He used 1940s vintage cars without energy absorbing bumpers, and created velocity changes (ΔV)

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as high as 11.3 km/hr.[9] The key measurements taken were during extension of the head and neck, possibly representing the so-called "whiplash" event. The impulse duration of the impacts were 0.16–0.29 sec. In this study, the two human test subjects received impacts that caused, respectively, 8.9 and 9.5 km/hr ΔV for the target vehicle with 5.0 *g* and 2.9 *g* at the subject's head. There were no reported injuries, so the so-called injury threshold was not reached. However, the location of the accelerometers was not mentioned, nor was there any indication that the acceleration force was resolved to the center of mass of the head. They also did not vector analyze the vertical and horizontal forces.

Of interest is that Severy et al also considered outcomes for the frontal collision, stating "The human subjects driving the rear car and restrained by the shoulder loop and lap-type safety belts reported no discomfort from collisions at 10 and 20 miles per hour [16 to 32 km/h]."[9] Low velocity front-end accidents are thought to be relatively safer than equivalent rear-end accidents.

In a motor vehicle accident (MVA), a key element in determining the potential for injury is the magnitude and direction of force actually applied to the human body. However, many aspects of the MVA must be factored into the equation. The mass and immediate pre-impact velocity of the striking (bullet) vehicle will help determine the initial amount of kinetic energy available for exchange between the striking and struck (target) vehicles. In most cases, some of this crush energy is absorbed in the "plastic" components of the vehicles, such as the bumper-absorbing systems and the vehicle's body itself as it deforms. However, these same components also contain "elastic" features that return energy in a "rebound" effect—the "coefficient of restitution." When a motor vehicle strikes a fixed barrier for which there is no rebound effect from the barrier, the ΔV equals the equivalent barrier speed (EBS). Where there is some rebound of a vehicle, depending on the coefficient of restitution, the resulting ΔV will be a sum of the pre-impact velocity and the outgoing or rebound velocity.

When analyzing an accident scenario, engineering reconstruction analysis sometimes relies upon crush parameters that can determine ΔV, or in the case of low velocity or no-damage accidents, the EBS. A sudden change of the vehicle's motion—ΔV or EBS—will result in acceleration of its occupant, a key location being the occupant's head, often calculated in terms of acceleration or gravitational equivalent ("*g*") forces. This is the bottom line that could lead to so-called whiplash or neck strain.

The Canadian Motor Vehicle Safety Regulation (CMVSR) 215 requires that vehicles' bumpers meet certain minimum impact limits. A series of pendulum and barrier impact tests are required, after which all of the lamps and reflective devices (except the license plate lamp) must remain free of cracks, continue to meet visibility requirements, and remain adjustable within allowable limits. In addition, the hood, trunk, and doors must operate normally, and the fuel, cooling, exhaust, propulsion, suspension, steering, and braking systems must all continue to operate normally. The pendulum impact must not damage any of the above when applied at 8 km/hr (5 mph) for the fully aligned impact, or at 4.8 km/hr (3 mph) for a 30° angled corner impact. In addition to the pendulum tests, the vehicle also must withstand an 8 km/hr impact into a fixed collision barrier with no damage. In the United States, the fixed barrier (EBS) no-damage bumper impact limit is 4 km/hr (2.5 mph). Although only implied, the Canadian regulations say that the vehicle must withstand an 8 km/hr EBS without residual deformity—i.e., a no-damage impact. These no-damage characteristics were confirmed with isolator-equipped Ford Escorts in a recent study.[10]

A recent study reported on accelerations at the head in human volunteers subjected to low velocity no-damage rear-end motor vehicle impacts in modern vehicles with shock absorbing bumpers.[3,12] West[12] used the same data collection system as in the present study (see Methods). Using West's data from 25 crash studies with three target vehicles that had adequate head support, and plotting head accelerations versus EBS, a predictable regression relationship can be formed using only the horizontal head *g* (the other axes were not used in this calculation):

$$g = 1.7\ \text{EBS} - 4.4\ (r = 0.92,\ P > 0.001)$$

None of the test subjects reported injury or distress, despite EBS up to 13 km/hr and head acceleration up to 18 *g*. In West's study, only the barrier impact speed was measured—the rebound effect of the impacts was not considered. Therefore, this formula cannot be used directly with ΔV unless the coefficient of restitution is known or assumed.

McConnell's[3] work used four different vehicles with four healthy volunteers and subjected them to rear-end impacts where the struck vehicle reached ΔV of 7.8 km/hr, resulting in a head force of up to 4.3 *g*. After multiple impact exposures of between 6 and 8 km/hr ΔV, three of the four physician test subjects noted very mild neck symptoms that began the next day and lasted for a few hours at most. Whether this represented "injury" was not determined.

Navin's micro-motion analysis of Hybrid II anthropomorphic dummies used pendulum impacts against a Volkswagon Rabbit to measure ΔV. As ΔV dropped, the percentage of calculated acceleration forces applied to the head rose.[7] Although the absolute degree of head motion correlated positively with ΔV, at the higher impact velocities, where there was some vehicle damage, a lesser proportion of energy appeared to be applied to the dummy. Presumably, more energy was dissipated into deforming the vehicle, and less proportion of energy was

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applied to accelerating the vehicle. This may mean that in the low velocity no-damage incident, a significant proportion of the energy, albeit low in absolute terms, is applied to the occupant. Although this was an important motion analysis study, it did not directly assess acceleration forces, ΔV was above the no-damage limit (over 8 km/hr), and the subjects were not human.

Head restraining devices have advantages in reducing neck strain in rear-end MVAs.[4] In Navin's dummy study[7] and in McConnell's human study,[3] at or about 8 km/hr ΔV the head would just strike the head restraining device. The presence or absence of head strike against the restraining device appears to be another marker of impact severity, the suggested head strike marker being 8 km/hr ΔV, the same as the no-damage bumper limit in Canada.

The next question concerns how much acceleration force is applied to an occupant in a no-damage accident, presumably below 8 km/hr EBS. Severy's two subjects did not mention injury at impacts of 8.9 and 9.5 km/hr ΔV, with 5.0 *g* and 2.9 *g* at the head, respectively. Mertz and Patrick's subject was reluctant to proceed past 14.5 km/hr ΔV. West's work suggested that healthy subjects could tolerate up to 13 km/hr EBS and 18 *g* acceleration at the head. McConnell's physician subjects tolerated 6–8 km/hr ΔV and 4.8 *g* at the head with only minimal 1 day-delayed symptoms that lasted for a few hours. Unfortunately, there are no published studies with large human populations that detail moderate, greater-than-8-km/hr EBS impacts. However, such collisions may expose the subjects to risk of injury. The exact level of impact that will cause injury to certain individuals or types of individuals is not known.

What do these "*g*" force parameters mean in everyday terms? In non-MVA events, boxers have routinely tolerated head blows of 70 *g* with an impulse duration of about 0.10 sec.[8] This is an order of magnitude increase over the expected blow from a no-damage rear-end accident.

Regarding day-to-day events, the present study analyzed the accelerations experienced at the head in volunteers, examining levels of force that could be comparable to the under 8 km/hr EBS, low velocity, no-damage rear-end motor vehicle incident.

Methods

Eight healthy subjects (four men and four women, ages 19–50 years [mean age 25 years]) volunteered for this project. They read and signed informed consent forms and had the opportunity to withdraw from all or part of the testing procedure at any time. The project was approved by a University Ethics Committee and complied with research on human subjects. Each subject participated by actively moving or by being passively jostled in 12 different events. One subject was repeatedly jostled at varying intensities in a wheeled chair (the 13th event). Table 1 describes the movement and jostling events.

Each subject wore a helmet that was firmly attached to the head. On the helmet were three bidirectional micro-machined accelerometers capable of recording from −20.00 to +20.00 *g*, with a sensitivity of 0.02 *g*.[11] The accelerometers measured head motion in three dimensions. The "x" horizontal axis was placed on the posterior of the helmet, about 1.7 cm from the occiput, and measured the flexion (+) and extension (−) direction. The "z" vertical axis was placed on the very top of the helmet, about 2.0 cm from the top of the skull, and measured downward (+) compressive motions and upward (−) tension motions. The "y" lateral axis was placed on the side of the helmet directly above the ear, about 1.5 cm from the scalp. The helmet appeared to have very little play when cinched tight, but this was not measured.

The accelerometers were sampled at 500 Hz by a Hewlett-Packard (Palo Alto, CA) computer, which was programmed to calculate acceleration maxima, minima, and means, which were tabulated using the program Automeasure.[11] Acceleration data were analyzed from the lowest point of the initial upswing of the positive curve to its peak, or the reverse for negative values. This measured the change of direction during flexion-extension motions. These motion parameters were not resolved to the center of mass of the head.

Table 1. List of Perturbations

Event	Description
Look left	Routine casual movement of head as if looking left
Startle	Unexpected; starter pistol discharged behind subject
Shoulder check	Driver's shoulder check, with sudden left head turn
Stand up	Stand upright suddenly from a kitchen chair
Head bob	Seated; passively drop head backward as if falling asleep
Sit down	Routine sit down into a kitchen chair from a standing position
Sneeze	Sniff finely ground pepper into nostrils; uninhibited sneeze
Cough	Simulated nonexaggerated cough
Crowd jostle	Unexpected bump against posterior left shoulder
Back slap	Anticipated hardy greeting slap on left upper back
Kick chair	Seated, relaxed, wheeled office chair kicked hard from behind
Hop off step	Hop off 20 cm step, land on both feet
Plop in chair	Plop passively backward into low-backed office chair

Description of 13 movement events. All were activities associated with daily living; none caused any hint of injury.

Results

No significant accelerations were obtained in the lateral direction (y axis). Even the "look left" and "shoulder check" events, which could have shown interesting lateral accelerations, showed maximum values of only 0.6 *g* and 1.1 *g*, respectively. In all other events, the key direction of acceleration was rearward "x," and downward "z." The head position was not measured, nor was the actual motion of the head. Only the forces and the direction of these forces that attempted to perturb the head were measured. The impulse duration ranged from 0.12–0.22 sec, mean = 0.19 second. The curve from the maximum "plop in chair" perturbation is shown in Figure 1, with an impulse duration of 0.16 sec.

An acceleration force vector, within the impact pulse duration, was calculated from the maximum "x" and "z" values for each event. Note that this was a vector of

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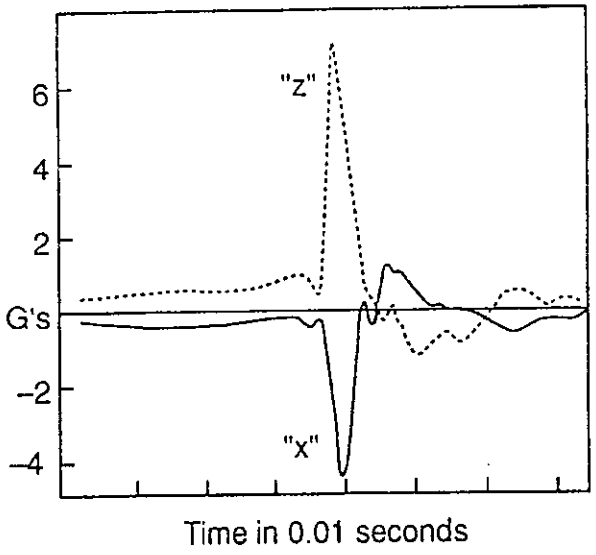

Figure 1. Accelerometer time curve. Typical acceleration time curve, "g" versus milliseconds × 10, for the "plop in chair" event measured at the head. The negative "x" axis force is rearward, the positive "z" axis is downward. This data were used to calculate the vector forces in Figure 2.

the forces only, not the direction of their application. These data do not purport to suggest components of torque, shear, or axial compression. The "look left" perturbation gave the minimum acceleration of 0.6 *g* at 26.3°. The "plop in chair" gave the maximum, which was up to 10.1 *g* at 54.9° (Figure 2, Table 2).

There was a wide range of values among the individual subjects for each event, with the mean of maximum values a factor of 2.4 over the minimum. The largest differences for maximum to minimum, with a factor of 4.4, was seen at the lower level acceleration events, where the maximum value still was very low. These events, although perturbing to a measurable degree, were so trivial they were almost unrecognizable by the subjects. During the study, there was no hint from the subjects that they were jostled in a manner that would approach injury or harm.

■ Discussion

Among the many factors that can influence the outcome of musculoskeletal stress or strain are various personal, social, cultural, psychologic, legal, and nomogenic issues.[2] This study did not seek to compare or factor the various issues that influence the outcomes from potential injury, except to say they are all important. However, a primary focus that is often overlooked is the dynamics of the accident itself and the degree to which the biomechanics of that event could lead to tissue damage. Where on the continuum of forces that perturb the body lurks the potential for harm? Is there a force below which no damage will ever occur? Is there a force above which injury is guaranteed?

Compounding the problem is that no two persons are alike. Some are weak and others are strong—from the physical and psychologic sense. A trivial perturbation to one person may, for another, appear to cause injury. In addition, no two "similar" perturbations are truly the same. What may appear the same is not likely to be so. Even for the day-to-day events measured in this study, such as hopping off a step or plopping down into a chair, the forces applied to the body are not the same for different individuals who appear to perform similarly.

There may be a range of forces that perturbs the body below which "normal" persons under "normal" circumstances would not likely be injured. This study used accelerations measured at the head as a way to compare the perturbations of individuals involved in simple everyday events to low velocity, no-damage, rear-end motor vehicle incident studies. Some events, such as swinging the head left and right, being startled, looking over one's shoulder, or simply standing up, created accelerations below or only slightly above the background of 1 *g* (range, 0.6 *g*–1.9 *g*). If injury appears to occur under

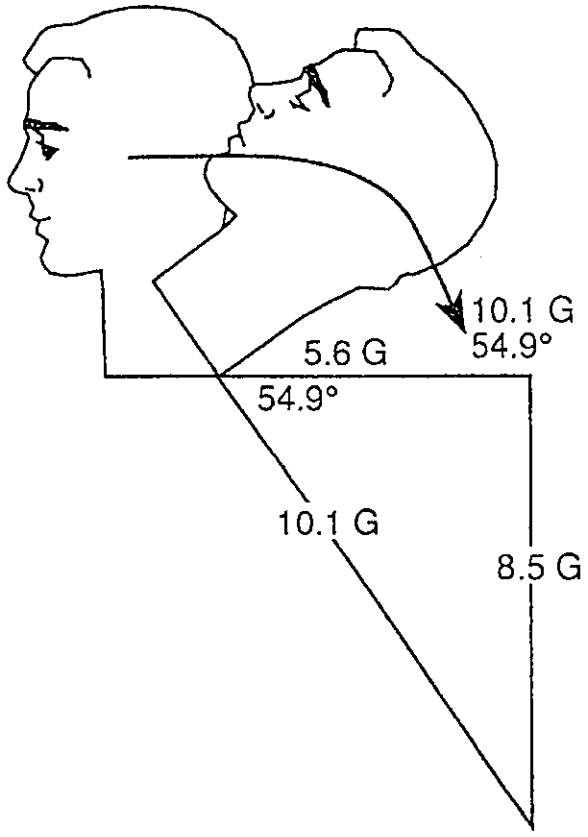

Figure 2. Vector forces. Schematic representation of the vector forces and direction for the high values of "plop in chair" event, scaled to represent the angle at which the forces would be expressed. The unequal triangle represents the "*g*" units and their vector. (The apparent axis of rotation of the head in this schematic is not the true motion of the head. It is an expression of the acceleration forces.)

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Table 2. Head "g" Force Perturbations of Daily Living

		Rear Directed Acceleration (Gs)			Vertical Directed Acceleration (Gs)			Vector Acceleration	Vector Angle
	Event	"x" Low	"x" High	"x" Mean	"z" Low	"z" High	"z" Mean	"x-z" Peak Value	"x-z" Degrees
A	Look left	0.1	0.6	0.3	0.1	0.3	0.1	0.6	26.3
P	Startle	0.2	0.7	0.5	0.2	0.6	0.4	0.9	40.5
A	Shoulder check	0.3	1.1	0.7	0.1	0.4	0.2	1.1	18.2
A	Stand up	0.4	1.5	0.8	0.6	1.2	0.9	1.9	38.0
P	Head bob	0.9	1.9	1.4	0.2	1.1	0.4	2.2	29.9
A	Sit down	0.5	1.6	1.1	0.4	2.0	1.0	2.5	52.2
A	Sneeze	0.7	1.5	1.0	0.5	2.5	1.8	2.9	48.8
A	Cough	0.5	3.0	1.1	0.2	1.8	0.7	3.5	30.5
P	Crowd jostle	0.8	1.9	1.4	0.7	3.0	1.8	3.6	57.9
P	Slap on back	0.5	2.7	1.7	0.5	3.1	1.8	4.1	48.3
P	Kick chair	1.0	3.7	2.1	0.7	2.3	1.3	4.3	31.6
A	Hop off step	1.3	4.5	2.7	2.9	6.7	4.6	8.1	55.9
A	Plop in chair	1.8	5.6	3.3	2.0	8.5	4.4	10.1	54.9
	Means	0.7	2.3	1.4	0.7	2.6	1.5	3.5	41.0

High, low, and means of eight subjects measured for acceleration *g* forces expressed in the rear direction (x axis), and downward vertical (z axis) for 13 simple events of daily living. Side to side y axis data was uneventful and was not tabulated. The acceleration vector analysis of *g* forces was calculated from the maximum values of x and z for each event. The angle of the forces represents the direction of the vector in degrees from horizontal. A = active, meaning a prepared planned movement. P = passive, meaning an uncontrolled or surprise motion. Only four pepper-induced sneeze measurements were collected on one subject. Only one subject was kicked from behind in the chair, at increasing intensities up to the maximum limit tolerated by the kicker.

such circumstances, then it can be considered to occur spontaneously.

Other simple daily events, such as sneezing, coughing, or being jostled as if in a crowd, were shown to create maximum accelerations to the head (and corresponding torque levels at the neck) of 2.9 *g* to 3.6 *g*. This level of perturbation was recognizable by the subjects, but also was considered trivial. The upper level of jostling experienced by the subjects was for hopping off a step and plopping down into a chair, with respective vector accelerations of 8.1 *g* and 10.1 *g*, neither of which caused any adverse notice by the subjects. Is this an upper limit of normal tolerance? Exploring the lower limits of routine events is safe, but exposing subjects to forces that could be considered injurious would be ethically treacherous.

Without the application of some external force, there can be no motion. Ultimately, it is the application of some external force that causes bodily motion that should be responsible for all that follows, particularly if physical bodily injury is to be considered. With the advent of sophisticated accelerometers and high-speed computer-based acquisition systems, collecting acceleration data for various bodily perturbations is feasible. The purpose of this study was to express an extension-flexion motion that could be related to the so-called "whiplash" motion of MVA scenarios. The extension range was not measured, only the accelerations or "*g*" forces. We found that in one event of daily activity, the vector acceleration of 10.4 *g* was experienced uneventfully. These values may be comparable in force and direction to low velocity no-damage rear-end MVAs. When comparing acceleration stresses between daily activities and MVAs, it is important only to compare the equivalent axis. For example, West's MVA bump study[12] used only the horizontal "x" axis. Therefore, when this type of data is compared to the acceleration perturbations of daily living, only the same axis should be referenced.

Note that this study was limited in the number of volunteers. The full spectrum of the population, with a presumed wide variance in physical and psychologic profiles, was not tested.

In this study, the accelerations experienced by the head in activities of daily living were greater than would be intuitively expected. Also, the accelerations appeared to be greater than those seen in the same parts of the body during some no-damage motor vehicle rear-end impacts. When assessing the claims of and potential for injury from an accident, many medical, psychologic, and possible nomogenic facets of the case need to be considered. One factor is the estimate of the forces that were applied to the person and the range of possible tissue damage that could be caused by applying such forces. With no-damage accidents, one can reassure an accident victim who had otherwise been frightened by rumors of horror and the mystery that sometimes follows the MVA "whiplash" scenario.

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Point of View

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This interesting and important paper quantifies some of the activities of daily living and suggests that many of the complaints of neck and low back pain need not be initiated by a single identifiable event. It tends to show that clinically based opinions on causation of spinal injury, such as disc herniation or sprain and strain, should not be based on patient history alone. Every attempt should be made to quantify the severity of the impact event so the likelihood of an injury can be assessed. Those who complain of pain after a minor insult often are already suffering from a pre-existing degenerative condition, and their discomfort could have been exacerbated temporarily by the impact. It behooves us to investigate further the causes of persistent physical pain, if it can exist at all without a psychological component.

A second point relates to the measurement technique. Some of the *g* levels appear to be rather high. Perhaps, using a helmet is not the best way to measure head acceleration. If this experiment is repeated, accelerometers mounted on a bite-plate should yield more accurate head acceleration data. This will, however, preclude coughing and sneezing.

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Failure Analysis Associates

Exponent®

Investigation of Amusement Park and Roller Coaster Injury Likelihood and Severity

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Investigation of Amusement Park and Roller Coaster Injury Likelihood and Severity

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Investigation of Amusement Park and Roller Coaster Injury Likelihood and Severity

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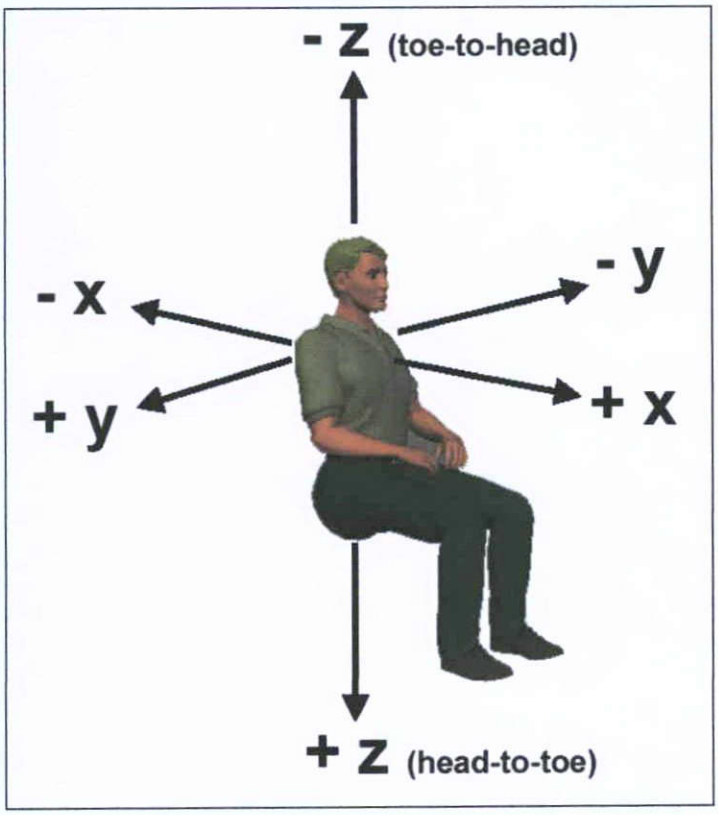
Acronyms and Abbreviations

AIS	Abbreviated Injury Scale
CAD	Carotid Artery Dissection
CPSC	Consumer Product Safety Commission
CSF	Cerebrospinal Fluid
ED	Emergency Department
FaAA	Failure Analysis Associates
FMVSS	Federal Motor Vehicle Safety Standard
GLOC	G-Induced Loss of Consciousness
HIC	Head Injury Criterion
JARI	Japanese Automakers Research Institute
MAIS	Maximum Abbreviated Injury Scale
NEISS	National Electronic Injury Surveillance System
NHTSA	National Highway Transportation Safety Administration
SAH	Subarachnoid Hemorrhage
VAD	Vertebral Artery Dissection



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Summary

Exponent® Failure Analysis Associates was retained on behalf of Six Flags to investigate the type, frequency and severity of injuries that occur at fixed amusement parks and assess the likelihood of injuries to patrons on rides.

This project was separated into six tasks:

- Review of the scientific literature
- Analysis of roller coaster accelerations including their magnitude and duration
- Analysis of occupant head acceleration data from a sample of Six Flags roller coasters
- Measurement of head accelerations for common daily or recreational activities
- Examination of first-aide station data from a sample of Six Flags parks
- Review of U.S. Consumer Product Safety Commission (CPSC) National Electronic Injury Surveillance System (NEISS) data

Exponent has come to the following conclusions within a reasonable degree of engineering and scientific certainty based on the information available at the time of this report. Each conclusion is discussed fully in the body of the report.

Roller Coaster Acceleration Levels

1. Over the last forty years, there has been no increase in the accelerations produced in roller coasters as determined from data supplied by Six Flags. Maximum speed data for 167 roller coasters and acceleration data for 110 roller coasters were compared with the year of initial installation. While top speeds have increased, maximum accelerations have remained essentially unchanged.

2. Computer analysis indicated that none of the 34 Six Flags rides with the highest levels of +Gz accelerations evaluated had accelerations with high enough magnitudes and long enough durations to cause loss of consciousness, even to a rider who was very susceptible to G-induced loss of consciousness (GLOC).

3. Common activities like sneezing, falling down, swinging on a swing, or being hit in the head with a pillow caused accelerations of the head that far exceeded the magnitude or duration of accelerations experienced by riders of roller coasters (as determined from rider acceleration data supplied by Six Flags). Being hit on the back of the head with a pillow was found to cause head accelerations as high as 11 G's in the y direction (side to side) and 14 G's in the +z direction (head to toe). Being spun on a tire swing generated a peak of negative 2.3 G's in the z direction (toe to head) sustained for a duration of more than 25 seconds. A simple sneeze generated nearly 4 G's in the x direction (front to back).

Head Injuries

4. After reviewing occupant head acceleration data supplied by Six Flags for 71 of their most dynamic roller coasters, Exponent has determined that it is highly improbable that a normal rider would suffer a serious head injury. Occupant head accelerations supplied by Six Flags for riders on 71 roller coasters were compared to head accelerations experienced during common activities using an index based on the Federally accepted Head Injury Criterion (HIC). The calculated HIC scores for the rides ranged from 0.2 to 9.4. Exponent's in-house testing found that getting hit on the head with a pillow generated a HIC score of 20.8 and a sneeze generated a HIC of 0.5.

5. The annual rate of spontaneous, non-traumatic, non-impact cerebrovascular injuries (e.g., vertebral artery dissections, carotid artery dissection, sub-arachnoid hemorrhages) that have occurred at amusement parks is far below the rates that one would expect at fixed theme parks based on attendance and average rates for the general population. The scientific literature reports that the rate of spontaneous, non-traumatic, non-impact cerebrovascular injuries for the population of the United States is approximately 25,000 injuries per year.

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CPSC Injury Data

6. The use of a single product code that includes amusement attractions of all types, the mis-match between the geographic distribution of amusement parks and NEISS hospitals, changes in the sample of hospitals beginning in 1997, and the redaction of ride and park specific identifiers reduces the usefulness of NEISS data for estimating amusement park ride injuries and assessing trends.

7. Additions of hospitals close to several major theme parks in 1997 are likely to have caused the reported increase in CPSC estimated injuries in 1997. Six of the newly added hospitals are within 20 miles of parks that had an estimated attendance of 35 million patrons in 1997. This represents a net increase of approximately 29 million fixed park attendees within 20 miles of a sample hospital. All analysis should be conducted with post 1997 data in order to remove this sample bias.

8. The CPSC data from 2001 include a total of 5,335 injuries of all types associated with fixed site amusement park rides in the year 2001. This number is lower than the number of injuries in the CPSC data associated with children's wagons (6,934) and beach chairs or folding lawn chairs (7,103) from 2000 NEISS data.

9. The majority of all injuries associated with fixed amusement park rides were found to be minor in nature and did not require hospitalization. The majority of the injuries were contusions, abrasions, strains and sprains, and lacerations. The CPSC has reported that since 1993 the rate of hospitalized injuries for fixed amusement park attendees was one out of 2.7 million attendees or 0.00004%. Less than 2% of all the injuries recorded by the CPSC NEISS related to fixed amusement park rides required hospitalization. This percentage is two points lower than the 4% of injuries requiring hospitalization for all products that the CPSC monitors. Data from 2001 showed a similar rate.

10. There was a 19% drop in total fixed site amusement park associated injuries for patrons from 2000 to 2001 in the CPSC NEISS data.

11. Exponent analysis of CPSC NEISS data from 1997-2001 showed no statistical increase in the national estimate of the number of injuries associated with fixed site amusement park attractions over that time period while attendance has increased.

12. Exponent analysis of CPSC NEISS data from 1997-2001 indicate that risk of injury associated with fixed site amusement parks has not exhibited a statistically significant trend during that time. Risk of injury associated with fixed site amusement park attractions has dropped in each of the last two years.

Six Flags Injury Data

13. Analysis of first-aide station data from five Six Flags parks, representing approximately 25% of all attendance of Six Flags parks for the years 1999 to 2001 showed that only 6% of all patrons complaining of injuries at the parks requested or required transport to a medical facility outside the park. Analysis of nine years of data from one park showed that only 5.8% of those transported from the park required hospitalization.

14. The injury rate for Six Flags patrons requiring or requesting transport to a medical facility outside the park was found to be seven injuries per million park attendees (0.0007%), with an estimated one serious injury (requiring overnight hospital stay) per 2.6 million park attendees (0.00004%).

15. The injury rate for Six Flags roller coaster patrons requiring or requesting transport to a medical facility outside the park was found to be one injury per million rides (.0001%). Serious injuries requiring an overnight stay at the hospital would be even lower.

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1 Literature Search

Exponent conducted an extensive review of 22 online databases of literature to obtain data on accidents associated with amusement park attractions, roller coaster design, occupant kinematics, occupant injury reports, and the medical facts behind reported associated injury types.

1.1 Search Methods

The keywords used in the search included medical terms, theme park related terms, accident and injury terminology and terms associated with similar fields of study. The search terms were combined in various patterns and combinations in order to break the search into manageable segments. The terms that were searched for included:

> *accident, amusement, aneurysm, artery, automobile, automotive, biomechanical, brain, car, carnival, carotid dissection, cerebral contusion, cerebrospinal fluid leak, cerebrovascular, cervical, chiropractic, computer model, chronic subdural hematoma, dissecting, decompensation of congenital retinal macrovessel, dissection, etiology, event, fatality, g-environment, g-force, head, head excursion, headache, hematoma, injury, intracranial, investigation, load, manipulation, mechanism, migraine, moment, neck, occurrence, pathology, pericallosal, phenomenon, physiotherapy, post traumatic migraine, rate or frequency, rehabilitation, ride(s), roller coaster, rollover, spinal, spinal cord compression by enterogenous cyst, spine, sport or recreation, subarachnoid hemorrhage trauma, syringomyelia, traumatic carotid artery compression, vehicle, vertebral artery dissection, water park, whirling*

1.2 Literature Search Results

From the databases searched and using combinations of the terms above, the results were then filtered to eliminate publications that dealt with treatment of injuries. The resulting searches yielded 1,209 potential literature items without duplicates. The number of items by database is presented in Table 1.1.

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Table 1.1 Number of articles identified by search category.

Search Category	Results Returned
Vertebral Artery Dissection	309
Cerebral Aneurysm and Biomechanics and/or Computer Modeling	600
Amusement Park Injury Rates	99
Amusement Park Injury Incidents	56
Amusement Park-Related Physical Conditions, such as Headaches	40
Automotive Rollovers – Injuries and Head Acceleration Data	100
Amusement Park Ride Accelerometer Data	5
Total Results Returned	**1,209**

For each of the 1,209 results an abstract or full text citation was acquired for initial review and a determination was made as to the applicability to the topics of interest. More than 150 articles were acquired initially for review. Additional articles have been added to the review as the project has progressed and new information was identified. The medical literature reporting injuries that have some association with amusement rides are primarily in the form of the case study or letter to the editor. These forms of reporting have a variable degree of peer review depending upon the journal and report only on the occurrence of an event that has been infrequently reported in the literature and may be of interest to physicians. No scientifically based, broad population relevant conclusions can be drawn given the typically low sample size in the reports.

1.3 Results

Exponent identified the following types of cerebrovascular injuries from the medical literature that have been reported to be associated with amusement park rides:

- Carotid and vertebral dissection
- Subarachnoid hemorrhage (SAH)
- Chronic subdural hematoma
- Cerebrospinal fluid leak
- Decompensation of congenital retinal macrovessel
- Cerebral contusion with SAH
- Syringomyelia
- Spinal cord compression by enterogenous cyst
- Post traumatic migraine
- Traumatic carotid artery compression

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There have been additional injury types reportedly associated with amusement park attractions publicized in certain amusement park ride injury reports, however these injury types have yet to be identified in the scientific literature. The discussion of injuries will be limited to those identified in Exponent's literature search.

1.3.1 Dissections of the Carotid and Vertebral Artery

An arterial dissection is defined as a tearing of the internal lining, intima, of an artery, which propagates and eventually blocks the flow of blood beyond the blockage. Carotid artery dissection (CAD) and vertebral artery dissection (VAD) can occur spontaneously but have also been associated with judo, yoga, golf, soccer, running, tennis, baseball, snow boarding, vigorous head/neck movement while dancing, falling on back, vehicular accident, lifting, ceiling painting, nose blowing, minor neck trauma, chiropractic manipulation, vigorous self-manipulation of the neck, and routine anesthesia. Risk of dissections is increased in females and people with hypertension (48% in one series), oral contraceptive use, diabetes mellitus, chronic headache syndromes, intrinsic vascular pathology, fibromuscular dysplasia and cystic medial necrosis. The mechanism is unknown and often the patient that presents with a dissection is a young, healthy individual. The combined incidence of both VAD and CAD is estimated to be 3.5 per 100,000 individuals, or roughly 9,200 per year over the last decade. The Chiropractic community, in response to a Canadian Medical Association Journal paper that reported that sudden neck movement such as that found in chiropractic manipulation was correlated to vertebral artery dissection, stated that it was impossible to predict who would be susceptible to this problem:

> *"To its credit, this manuscript correctly suggests that a variety of neck movements could precipitate vertebrobasilar artery events, in keeping with a large and compelling body of literature.[7-12] Spinal manipulation represents but a tiny fraction of these precipitating movements and is almost impossible to identify with any regularity as the predominating cause of an arterial dissection."*
>
> *The Foundation for Chiropractic Education and Research, Response to Vertebral Artery Dissection Study: Canadian Medical Association Journal, Anthony L. Rosner, Ph.D., April 10, 2001*

Although some form of sudden neck rotation with bending seems a consistent theme in the possible development of a carotid or vertebral dissection, there are no injury thresholds for this rare event. Even if thresholds based on known forces involved in chiropractic manipulation could be developed, it is not known if the criteria would be applicable to those susceptible to this rare injury.

1.3.2 Subarachnoid Hemorrhage

A subarachnoid hemorrhage involves bleeding between the middle membrane covering of the brain and the membrane covering the brain itself, within the cerebrospinal fluid (CSF) filled spaces surrounding the brain (also known as the subarachnoid space). The most common cause of any form of subarachnoid hemorrhage is mechanical (penetrating or blunt) trauma. In the

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case of spontaneous subarachnoid hemorrhage, 95% of the cases are a result of a ruptured aneurysm. This may occur from a ruptured cerebral aneurysm or arteriovenous malformation, but some result from unidentified causes. Annual incidence of nontraumatic aneurysmal SAH is 6-25 per 100,000, or between 16,000-66,000 per year in the United States. Cerebral aneurysm formation is a long-term process of vessel weakening thought to be associated with the risk factors of hypertension, ischaemic heart disease, diabetes mellitus, hyperlipidaemia, and arteriosclerosis. Lifestyle habits such as smoking, alcohol consumption, and medications such as anticoagulants, oral contraceptives, or hormone replacement therapy have also been published as risk factors. The ultimate rupture of a cerebral aneurysm is assumed to be associated with an increase in transluminal cerebrovascular pressure of some origin. In the case of the z accelerations generated in roller coasters, the fluid nature of the blood allows it to flow relative to the solid structures of the head. Positive +Gz accelerations cause a reduction of the vessel pressure (perfusion pressure) within the brain rather than cause an increase. This decreases the transluminal pressure and thus decreases the likelihood of SAH. Conversely, during negative -Gz accelerations on roller coasters, the pressures within the cerebrovasculature and in the surrounding cerebrospinal fluid space increase in parallel. This effect combined with the counter-pressure action of the skull protects the cerebrovasculature from high transluminal pressures.

1.3.3 Chronic Subdural Hematoma

A subdural hematoma is a collection of clotted blood that exists under the dural (outermost) membrane of the brain. An acute subdural hematoma is one that is clotted which is found in a time period of up to several days after the initiating event. A subacute subdural hematoma is where there is a mixture of clotted and fluid blood, which is found in a time period of several days to three weeks after the initiating event. A chronic subdural hematoma is one where the hematoma is fluid, which is found in a time period longer than three weeks after the initiating event. The chronic type is a result of an initial insult or acute subdural hematoma, which can be traumatic or non-traumatic. Traumatic subdural hematoma can result from a contusion or laceration of the brain tissue or as a result of the tearing of bridging veins in the brain. The incidence of chronic subdural hematoma is 1-2 per 100,000 people per year, or roughly 2,600-5,300 per year in the United States. The majority of the patients with chronic subdural hematoma are elderly or chronic alcoholics. Cerebral atrophy is apparently an important association to the development of this injury. The associated head trauma is often stated as "mild" and in up to one-half of the cases any trauma is denied. While the exact cause in the case of chronic subdural hematoma is unknown, the rupture of bridging veins is often attributed to the condition.

Injury thresholds for acute subdural hematoma have been published. The mechanism of injury has been established as rotational acceleration of the head with thresholds for injury of 12,500 rad/s^2 at 60 rad/s. (Thibault and Gennarelli, 1990) No head rotational acceleration data have been provided to evaluate the risk of such an injury in this analysis of accelerations experienced by roller coaster riders.

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1.3.4 Cerebrospinal Fluid Leak

A cerebrospinal fluid (CSF) leak occurs when there is a leakage of spinal fluid from the subarachnoid space to the extradural space. This leakage results from a tear in the dura that can be traumatic or due to surgery or some other intervention. CSF is forced through the hole in the dura by the intradural pressure (intracranial or intraspinal), which is higher than atmospheric pressure. Known associations with CSF leakage are generalized connective tissue disorder involving spinal meninges and events reported such as roller coaster exposures, white-water rafting, a bump into table during a brawl, jet-skiing, childbirth, weightlifting, playing volleyball, sexual intercourse, jogging and a fall on the buttocks while roller-blading. Traumatic induction of a CSF leak has been associated with a fracture of the skull base (basilar skull fracture). The most common sites for CSF leak are from the nose and ear. There is no published estimate for the rate of CSF leaks.

1.3.5 Decompensation of Congenital Retinal Macrovessel

A congenital retinal macrovessel is a large vessel, usually a vein, which traverses through the central macula and has large tributaries extending on both sides of the horizontal raphe. This congenital formation typically does not affect visual acuity. This particular injury mode, although very rare, was associated with retinal arteriovenous and cilioretinal anastomoses, which are connections to other vessels that would decrease blood circulation to the retina. While this anomaly had not previously presented as a problem in the sole case reported in the literature due to compensation of the circulatory system, this one person experienced 10 to 15 roller coaster rides per week over a 3-month period. The reporting physicians speculated that the changes in venous pressure during such exposures caused leakage in the arteriovenous communications, which led to the decompensation. This finding had never been reported before and the causation link is speculative. There are no injury criteria defined for this anomaly.

1.3.6 Cerebral Contusion with SAH

A cerebral contusion is a focal injury that results when localized mechanical forces damage the small blood vessels and other tissue components of the neural parenchyma. Bleeding from the damaged blood vessels is the most obvious feature of this injury, which can extend into the subarachnoid space. These focal injuries are a result of head impact.

Injury tolerances for head impact have been established through research and testing. The Head Injury Criterion (HIC) is the most used criterion to assess the likelihood of an injury when head impact is involved. In the "Final Economic Assessment, FMVSS No. 201, Upper Interior Head Protection", NHTSA, June 1995, the agency utilized two different sets of HIC versus injury severity curves. These were labeled by NHTSA as the Expanded Prasad/Mertz curves and the Lognormal Curves. Prasad/Mertz developed the AIS 4+ curves and NHTSA developed additional curves based on the AIS 4+ Prasad/Mertz curve. The HIC is discussed fully in the FMVSS standard and the mechanics and computations for the score will be discussed in a later section of this report.

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1.3.7 Syringomyelia

Using information from the National Institute of Neurological Disorders and Stroke, syringomyelia is a disorder in which a cyst forms within the spinal cord. This cyst, called a syrinx, expands and elongates over time, destroying the center of the spinal cord. Since the spinal cord connects the brain to nerves in the extremities, this damage results in pain, weakness, and stiffness in the back, shoulders, arms, or legs. Other symptoms may include headaches and a loss of the ability to feel extremes of hot or cold, especially in the hands. Each patient experiences a different combination of symptoms.

About 21,000 American men and women have syringomyelia, with symptoms usually beginning in young adulthood. Signs of the disorder tend to develop slowly, although sudden onset may occur with coughing or straining. If not treated surgically, syringomyelia often leads to progressive weakness in the arms and legs, loss of hand sensation, and chronic, severe pain.

A number of medical conditions can cause an obstruction in the normal flow of cerebrospinal fluid, redirecting it into the spinal cord itself. For reasons that are only now becoming clear, this results in syrinx formation. Cerebrospinal fluid fills the syrinx. Pressure differences along the spine cause the fluid to move within the cyst. Researchers believe that it is this continual movement of fluid that results in cyst growth and further damage to the spinal cord.

Two forms of syringomyelia are thought to exist. In most cases, the disorder is related to an abnormality of the brain called a Chiari I malformation, named after the physician who first characterized it. This anatomic abnormality causes the lower part of the cerebellum to protrude from its normal location in the back of the head into the cervical or neck portion of the spinal canal. A syrinx may then develop in the cervical region of the spinal cord. Because of the relationship that was once thought to exist between the brain and spinal cord in this type of syringomyelia, physicians sometimes refer to it as communicating syringomyelia. Here, symptoms usually begin between the ages of 25 and 40 years and may worsen with straining or any activity that causes cerebrospinal fluid pressure to fluctuate suddenly. Some patients, however, may have long periods of stability. Some patients with this form of the disorder also have hydrocephalus, in which cerebrospinal fluid accumulates in the skull, or a condition called arachnoiditis, in which a covering of the spinal cord--the arachnoid membrane--is inflamed.

The second major form of syringomyelia occurs as a complication of trauma, meningitis, hemorrhage, a tumor, or arachnoiditis. Here, the syrinx or cyst develops in a segment of the spinal cord damaged by one of these conditions. The syrinx then starts to expand. This is sometimes referred to as noncommunicating syringomyelia. Symptoms may appear months or even years after the initial injury, starting with pain, weakness, and sensory impairment originating at the site of trauma.

The primary symptom of post-traumatic syringomyelia is pain, which may spread upward from the site of injury. Symptoms, such as pain, numbness, weakness, and disruption in temperature sensation, may be limited to one side of the body. Syringomyelia can also adversely affect sweating, sexual function, and later, bladder and bowel control.

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Some cases of syringomyelia are familial, although this is rare. In addition, one form of the disorder involves the brainstem. The brainstem controls many of our vital functions, such as respiration and heartbeat. When syrinxes affect the brainstem, the condition is called syringobulbia.

There are no published injury criteria for syringomyelia and no recommendations can be made.

1.3.8 Spinal Cord Compression by Enterogenous Cyst

An enterogenous cyst, a developmental anomaly derived from the foregut, is a rare cause of slowly progressive spinal cord compression. In the single case reported in the literature, the patient's progressive course of spinal cord compression was rapid and the symptoms developed after attending an amusement park where she rode differing types of acceleration-imposing rides. In the lone case of this type of injury associated with an amusement ride, the reporting physician's correlations of this rare occurrence to the park activities were speculative and centered on repeated hyperextension of the neck. The exact amusement rides encountered were not delineated but direct investigation of the specific rides would be required to substantiate these speculations. While there are injury criteria for neck injury, there are no injury criteria for this entity.

1.3.9 Post-Traumatic Migraine

While other post-traumatic headaches related to amusement ride exposure have been related to other problems such as SAH, a one-patient case report was published where a patient had post-traumatic headache without any definable brain injury. According to the International Headache Society, post-traumatic migraine is defined as headache associated with head trauma and is part of the presentation associated with the post-traumatic or post concussion syndrome that follows significant head injury. The occurrence of the condition is not necessarily associated with definable central nervous system injury and can occur whether or not unconsciousness occurred at the time of trauma. The syndrome is characterized by headache, vertigo, impairment of memory and concentration, and variable degrees of emotional impairment. One 1944 report indicated that even minor trauma could cause chronic headache and aggravate migraine in susceptible individuals. Injury thresholds for concussion have been published at an angular acceleration threshold of 8,000 rad/s^2 at 75 rad/s angular velocity for incidents without head impact. For incidents with head impact, the Wayne State and the Japanese Automakers Research Institute (JARI) head injury curves indicate thresholds for concussion starting at 80G to 100G for impact duration of 6 to 12 msec and increasing to 300G for 1 msec impact durations.

1.3.10 Traumatic Carotid Artery Compression

A single patient case study reported the finding of a thrombosis (blood clot) in the internal carotid artery in a 13-year-old girl who demonstrated a speech defect immediately after stepping off a roller coaster. The origin of the thrombosis was speculated to be due to a direct impact of the neck with the restraint harness, which caused blood clot formation within the intima of the left internal carotid artery. No analysis of the actual ride characteristics was discussed. Our review found no injury criteria for such an event.

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1.4 Discussion

Recent accident reports have identified several other types of injuries in the descriptions of the accident; these would include ruptured middle ear, retinal tears, and axonal damage with fornix tear. These injury mechanisms were not addressed in the initial literature search and it is recommended that additional searches be performed to investigate these injury types.

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2 Roller Coaster Accelerations and Human Response

2.1 Background

A "G" is a unitless measure of the acceleration of an object normalized by the acceleration caused by gravity. Neglecting air resistance, Earth's gravitational pull causes free-falling objects to change their speeds by a constant of 9.81 m/s^2 (32 ft/s^2). Dividing acceleration (calculated as change of velocity divided by time) by this constant yields the acceleration in Gs. Because acceleration is related to velocity and time, two different rides traveling at two different speeds may create the same accelerations if the radius of the turns' vertical and horizontal curvatures were different. For example, a roller coaster traveling at 50 mph going through the bottom of a vertical curve may generate 3Gs. If the speed of the roller coaster is increased to 100 mph and the vertical radius of curvature is increased by four times, the coaster will still generate 3Gs. Understanding this relationship is critical when examining the descriptive information provided with roller coaster advertisements and specifications. One cannot conclude that a ride will create higher accelerations just because it is taller and has a higher maximum speed. The converse is also important: just because a roller coaster is short and slow, one cannot assume that the accelerations experienced will be low.

Scientific advances in roller coaster technology, manufacturing, and materials allowed coasters to become taller and faster. Also, the number of roller coasters built each year has increased as the popularity of theme parks has increased over the years. Six Flags provided maximum speed data versus the year of manufacture to Exponent for 167 roller coasters built since 1967. Some of the roller coasters included in this analysis are not currently in service. Analysis of these data showed that there has been a statistically significant increase in maximum speed over that time. Figure 2.1 shows the data for maximum speed plotted against year of manufacture. The plot also displays the fitted linear regression line and the confidence intervals for the prediction.

Acceleration data gathered for the majority of Six Flags roller coasters were also made available to Exponent. Maximum vertical (z-axis) and lateral (y-axis) accelerations were provided for 110 roller coasters, these acceleration values were compared to the year of manufacture. Figure 2.2 and Figure 2.3 show the data plots for these comparisons along with the linear regression lines. For both comparisons, no statistically significant changes in the vertical or lateral accelerations were found.

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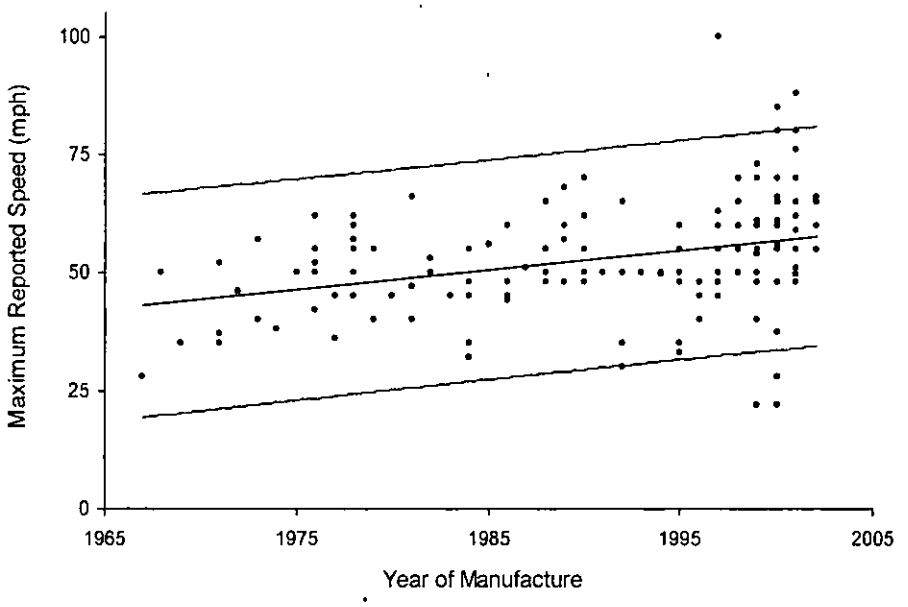

Figure 2.1 Plot of Six Flags roller coaster maximum speed versus year of manufacture and linear regression with 95% confidence interval.

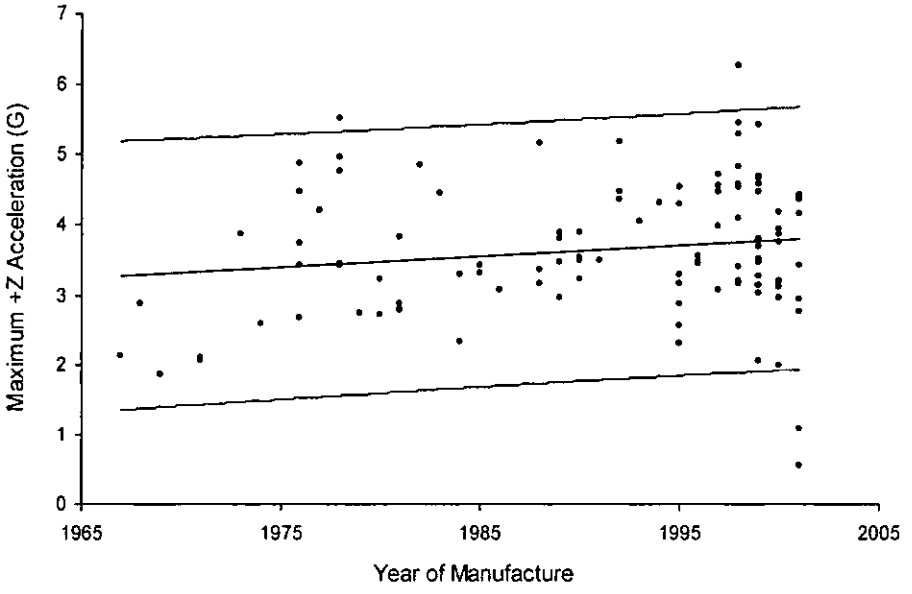

Figure 2.2 Plot of Six Flags roller coasters maximum +z-axis (head-to-toe) acceleration versus year of manufacture and linear regression with 95% confidence interval.

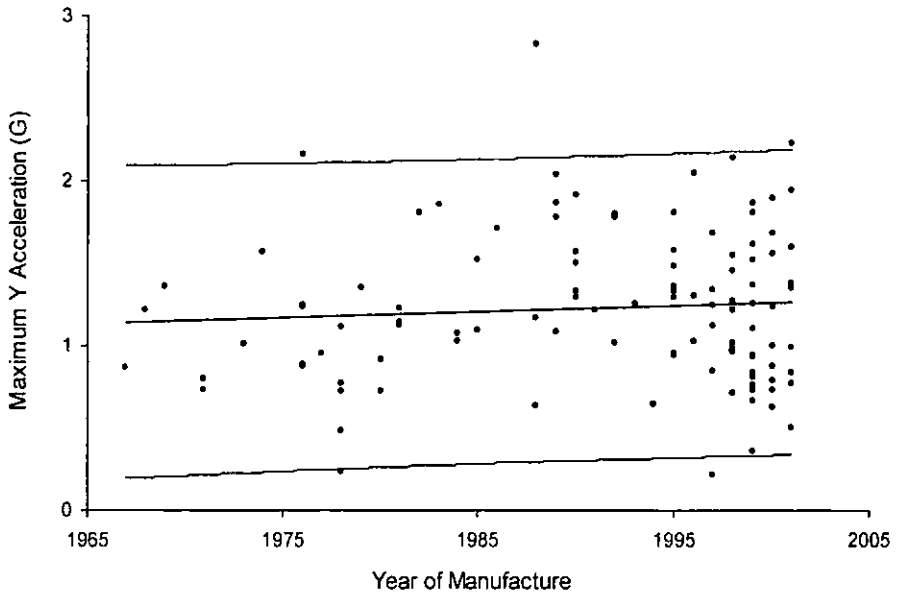

Figure 2.3 Plot of Six flags roller coasters maximum y-axis (lateral) acceleration versus year of manufacture and linear regression with 95% confidence interval.

Additionally, there have been recent comparisons of current roller coaster G accelerations experienced by occupants to those experienced by space shuttle astronauts and racecar drivers stating that coasters generate accelerations that exceed those of the space shuttle or racing cars. It is noteworthy that these comparisons have failed to consider the duration of the acceleration exposure. One important concern when examining human response to accelerations is loss of consciousness or "blacking out". In order to address this concern, Exponent evaluated ride acceleration data supplied by Six Flags for a sample of their rides.

2.2 G-Induced Loss of Consciousness Analysis

To examine the likelihood of a rider experiencing a G-induced loss of consciousness (GLOC), data from a sample of roller coasters from Six Flags parks across the U.S. were analyzed. Six Flags provided Exponent with 124 sets of acceleration data for 71 roller coasters out of approximately 176 potential roller coasters within their parks. These data were collected prior to Exponent's retention and were readily available for analysis. Data were not initially collected for the purpose of GLOC analysis; however, they were converted for that purpose.

2.2.1 GLOC Background

When an occupant of a vehicle is exposed to an increase in +Gz (head-to-toe acceleration), the pressure required to perfuse the eyes and the brain increases and blood begins to pool in the capacity blood vessels of the lower limbs. With increased acceleration levels, the perfusion pressure requirements increase and the volume of blood returning to the heart decreases further. The eyes and the brain receive an ever-decreasing amount of oxygenated blood. If the duration of the exposure is long enough, the eyes, requiring a greater perfusion pressure owing to the

intraoccular pressure, will manifest symptoms first such as a loss of peripheral vision, which can proceed to a total loss of vision if the acceleration level is high and long enough. As the acceleration level and duration increases, unconsciousness can occur where the vehicle occupant additionally looses postural control. The vehicle occupant would regain consciousness once the acceleration level was below their perfusion pressure threshold, which would be higher than normal due to activation of cardiac compensation mechanisms. Many experimental subjects and training participants have experienced acceleration-induced unconsciousness episodes without any lasting effects. The concern with respect to an amusement park attraction rider is the experience of losing consciousness and the lack of postural control, which might result in an injury.

2.2.2 Prediction of Acceleration Induced Loss of Consciousness

To investigate the potential for acceleration induced loss of consciousness, a computer model developed by M. Technologies was used. M. Technologies of Huntingdon Valley, PA is a wholly owned subsidiary of EDO Corporation, a supplier of advanced electronic, electromechanical and information systems and engineered materials to the government, military, and industry. The model is available through the Crew Systems Engineering Department, Naval Air Warfare Center- Aircraft Division, Patuxent River, MD

This model has been used by M. Technologies for various experimental protocols and research into loss of consciousness. The model has also been used to develop acceleration profiles used in experimental protocols for intentional loss of consciousness experiments where aircraft recovery was studied. Currently, the model is a part of the US Navy's Smart Advanced Life Support System as a predictive module in an overall control system scheme. The model was designed to predict if an unconsciousness event will occur or had occurred based on z-axis acceleration data and physical characteristics of the vehicle occupant. The potential for acceleration induced unconsciousness was predicted using the Cammarota model. This model was developed based on the use of percolation theory to determine when communication was lost in a node matrix. The parameters used for node on/off state are acceleration, blood pressure, and eye level loss of pressure as a function of acceleration, pressure loss as a function of time and acceleration, O_2 saturation loss as a function of time and acceleration, and tissue O_2 utilization rate.

As acceleration level increased, nodes would be lost within the matrix. An unconsciousness event was declared when communication, "top to bottom", was lost within the matrix. Four historically significant GLOC studies were used to validate the predictive capability of the model. The model was validated by accurately predicting the result of the following large-scale, historically significant studies of human response to G acceleration.

The first study by Rosen (1943), titled "Acute Arrest of Cerebral Circulation" involved testing 137 people who were subjected to acute cessation of cerebral circulation by a cervical pneumatic cuff. This study established that the time to unconsciousness when the brain is quickly deprived of perfusion was about 6 seconds. One could argue that the vertebral arteries are not occluded totally and venous drainage is impeded in this approach but still the study was able to establish a baseline time to unconsciousness.

The second study by Cochran (1954) titled "Variations in Human G Tolerance to Positive Acceleration" involved testing 1,000 people who were subjected to early centrifuge exposures to

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unconsciousness. This study is notable because it involved a large number of subjects and was able to establish the acceleration level and time at which loss of peripheral vision, blackout, and unconsciousness take place. This study is somewhat flawed by the slow response of the centrifuge so the times to unconsciousness are shorter than higher onset machines. However, the model was able to accurately predict the human response to the slow-onset machine.

The third study by Beckman (1954) titled "Human Tolerance to High Positive G Applied at a Rate of 5 to 10 G per second" involved testing nine people who were subjected to centrifuge acceleration to unconsciousness at levels of 6 to 15G with onset rates ranging between 3.5 to 9.6 G/second. This study is notable because it was able to establish the time to unconsciousness for high-level, high-onset acceleration that was considered, at that time, similar to future jet fighter aircraft acceleration profiles. The times to unconsciousness for high G and onset of acceleration were significantly shorter than those found by Rossen (1943) and were attributed, while not proven, to the drainage of blood from the head during the acceleration exposure.

The fourth study by Houghton (1985) titled "Performance and Physiological Effects of Acceleration-Induced (+Gz) Loss of Consciousness" involved testing eight people who were subjected to gradual and rapid onset rate accelerations to unconsciousness while measuring neurocognitive performance in the centrifuge before and after the unconsciousness event. The study is notable because it was able to establish the time to return to consciousness after a GLOC.

In order to examine the likelihood of GLOC on roller coasters, a fictitious rider was created. This fictitious rider is assumed to be an individual who is highly susceptible to GLOC because of various physical conditions. The physical parameters used to create this individual are unlikely to be exhibited by any single person. The individual is estimated to be in the 99.9th percentile in terms of inability to resist +Gz acceleration. The characteristics of such a fictitious rider as compared to a normal individual are shown in Table 2.1. The model allows for the independent manipulation of each of the three parameters to create a rider that has each of the individual characteristics of a 99.9th percentile individual. It is extremely unlikely that any single individual would be in the 99.9th percentile for all three of these characteristics.

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Table 2.1 Physical characteristics of subject used in the GLOC model.

	99.9th Percentile Most Susceptible (1)	5th Percentile	50th Percentile	95th Percentile	99.9th Percentile Least Susceptible (2)
Eye level blood pressure drop 18.3 +/- 3 mmHg	27.3	23.1	18.3	13.5	9.3
Heart level Mean Blood Pressure (Resting Systolic Blood Pressure) 130 +/- 10 mmHg	100	114	130	146	160
Metabolic Offset 0 +/- 10 unitless	-29	-16	0	16	29

(1) This subject is assumed to loose blood pressure at the level of the eyes and the brain at the highest degree for each additional G level, has the lowest cardiac driving pressure to sustain perfusion of the brain, and uses oxygen at the fastest rate.

(2) This subject is assumed to loose blood pressure at the level of the eyes and the brain at the lowest degree for each additional G level, has the highest cardiac driving pressure to sustain perfusion of the brain, and uses oxygen at the slowest rate.

The z-axis (head-to-toe) acceleration data from the sample of roller coasters were input into the computer model with the physical parameters of the fictitious rider with the highest susceptibility to GLOC or the lowest tolerance to increased acceleration. Consequently, the computer model generated plots of the time history of the ride acceleration with the predicted physiological responses of the rider.

With respect to the amusement park rides, roller coaster data from Six Flags with peak acceleration levels over 3.5Gs in the z-axis direction were selected for modeling. This acceleration level was chosen to represent rides with the greatest potential to induce unconsciousness events. The least capable rider was established using the lowest physiological capabilities to withstand such a stressor recorded in the scientific literature as indicated in

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Table 2.1. These were namely the largest loss of eye level blood pressure as a function of G level, the largest loss of oxygen saturation as a function of G level and the highest metabolic utilization of oxygen. Since the model required a sampling rate of one measurement every 0.1 second and the Six Flags vehicle inertial data were sampled at every 0.002 second, a decimation in time was performed using the MATLAB "Decimate" function. This function automatically applies a digital filter to avoid aliasing (the loss or creation of false signals due to sampling); the filter used a 4 Hz cutoff frequency for the case of decimation from 500 Hz to 10 Hz.

2.2.3 Results

As a demonstration of the model's function, and because no unconsciousness events were predicted for the roller coaster data, output data from aerial combat maneuvers are presented. Table 2.2 defines the parameters of the model that can be adjusted to create vehicle occupants of varying tolerance to GLOC.

Table 2.2 Key parameter labels in model output images.

Parameter Label	Parameter Description
Gz	Acceleration time history
BP	Eye level blood pressure
BF	% Brain blood flow
OXY	% Oxygen saturation at brain
NM	"Neural Mass" indicator (model specific)
CM	"Cluster Mass" indicator (model specific)
ST	State: White line – normal Yellow line – transient effect Red line – unconsciousness

Figure 2.4 shows examples of aerial combat exercises taken from actual training. Using the subject parameters, a GLOC is predicted because the +Gz acceleration exceeded the level and duration needed to reduce the re-supply of oxygenated blood to the brain and also was sufficiently long that the oxygen reserve was depleted. While the exposure is discontinued in Figure 2.4, Figure 2.5 shows the results for an aerial maneuver when the forces are repeated without allowing for recovery. Note the unconsciousness event followed by a recovery from unconsciousness with a repeated unconsciousness event. This pattern is repeated throughout the model prediction.

Thirty-four roller coasters were evaluated. Two examples of the output from the computer program are presented in Figure 2.6 and Figure 2.7.

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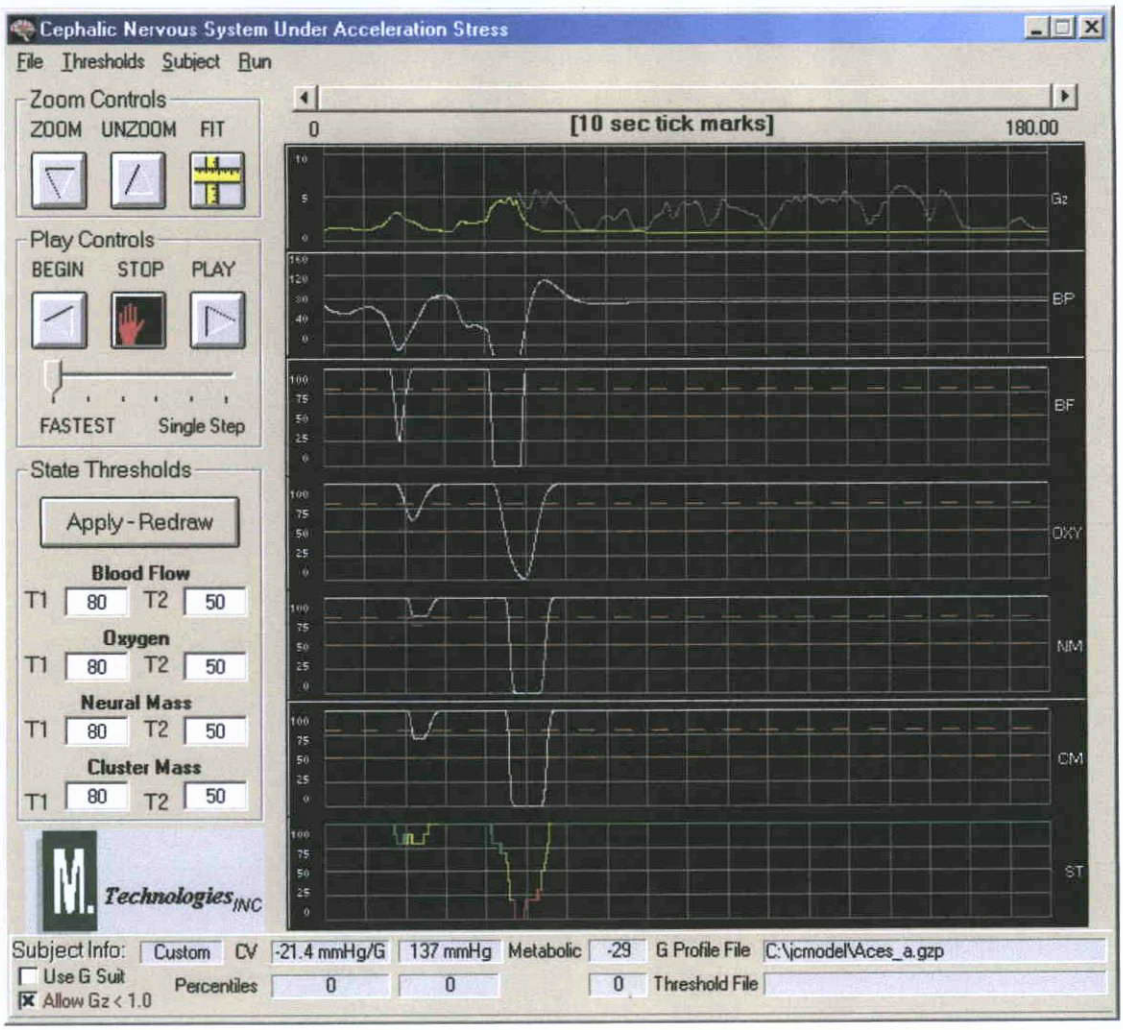

Figure 2.4 Aerial combat maneuver showing a predicted unconsciousness event (red).

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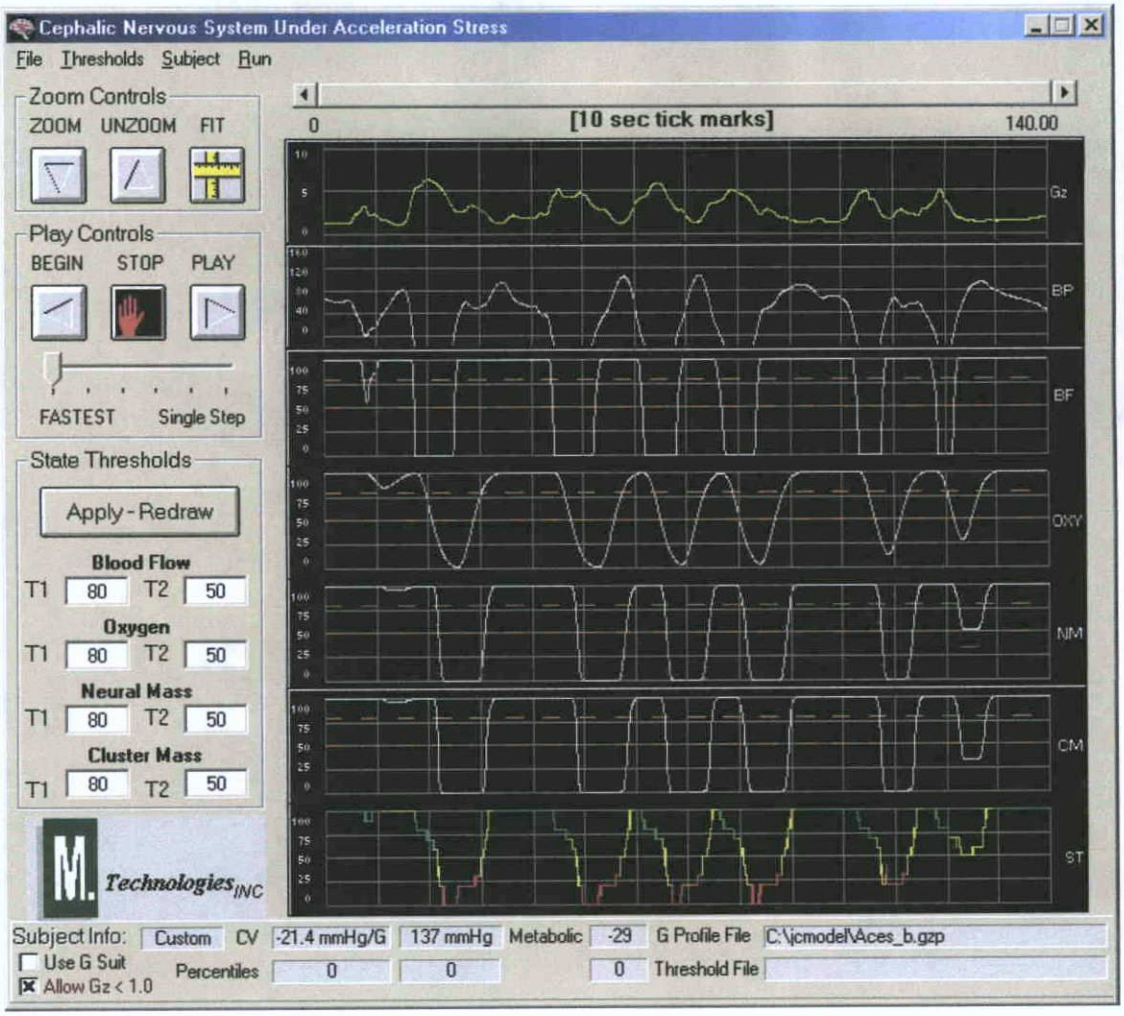

Figure 2.5 Repeat of aerial combat maneuver without decay of acceleration to show predicted multiple unconsciousness events (red).

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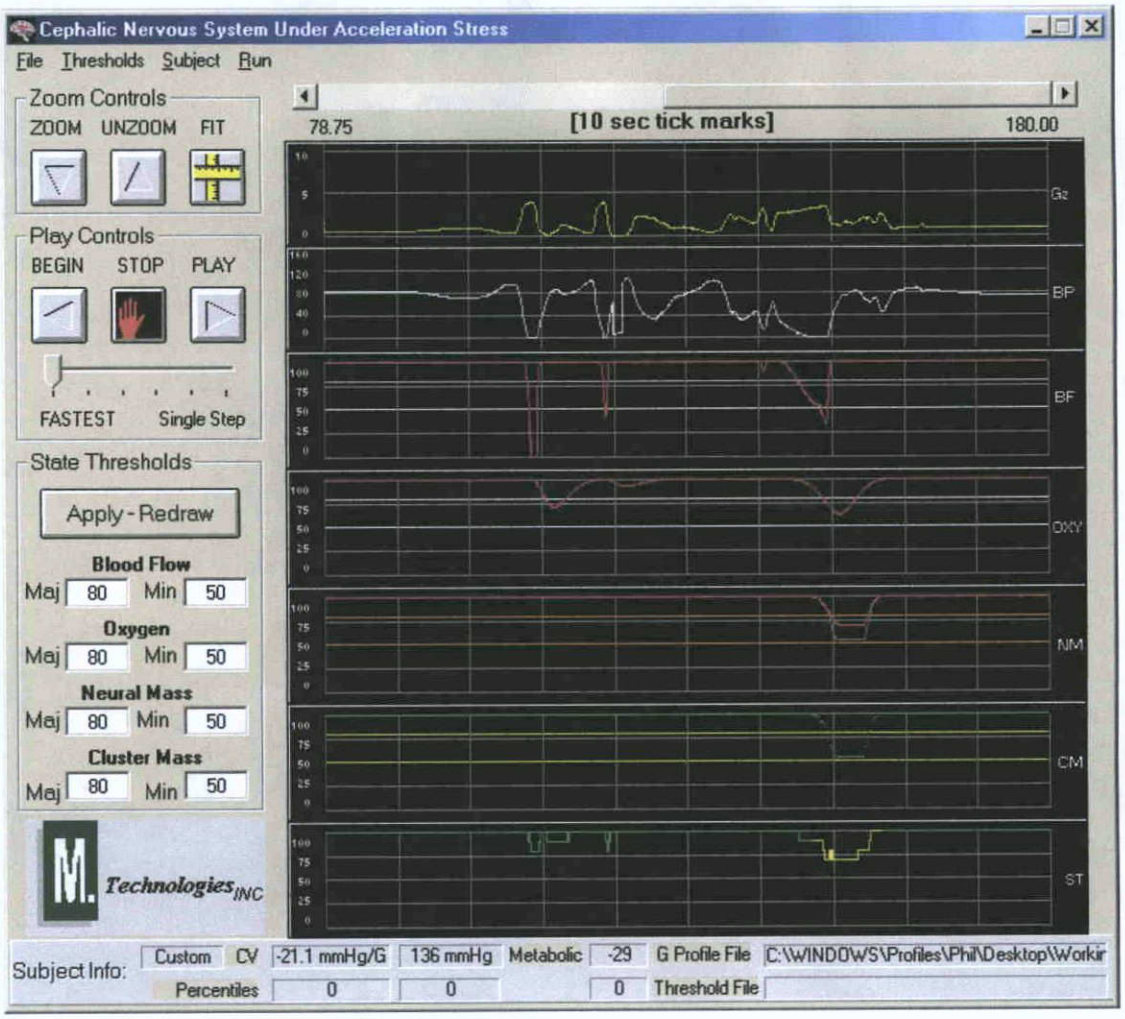

Figure 2.6 Predicted occupant response to Gz accelerations on Steel Roller Coaster 76.

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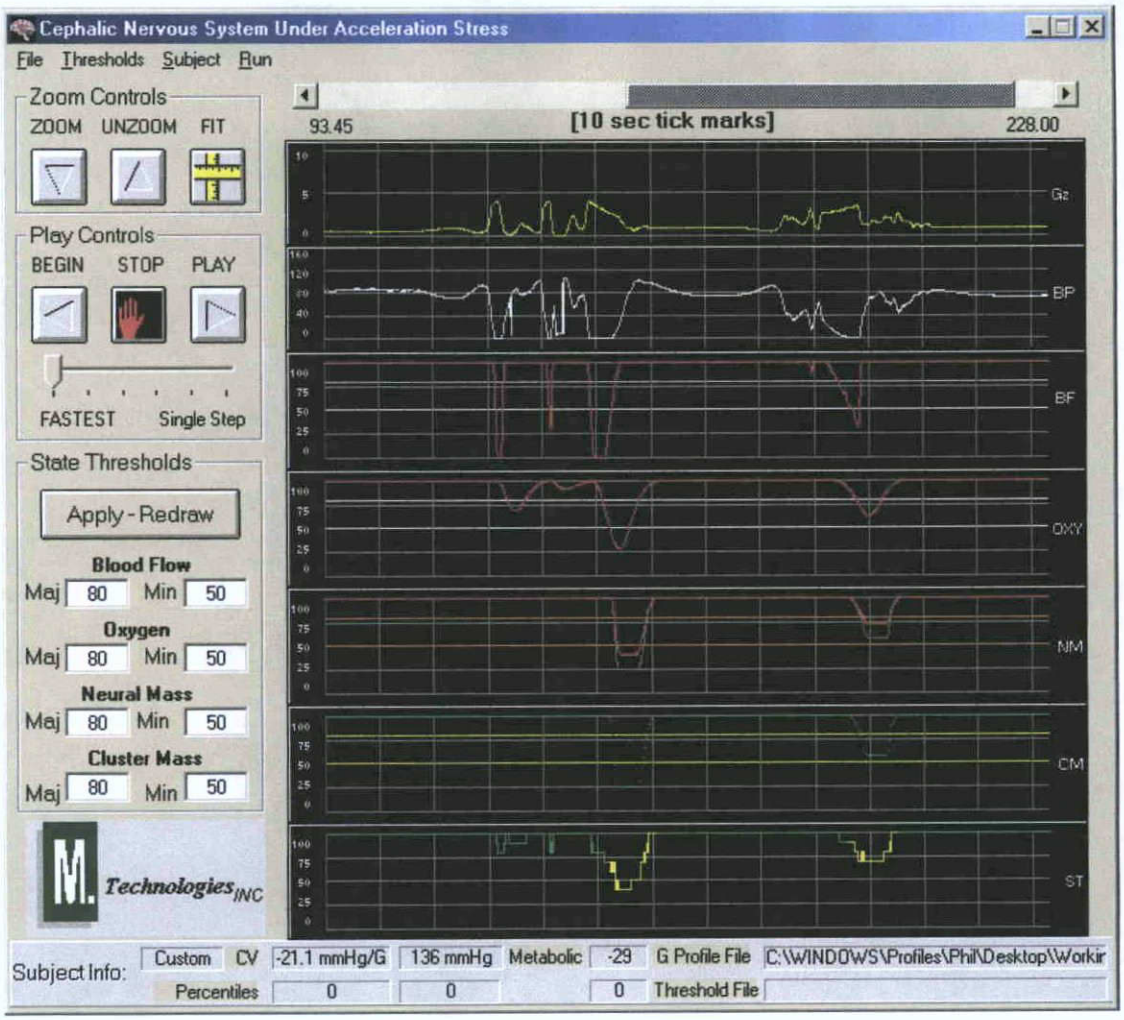

Figure 2.7 Predicted occupant response to Gz accelerations on Steel Roller Coaster 41.

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2.3 Discussion

Six Flags roller coasters' maximum speeds have significantly increased over the last 35 years. However, no significant increases in roller coaster maximum z-axis or y-axis accelerations were found over the last 35 years.

Computer model predictions of unconsciousness events for a fictional person with physical characteristics equating to the most susceptible to GLOC, showed no unconsciousness events for the Six Flags roller coasters. These results were primarily due to the short durations of the Gz excursions. The onset of GLOC is a function of both the amplitude and duration of the vertical acceleration. A Gz amplitude that exceeds the threshold without sufficient duration does not induce GLOC. Transient physiological disturbances in roller coaster rides were predicted and are akin to the everyday disturbances that one experiences as one stands from a sitting or a lying position. Both Gz levels and durations must be considered in the design of roller coaster rides. These design considerations are described in studies by Cochran in 1954 and by Whinnery et al in 1990.

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3 Roller Coaster Occupant Head Acceleration Analysis

3.1 Background

Injury tolerances for head impact have been established through research and testing by the National Highway Transportation Safety Administration (NHTSA) and other government standards agencies. The Head Injury Criterion (HIC) is the most used tool to assess the likelihood of an injury when head impact is involved. The HIC uses head acceleration data usually gathered from biophidelic crash test dummies that are instrumented with head accelerometers. The accelerometers collect head accelerations for all three axes (x, y, and z). The resultant vector is computed by combining the three vectors.

The HIC is designed to be an injury metric for the prevention of serious to fatal brain injury and skull fracture. Good HIC performance protects against injuries such as brain contusions, subdural hematomas, and skull fracture from blunt impacts. HIC has been used to evaluate the effectiveness of vehicle interior padding, airbags, bicycle helmets and playground ground-cover materials. HIC is not relevant to penetrating blows, aneurysms and arterial defects. In addition, HIC does not measure or predict perceptive phenomena such as vertigo or muscle, tendon, or ligament strains.

The tests on which HIC is based are "hard" impacts to the head, generally with durations of 10 msec or less. Therefore data without sufficient frequency content to capture these "hard" impacts is not directly applicable to HIC. HIC is an integration over a maximum time window of the linear resultant acceleration at the center of gravity of the head. The equation for the calculation of the HIC is provided in Figure 3.1.

$$HIC = max\left[\frac{1}{t_2 - t_1}\int_{t_1}^{t_2} a\,dt\right]^{2.5}(t_2 - t_1)$$

Figure 3.1 HIC score calculation equation.

The calculated HIC is used in a series of equations to determine the likelihood of an injury for a specific severity. The injury severity is indicated on an Abbreviated Injury Scale (AIS).

The AIS, first developed by the Association for the Advancement of Automotive Medicine in 1971, is a consensus-derived, anatomically based system that ranks individual injuries by body region on a scale of 1 to 6 as follows: 1=minor, 2=moderate, 3=serious, 4=severe, 5=critical, and 6=maximum/currently untreatable. The AIS is intended as a measure of the severity of the injury itself and not as a measure of impairments or disabilities that may result from the injury. It does not assess the combined effects of multiple injuries to a patient. The AIS was revised and updated several times, with the most recent revision in 1990. MAIS represents the maximum

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injury severity of any injury received by a person, regardless of the nature or location of the injury.

In the "Final Economic Assessment, FMVSS No. 201, Upper Interior Head Protection", NHTSA, June 1995, the agency utilized two different sets of HIC versus injury curves. These were labeled by NHTSA as the Expanded Prasad/Mertz curve. Prasad/Mertz developed the original AIS 4+ curves; the other curves were developed by NHTSA based on the AIS 4+ Prasad/Mertz curve. This tool was used to compare the magnitude and duration of head accelerations on roller coasters to common daily activities.

It is likely that head impacts in amusement rides occur with lower relative head to impact surface velocities than those in automobile accidents. Ride restraint padding extends the total time of a head impact and mitigates the peak acceleration level, thus HIC scores decline for padded impacts. The sampling rate and channel frequency class (CFC) are critical to using HIC calculations. In crash testing, a class 1000 filter is used for head acceleration, which corresponds to a minimum sampling rate of 10,000 points per second.

Data sampled every 10 msec (100 Hz) could miss entirely a "hard" head impact on a rigid surface when applied to the HIC calculation. However, short duration, hard impacts are not expected in the amusement ride environment. Low frequency acceleration data, with no anticipated high frequency content, that result in very low computed HIC values are an indicator of very mild head impacts that have very small brain injury risk according to the expanded Prasad/Mertz curves.

Occupant head acceleration data from test subjects on roller coaster rides and subjects performing common recreational activities were analyzed using the HIC calculation software. The software is available from the NHTSA web site at http://www-nrd.nhtsa.dot.gov/software/signal-analysis/downloads.html. The software uses the x, y and z-axis data or the resultant acceleration data. The software generates a plot that displays the resultant acceleration vector magnitude and the HIC score. These calculated HIC scores do not have the same meaning as HIC Scores calculated from acceleration data sampled to CFC1000. However, the HIC score does use the magnitude and duration of the accelerations in the calculation. HIC scores from roller coaster occupants will be utilized in making relative comparisons between roller coaster rides and head accelerations experienced in everyday life. Figure 3.2 displays an example plot of a HIC analysis for a person being hit moderately hard on the head three times with a common foam pillow. It is important to remember that the G's displayed are a combination of the x-, y-, and z-axes acceleration vectors.

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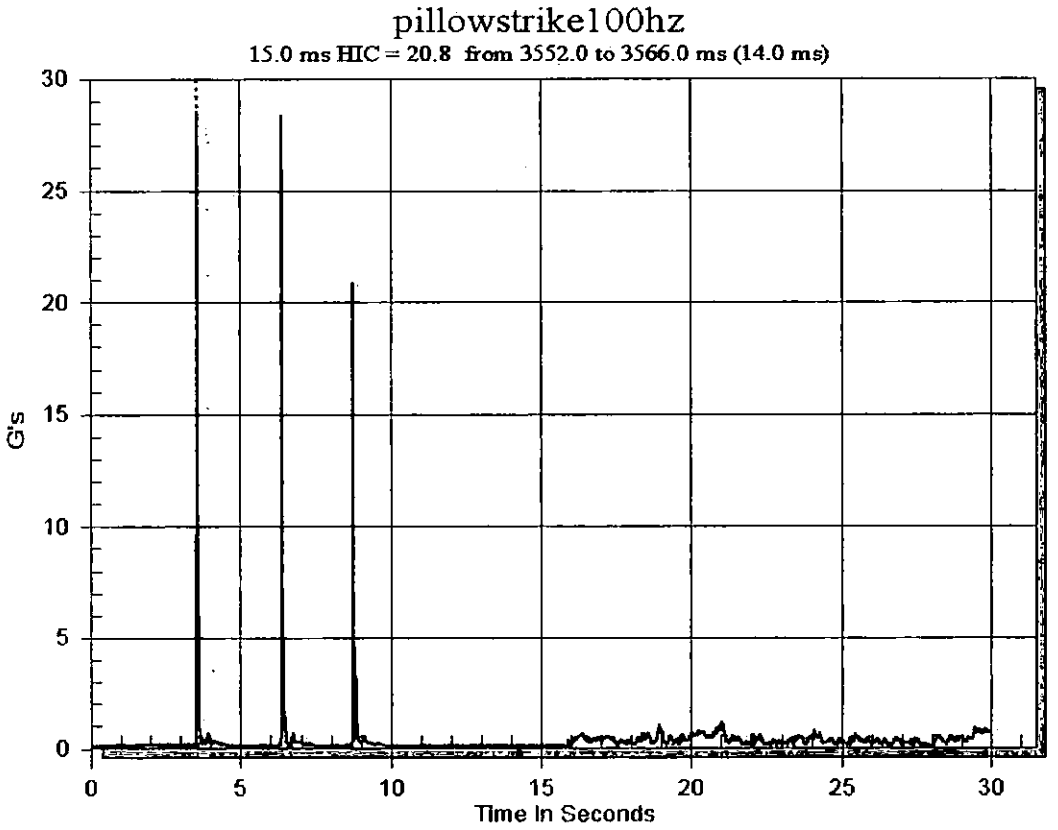

Figure 3.2 Plot of resultant head accelerations from three moderate head strikes with common foam pillow.

3.2 Results

All HIC scores for the sample of Six Flags rides were found to be extremely low. Table 3.1 lists the HIC scores for 71 different rides. For comparison, the data analysis showed that getting hit on the head with a pillow generates a HIC score that is on average far greater than the scores calculated from the ride data. Maximum HIC scores for the common activities studied are displayed in Table 3.2.

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Table 3.1 HIC scores for available rides.

Roller Coaster	HIC Score
Steel-112	9.4
Wood-015	8.3
Steel-077	7.2
Steel-142	6.8
Steel-129	6.8
Steel-060	6.4
Steel-139	5.0
Steel-150	4.8
Steel-108	4.2
Steel-059	3.9
Steel-113	3.9
Wood-024	3.7
Steel-049	3.6
Wood-030	3.2
Steel-148	3.2
Steel-043	3.1
Steel-006	3.0
Steel-008	2.8
Wood-026	2.8
Steel-034	2.8
Steel-135	2.7
Steel-005	2.3
Steel-050	2.2
Steel-131	2.2
Wood-001	2.2
Steel-035	2.2
Steel-134	2.1
Steel-036	2.1
Steel-040	1.9
Steel-132	1.9
Steel-047	1.9
Wood-008	1.8
Steel-031	1.8
Steel-103	1.8
Steel-070	1.8
Steel-141	1.6

Roller Coaster	HIC Score
Wood-029	1.6
Steel-133	1.6
Steel-106	1.5
Steel-045	1.5
Wood-040	1.5
Steel-003	1.4
Wood-019	1.4
Steel-078	1.3
Steel-076	1.3
Steel-145	1.3
Steel-079	1.3
Wood-031	1.3
Wood-012	1.3
Steel-061	1.3
Wood-020	1.2
Wood-013	1.2
Steel-027	1.1
Wood-029	1.1
Wood-032	1.1
Wood-028	1.0
Steel-161	0.9
Steel-075	0.9
Wood-025	0.9
Steel-044	0.8
Wood-009	0.7
Steel-042	0.7
Steel-073	0.7
Steel-072	0.4
Wood-011	0.4
Steel-001	0.4
Steel-056	0.4
Steel-136	0.3
Steel-063	0.3
Steel-163	0.3
Steel-162	0.2

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Table 3.2 Maximum HIC scores calculated for nine subjects performing common activities.

Activity	HIC
Hit On the Head with Pillow	20.8
Falling Down on Exercise Mat	15.2
Jumping on a Pogo Stick	1.4
Sneezing	0.5

3.3 Discussion

The analysis of the Six Flags data from 71 of their most dynamic roller coasters revealed that the accelerations experienced by the riders are comparable to or lower in severity than the accelerations experienced during common activities. These findings cannot predict the likelihood of an individual who has a pre-existing medical condition or has other elevated risk factors suffering an injury on one of these rides. However, as the data indicate, that same individual is at least as likely to have suffered the injury had they fallen down, sneezed or been hit in the head with a pillow. Individuals who have known pre-existing conditions should exhibit the same care in choosing to a ride roller coaster as they would before participating in any activity that may subject them to minor head impacts.

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4 Head Acceleration Data from Daily Activities

4.1 Background

When standing still, the human body is subject to 1 G of acceleration in the positive z direction (head-to-toe). During every movement of the body, the limbs and head experience changes in accelerations depending on the velocity and magnitude of change in position or direction. In order to put roller coaster occupant head acceleration data in context, it is necessary to have a frame of reference. First, it is important to distinguish impact accelerations from non-impact accelerations. Impact accelerations result from the physical contact of a head with an object. Non-impact head accelerations are caused by a change in direction or an increase in movement speed of the head (e.g., standing up, turning your head, coughing, swinging on a swing). Allen, et. al. (1994) reported the results of a study that collected head acceleration data for the x and z-axis for a number of common daily activities. Table 4.1, presents those test results.

Table 4.1 Maximum acceleration values from selected tasks (Allen, et. al., 1994).

Task	Maximum x	Maximum z
Plop in chair	5.6	8.5
Hop off a step	4.5	6.7
Slap on the back	2.7	3.1
Crowd jostle	1.9	3.0
Sneeze	1.5	2.5
Sit down	0.5	2.0
Cough	3.0	1.8
Head bob	1.9	1.1
Look left	0.6	0.3

Exponent conducted testing to obtain additional human subject head acceleration data. The objective of the testing was to measure head accelerations experienced by a cross section of human subjects while performing various common recreational activities. The testing was conducted over four days beginning on March 11, 2002 at Exponent's indoor Test and Engineering Center in Phoenix, Arizona.

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4.2 Test Tasks

The tasks consisted of the following:

- Riding a swing
- Running through an obstacle course
- Sneezing
- Falling forward onto a padded exercise mat
- Being struck on the back of the head with a pillow
- Jumping on a pogo stick
- Spinning on a wound up tire swing

4.2.1 Swinging Task

A commercial swing was built with a 15-foot overhead crossbar, a rigid seat, and chains supporting the swing. At the beginning of the test the subjects were pulled back to a height of approximately 3 feet, the data acquisition system was triggered, and then the subject was released. Subjects were instructed to "pump" the swing by leaning forward and backward and flexing and extending their legs to increase the height of the swinging action as best they could during the 30 seconds of data acquisition.

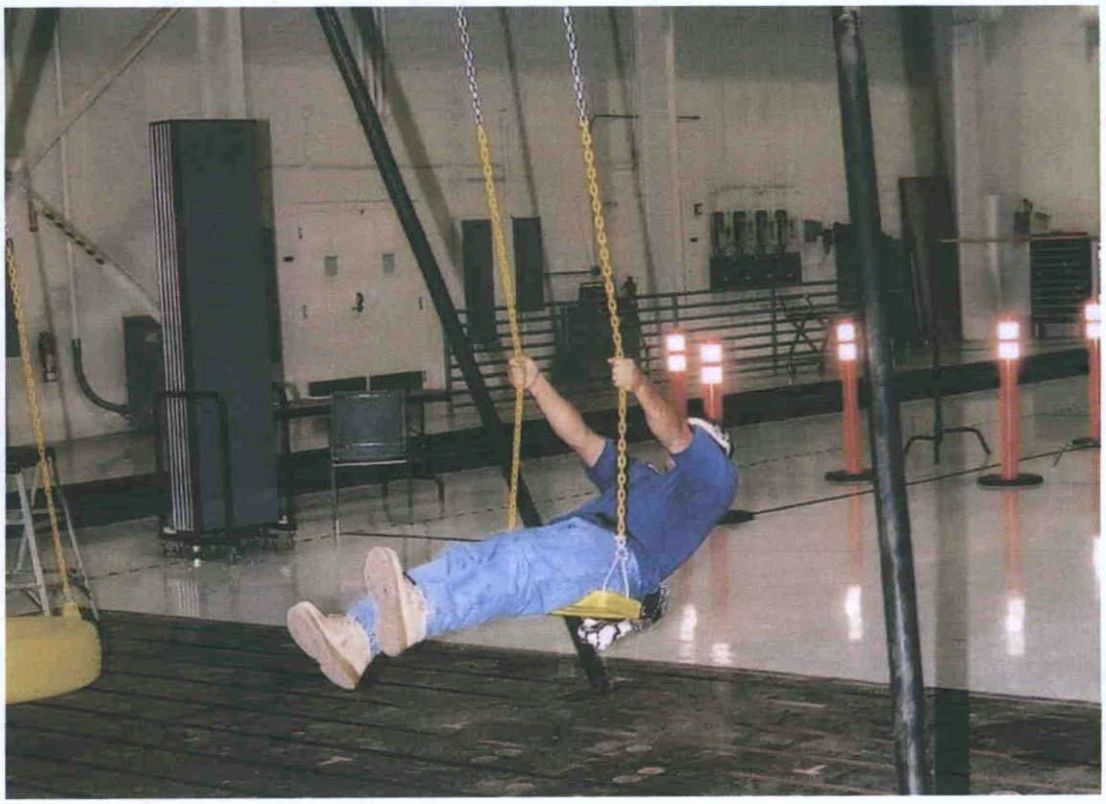

Figure 4.1 Photograph of subject swinging.

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4.2.2 Obstacle Course Task

The obstacle course task was set up to require quick lateral movements in a confined area similar to a what a person may experience while playing soccer or basketball. Subjects followed a predetermined path through vertical pylons. Subjects were instructed to finish the course as fast as they could. After completion of one run, subjects walked back to the beginning of the course and repeated the run.

Figure 4.2 Photograph of obstacle course.

4.2.3 Sneeze Task

Each subject attempted to sneeze using various methods. No photographs or video were taken during this task. Only one subject was able to sneeze.

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4.2.4 Falling Down Task

Subjects stood in front of an exercise mat and were instructed to fall to their knees, chest and stomach. Subjects were told that they should catch themselves with their hands at the last moment. No additional instructions about how to perform the fall were given. Subjects exhibited significant variation in their falling methods. Some of the subjects fell to their knees first and then to their chest, while others fell directly to their chest. Head accelerations varied significantly depending on the method of the fall. Subjects repeated this task three times.

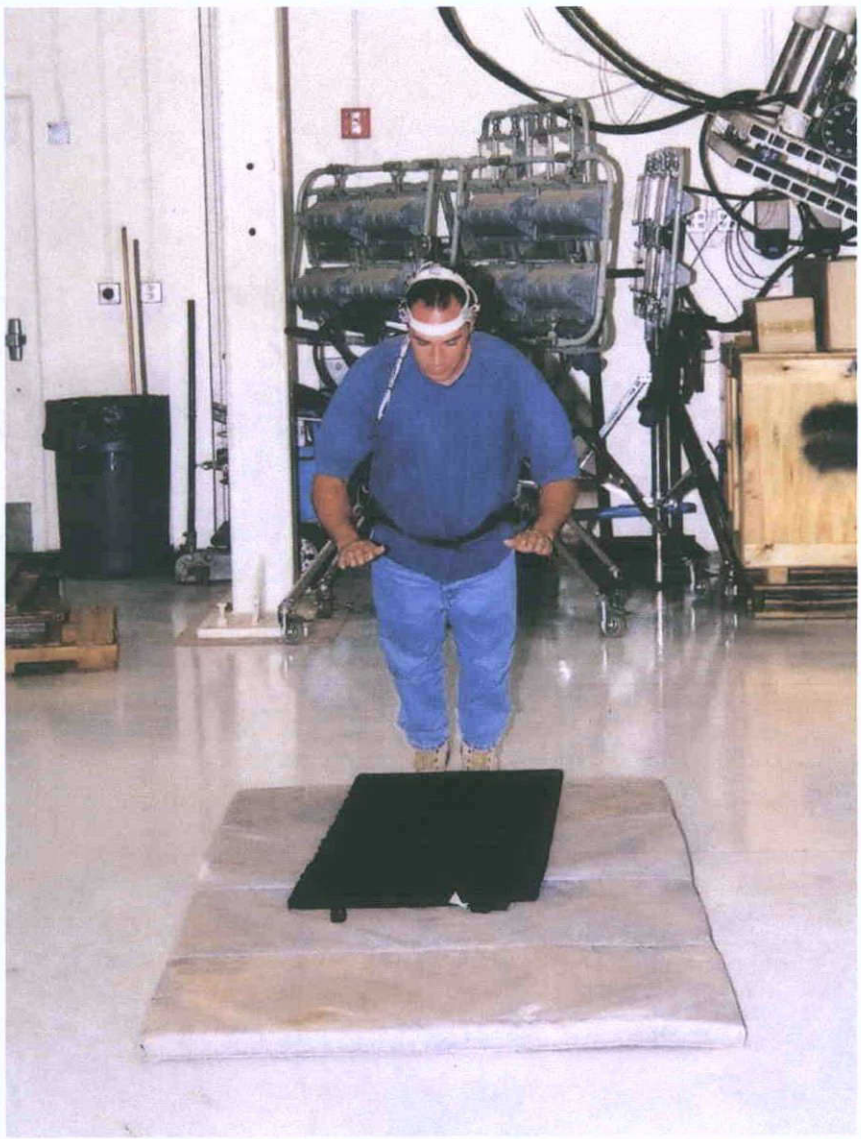

Figure 4.3 Photograph of subject falling face first onto exercise mat.

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4.2.5 Pillow Impact

Subjects were struck at the back of the head three times with a common foam pillow. Subjects were warned prior to each impact. The experimenter swung the pillow with moderate force using one hand through approximately a 120-degree arc in approximately 0.67 seconds.

Figure 4.4 Captured still frame video from pillow strike task, post impact.

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4.2.6 Pogo Stick Task

Subjects were provided with an air suspension pogo stick and instructed to attempt to jump up and down as many times as possible during the 30 seconds of data collection. The data acquired included jumping on the pogo stick and any acceleration that resulted from stepping or jumping off the pogo stick if they lost their balance.

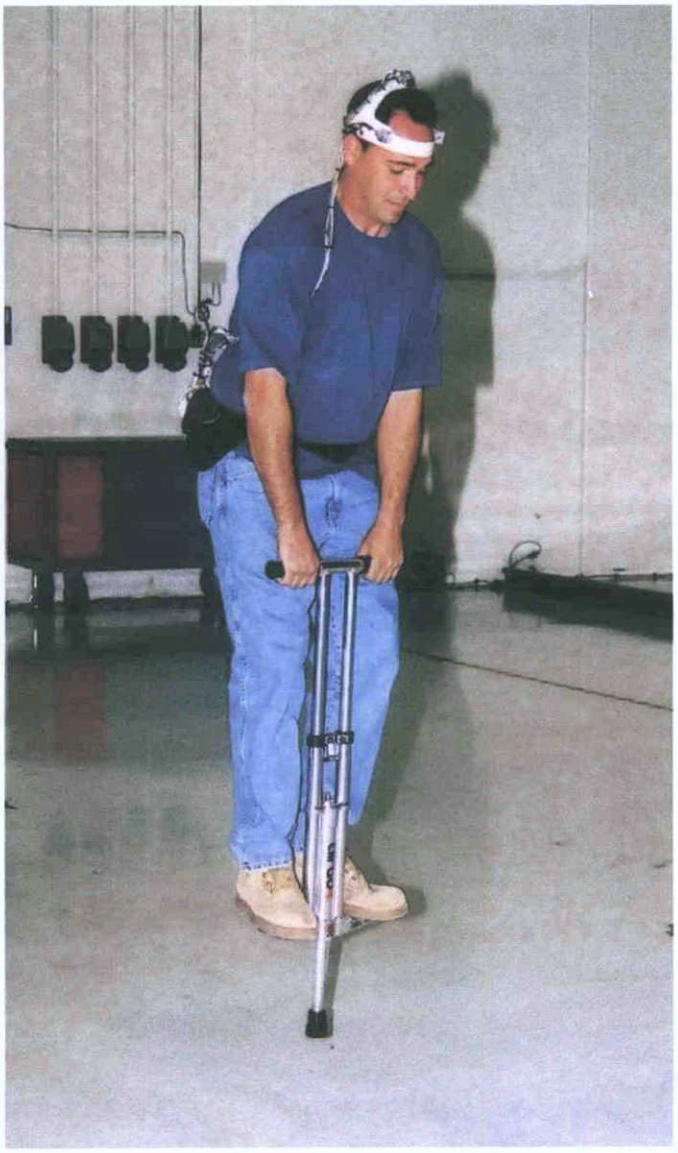

Figure 4.5 Photograph of subject on pogo stick.

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4.2.7 Tire Spin Task

A commercial playground tire swing was attached at three points so that the opening of the tire was in the vertical direction. The tire was suspended from a crossbar 15 feet off the ground. The tire was pre-wound 25 turns before subjects were seated on the tire. Subjects used a ladder to climb onto the tire so that their body was centered in the opening of the tire. Subjects were instructed to select an upper body position that was comfortable and try to maintain that position during the entire test. The test subjects usually selected a position that put their torso at a forty-five degree angle relative to the vertical axis. The data acquisition system was triggered and the subject was released. No additional rotational input was provided. During the 30 seconds of data acquisition, the tire spun completely down and began to wind back up. The tire rotation speeds reached a maximum speed of approximately 60 rpm.

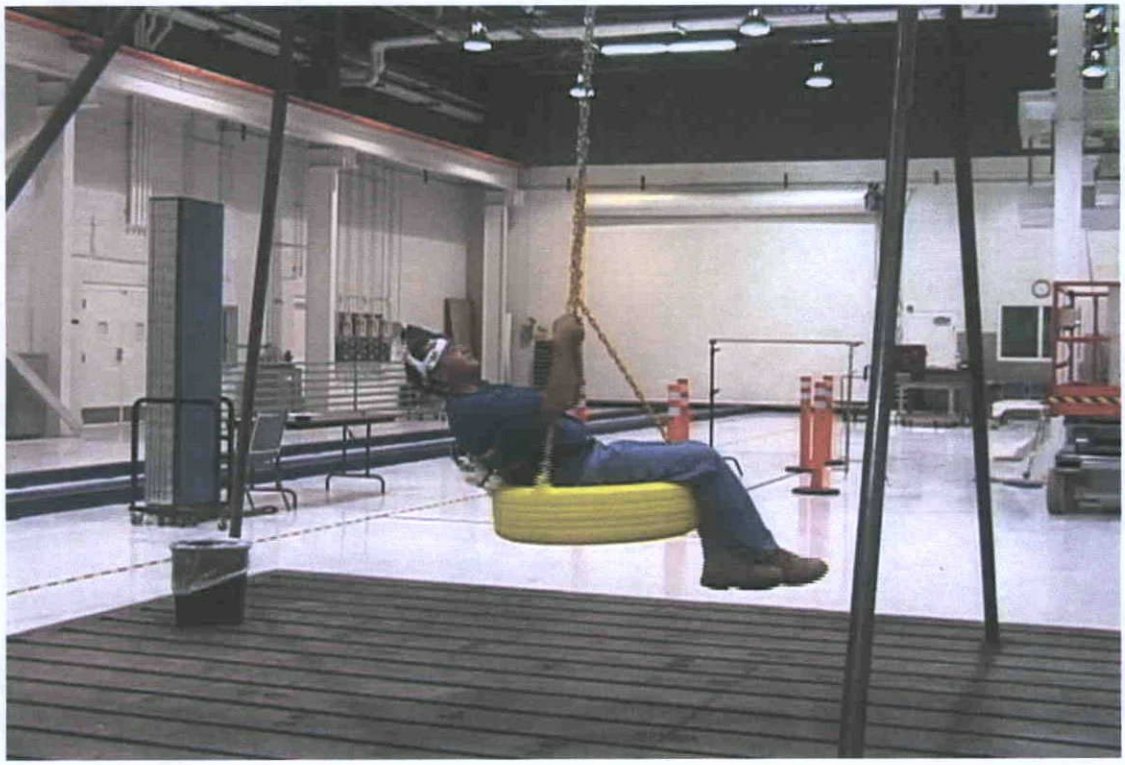

Figure 4.6 Photograph of subject at beginning of tire swing spin task.

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4.3 Test Subjects

Nine subjects were selected from the local area to represent a range of human sizes and ages. Each subject was informed of the activities and signed a special consent form to participate. Table 4.2 describes the test subjects. The size is an approximation of the percentile classification. The weight of each subject includes the 8-pound instrumentation package.

Table 4.2 Height and weight information for test subjects.

Gender	Size %	Age	Weight (lbs)	Height (in)	S-height (in)
M	90th	28	203	71.0	35.7
M	50th	39	185	69.3	35.9
M	95th	40	228	72.6	37.8
F	5th	38	132	60.6	33.0
F	50th	39	147	66.3	33.5
M	95th	17	178	73.6	38.2
F	95th	14	122	66.0	33.8
M	50th	15	188	69.9	35.2
M	95th	41	213	72.0	38.1

4.4 Test Procedure

Each subject was given clear instructions on each of the activities and testing requirements. The subjects completed a survey form, which was designed to capture brief information about medical history, life style, level of physical activities and risk taking behavior. In addition, all subjects signed the Informed Consent Form prepared for this purpose. All subjects were required to wear comfortable shoes and clothing. The subject was fitted with the head accelerometers and the data acquisition system before they were weighed and measured. Two still photographs, a frontal view and a side view of the standing subject, were obtained before the test. In addition to the still photographs, a video camera was used to record each activity.

4.5 Instrumentation and Data Acquisition

Test instrumentation consisted of three triaxial accelerometer blocks. Each block consisted of three Entran 25G calibrated accelerometers. The measurements at each location were in the longitudinal x-direction, the lateral y-direction and the vertical z-direction. The blocks were mounted on a tight fitting head form, which along with a section of the output signal wires weighed 0.5 pounds. Once placed on the subject's head the form was adjusted for a snug fit to prevent relative motion between the head and the

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accelerometers. A fitted head form will automatically place one block at the top of the head and one block at each of the right and left temples. The output signal cable was strain-relieved and connected to the data acquisition system.

The data was acquired with a Diversified Technical Systems TDAS2 data recorder using specialized software for setup, control and data transfer. The data acquisition frequency was 500 Hz. The data was processed using a 10 Hz digital filter. The data was filtered at this level to match the data provided by Six Flags for the roller coaster vehicles. HIC calculations were performed on data that was filtered at 100 HZ to match data provided by Six Flags for occupant head acceleration in their roller coaster rides, which made comparisons between the two tasks possible. The data acquisition system and its power supply, which weighed 8 pounds, were fitted onto a waist belt and worn by the subject during the tests.

4.6 Results

Data from all nine subjects and seven tasks were analyzed to determine peak accelerations and durations for all three axes. All measurements were made in relation to the head orientation not relative to the earth. The maximum values for peak accelerations and durations are displayed in Table 4.3 through Table 4.6. For some of the signals the peak acceleration did not occur at the same point as the signal with the longest durations. These tasks have duplicate rows to separately illustrate maximum peaks and durations. All accelerations along the z-axis have the normal 1G of acceleration caused by the earths gravity removed. For example the peak value generated for the pogo stick task was 3.0 Gs in the +z direction this is three additional Gs of acceleration so the total acceleration would be 4.0 Gs when the earths gravity is included.

Table 4.3 Maximum x-axis (forward-to-backward) accelerations.

Task	Duration (s)	Peak (Gs)
Swing	1.74	2.7
Obstacle Course	0.07	2.6
Obstacle Course	0.62	1.6
Sneeze	0.83	3.9
Falling Down	0.13	16.3
Pillow Strike	0.01	28.1
Pogo Stick	0.30	4.1
Spinning on a Tire Swing	26.18	1.7

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Table 4.4 Maximum y-axis (right-to-left) accelerations.

Task	Duration (s)	Peak (Gs)
Swing	-	-
Obstacle Course	0.29	2.6
Sneeze	0.63	1.6
Falling Down	0.10	4.2
Pillow Strike	0.01	11.0
Pogo Stick	0.36	1.3
Spinning on a Tire Swing	-	-

Table 4.5 Maximum +z-axis (head-to-toe) accelerations.

Task	Duration (s)	Peak (Gs)
Swing	2.74	1.4
Obstacle Course	0.04	2.3
Sneeze	0.95	2.5
Falling Down	0.03	8.4
Pillow Strike	0.02	14.6
Pogo Stick	0.48	3.0
Spinning on a Tire Swing	-	-

Note these data do not include the +1G from earth's gravity.

Table 4.6 Maximum -z-axis (toe-to-head) accelerations.

Task	Duration (s)	Peak (Gs)
Swing	0.81	0.7
Obstacle Course	0.03	5.5
Sneeze	0.11	1.0
Falling Down	0.02	7.3
Pillow Strike	0.01	14.7
Pogo Stick	0.19	4.5
Spinning on a Tire Swing	26.16	2.3

Note these data do not include the +1G from earth's gravity.

Data from four tasks -falling down, pogo stick, sneeze and pillow strike were analyzed with the NHTSA HIC analysis software. The results from the analysis are presented in Table 4.7.

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Table 4.7 Maximum HIC scores for falling down, pogo stick, sneeze and pillow strike to the head.

Task	HIC Score
Hit on the head with pillow	22.6
Falling down on exercise mat	15.2
Jumping on a pogo stick	1.3
Sneezing	0.5

4.7 Discussion

Based on comparing the data from these tests with those from subjects on roller coaster rides, the common activities generated accelerations that exceed the magnitude or duration of accelerations experienced by riders of roller coasters. The tasks that were examined in this study included activities that most people would consider very benign and safe for a normal person. The data showed that being hit on the head with a pillow was found to cause head accelerations as high as 11Gs in the y direction (side to side) and 14 Gs in the +z direction (head to toe). Being spun on a tire swing generated a peak acceleration of 2.3 Gs in the -z direction (toe to head), which was sustained for more than 25 seconds. A simple sneeze generated nearly 4 Gs in the x direction (front to back). The test activities did not approach maximum acceleration values that could have been generated for these tasks had the focus of the study been to determine the maximum values. This study does not address head impacts that occur every day without resulting in traumatic cerebrovascular injuries, such as those occurring when people bump their heads on cupboards, tables, or other hard objects.

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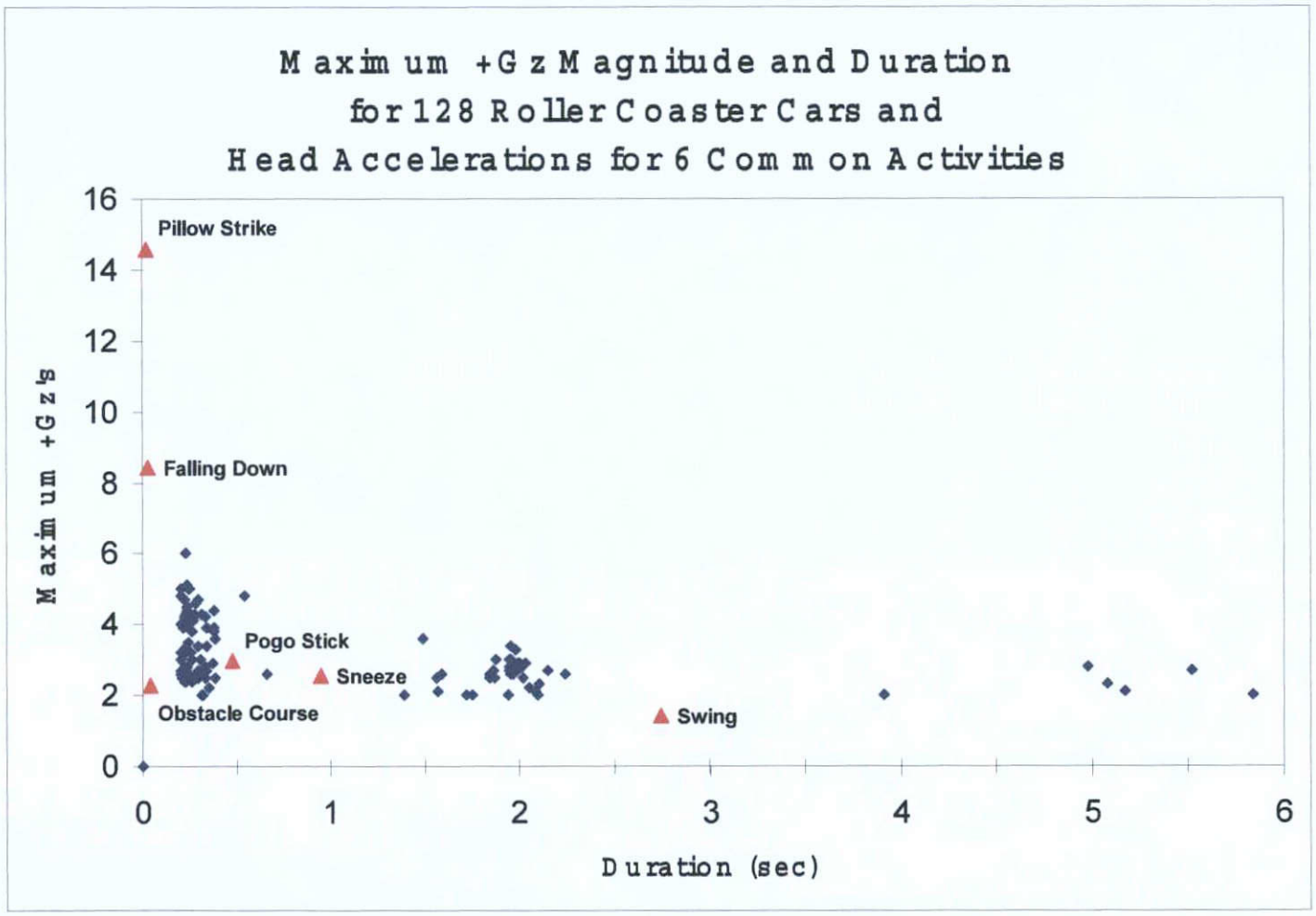

Figure 4.7 Plot of maximum +Gz accelerations for 128 roller coaster cars and head accelerations for six common activities.

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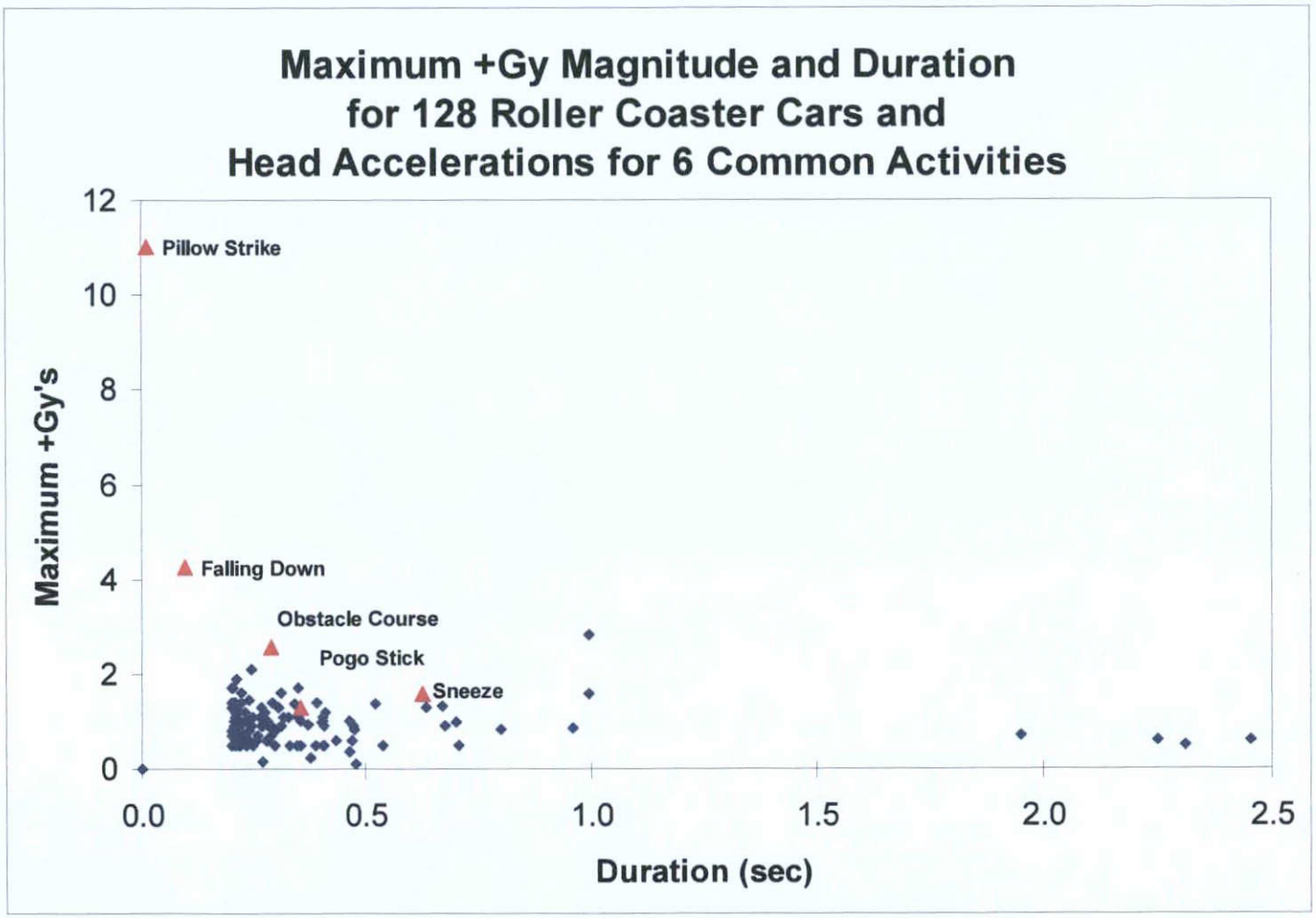

Figure 4.8 Plot of maximum +Gy accelerations for 128 roller coaster cars and head accelerations for six common activities.

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5 Use of CPSC NEISS Data for Assessing Amusement Park Ride-Related Injuries

5.1 Background

This section describes U.S. Consumer Product Safety Commission (CPSC) data on hospital emergency room-treated injuries involving amusement rides and comments on some of the limitations of its use. Injury data are presented for calendar years 1993 through 2001. This section provides updated data to previous CPSC reports summarizing amusement ride incidents by adding totals for 2001 and discusses conclusions published by CPSC comparing data from 1993-1996 to data collected from 1997-present.

The Consumer Product Safety Act of 1972 included the following text

> (1) The term "consumer product" means any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term does not include...
>
> Such a term includes any mechanical device which carries or conveys passengers along, around, or over a fixed or restricted route within a defined area for the purpose of giving its passengers amusement, which is customarily controlled or directed by an individual who is employed for that purpose and who is not a consumer with respect to that device, and **which is not permanently fixed to a site** [emphasis added].

Fixed-site amusement rides are excluded from CPSC jurisdiction by Section 3 (a) (1). Nonetheless, injuries related to fixed-site amusement rides are collected by the CPSC under a product code, 1293 - Amusement Attractions, including rides. Data for injuries involving fixed site, mobile site and unspecified sites are not coded separately at the time of collection. The same product code is used to include fixed-site rides at Disneyland, mobile-site rides at state fairs, coin-operated rides outside of stores and restaurants, and mechanical bulls among others. This absence of separate codes for fixed and mobile sites means each record must be reviewed manually to separate the fixed from the mobile site rides before any analysis of amusement parks can be conducted.

5.2 CPSC Data Collection Process

CPSC uses several data collection methods to monitor the injuries associated with consumer products. One of those systems is the National Electronic Injury Surveillance System or NEISS. NEISS injury data are gathered from the emergency departments of 100 hospitals selected as a probability sample of all 5,300+ U.S. hospitals with

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emergency departments. The data collection process begins when a patient is admitted to the Emergency Department (ED) of a NEISS hospital. An ED staff member elicits information as to how the injury occurred and enters that information in the patient's medical record.

At the end of each day, a NEISS hospital coordinator reviews all ED records for the day, selecting those that meet the (current) criteria for inclusion in NEISS. The NEISS coordinator abstracts pertinent data from the selected ED record and transcribes it in coded form to a NEISS coding sheet using rules described in a NEISS Coding Manual.

For each injury record, the NEISS coordinator assigns a product code from an alphabetical listing of hundreds of products and recreational activities. If the ED record contains additional product detail, the coordinator includes that in a line or two of narrative text (e.g., injured on ride at amusement park). Patient age, gender, injury diagnosis, body parts affected, and incident locale are among other data variables coded. The data are uploaded to the CPSC office in Washington D.C. and after undergoing a second computer editing process, acceptable cases are automatically incorporated into the Commission's permanent NEISS database.

5.3 Selecting Hospitals for NEISS

The NEISS sample of hospitals is periodically redesigned to update and improve the sample and thereby maintain the validity of injury estimates. This is necessary because, over time, new hospital emergency departments open, others close, while still others change significantly in size (as measured by the number of ED visits).

NEISS sampling statisticians have provided a systematic means for updating the sample of hospitals while retaining the basic sampling plan. In order to minimize the statistical variance while ensuring an adequate geographic distribution, the sampling frame is stratified by hospital size and ordered by geographic location.

In 1997, CPSC updated the NEISS sample to reflect the distribution of U.S. hospitals with emergency departments. The current NEISS sample includes 100 hospitals grouped into five strata, four representing hospital emergency departments of differing sizes and a fifth representing emergency departments from children's hospitals.

The CPSC states in their sample update publication **"Data users should carefully consider the likely impact of system updates and modifications, especially when comparing estimated injuries over time."**

The CPSC uses a specific method to examine the effects of sample redesign. A subset of the sample hospitals belonging to the pre and post redesign sample are used to measure the effect of the sample redesign by calculating the total estimated injuries before and after the sample change and calculating the percent change for individual products and for the database as a whole.

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5.4 Effects of Sample Design Changes on Amusement Park Injury Estimates

The sampling stratification used to select hospitals for NEISS provides reasonable estimates of injuries for consumer products that are somewhat uniformly distributed throughout the United States. For activities such as visiting amusement parks, the distribution of hospitals is not designed to correspond with the distribution of amusement parks. The national estimate of amusement park ride injuries for any given year will be in error because of the mis-match in the distributions. In addition when the sample of hospitals is changed, the method used for most consumer products to assess the changes in national estimates due to changes in the sampling distribution will not be accurate when applied to amusement parks. The estimates from each sample of hospitals are impacted differently as the number of hospitals within close proximity to large theme parks changes.

When the NEISS sample design changed in 1997, a total of 21 hospitals were dropped and 36 hospitals were added to the database. Exponent conducted a search for amusement parks with at least one roller coaster within 20 miles of the sample hospitals that were added and those that were dropped. For the hospitals that were dropped, there were 29 fixed-site amusement parks within 20 miles of the hospitals. For the hospitals that were added, there were 37 parks with at least one roller coaster within 20 miles.

The added hospitals had numerous, very large amusement parks that were not close to sample hospitals dropped from the earlier sample. These parks include Disneyland, Disney's California Adventure, Knott's Berry Farm, Universal Studios Hollywood, Six Flags Great Adventure, Six Flags Over Texas, Six Flags Elitch Gardens, and several in Las Vegas, including MGM Grand Adventures, and New York - New York, NASCAR Café, and the Stratosphere Tower.

There were only two parks with attendance that ranked in the top 50, according to Amusement Business magazine, within 20 miles of the hospitals that were dropped from the 1996 sample. They were ValleyFair! and the State Fair of Texas. The total attendance for these two parks in 1996 was 4,758,749. There were ten parks with attendance that ranked in the top 50 within 20 miles of the hospitals that were added to the 1997 sample. They were Wyandot Lake, Worlds of Fun, Universal Studios Hollywood, Six Flags Over Texas, Six Flags Great Adventure, Six Flags Elitch Gardens, Casino Pier, Lake Compounce, Knott's Berry Farm, and Disneyland. The total attendance for these ten parks in 1997 was 34,681,500. Between the hospitals eliminated and those added, the new sample of hospitals potentially provides services to 29,922,751 more visitors to fixed amusement parks. The increased attendance at these added parks increases the likelihood that amusement park injuries will be included in the sample, which in turn increases the national estimate of injuries even if there were no actual increase in such incidents nationwide. Further, the addition of these fixed site parks will disproportionately increase the distribution of fixed site injuries within the sample, while mobile site injuries will remain the same. The data for the years covered by each sample set can be used to examine trends in amusement park attraction associated injuries; however, trends cannot be established using injury estimates from different samples.

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One hospital, located within 10 miles of Disneyland and Knott's Berry Farm, had an average hospital weight from 1997-2000 of 67.4. These two parks have had an average annual attendance of 17 million patrons. This means that for every injury that is recorded at this hospital the national estimate will increase 67.4. The sanitization of the data by CPSC, which eliminates park names from the injury records, and removes hospital ID from data records, prevents a complete analysis of the effects of the hospital sample change in relationship to the proximity to very large theme parks.

5.5 Amusement Ride-Related Injuries

Through a Freedom of Information Act request, Exponent obtained the CPSC NEISS data on amusement attractions, including rides (product code 1293). NEISS records were analyzed for calendar years 1990 through 2001. Applying the coding scheme developed by the CPSC and using the narrative comments in the records, each case was classified into 1 of 5 mutually exclusive and exhaustive categories: not a ride (out of scope), fixed-site ride, mobile-site ride, unknown-site ride, or unknown if ride. Cases involving coin-operated rides or free-play attractions often found at restaurants or shopping centers, dunk tanks, alpine and water slide amusements, wave machines, "moon walks," inflatable slides, mechanical bulls, playground equipment, etc., are examples of cases coded not a ride. Cases involving roller coasters or "whirling" rides are examples of cases coded fixed-site, mobile-site, or unknown-site ride: if the case narrative stated the name of an amusement park or that the incident occurred at a park or involved an amusement park ride, then the case was coded fixed-site, some park names were not deleted from the records; if the narrative stated that the incident occurred at a carnival, fair, or festival, then the case was coded mobile-site; if the narrative gave no site information, then the case was coded unknown-site. Cases with comments such as "Fell on ride at ***." were coded by Exponent as unknown-site. The CPSC would have the advantage of knowing what information was redacted. Cases involving a "merry go round," with no indication of whether it was playground equipment or an amusement ride as defined by the Consumer Product Safety Act, are examples of cases coded unknown if ride.

The coding process attempted to duplicate the methodology followed by the CPSC. However, due to the CPSC policy of "sanitizing" the narrative comments by redacting any reference to a ride name, park name or retail location, there were differences between totals calculated by Exponent and the CPSC. The data sanitization policy makes determining the type of attraction more difficult for non-government researchers using publicly available data. Due to the removal of ride and park identification information, coding by Exponent resulted in much higher numbers of unknown-site records for each of the years. For this reason the remainder of the report uses data published by the CPSC for the years 1997-2000 and adds the data analyzed by Exponent for 2001.

Table 5.1 displays national estimates of hospital emergency room-treated injuries related to amusement rides by year. Unknown-site injuries were allocated to fixed-site and mobile-site estimates in the proportions observed in known-site estimates each year. For example, the fixed-site estimate for 2001 is 0.59 of the sum of the fixed-site and mobile-site estimates, so 0.59 of the unknown-site estimate for 2001 is added to the fixed-site estimate, and 0.41 of the unknown-site estimate for 2001 is added to the mobile-site

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estimate. Exponent estimated a total of 9,035 hospital emergency room-treated injuries occurred in 2001 for all amusement attractions. Figure 5.1 displays the NEISS estimates presented graphically in Table 5.1.

Table 5.1 National estimates for fixed-site, mobile-site and total injuries associated with amusement attractions.

Year	Fixed	Mobile	Total
1997	5,353	2,562	7,915
1998	6,523	2,751	9,274
1999	7,629	2,788	10,417
2000	6,594	3,985	10,580
2001	5,335	3,700	9,035

Numbers may not sum to totals due to rounding.

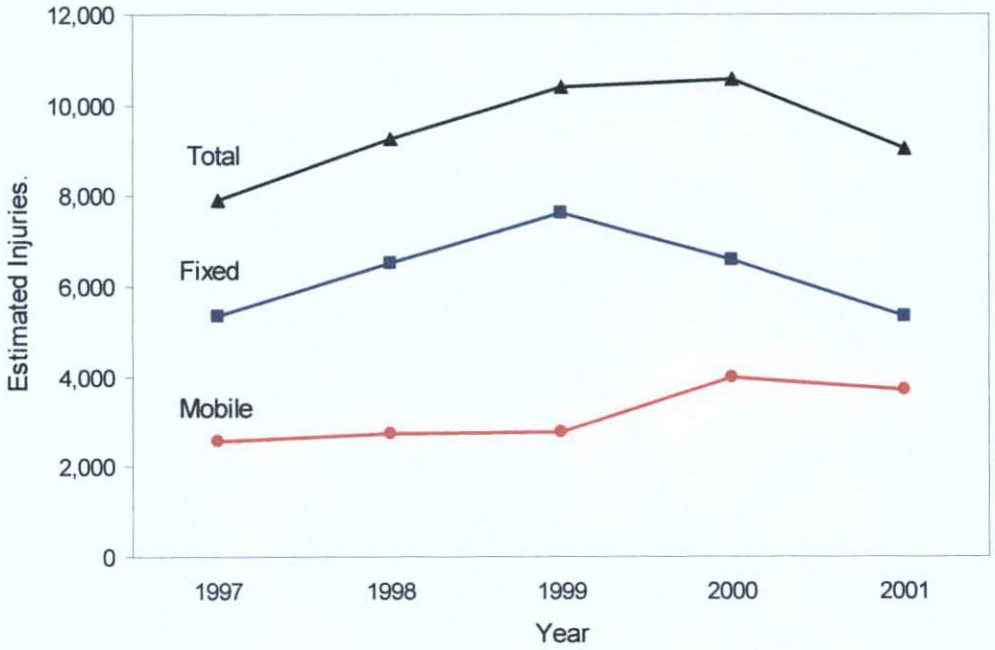

Figure 5.1 National estimate of fixed-site, mobile-site and total injuries associated with amusement attractions.

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Table 5.2 Risk of injury per million park attendees.

Year	National Attendance (millions)	Risk of injury per Million Park Attendees
1997	300	17.8
1998	300	21.7
1999	309	24.7
2000	317	20.8
2001	319	16.7

Table 5.2 displays the fixed-site injury risk from 1997-2001. Linear regression analysis of fixed-site, and total injuries showed no statistically significant trend for the years 1997-2001. Mobile-site injuries showed a marginally significant increasing trend (p=0.057) for the years of 1997-2001. Linear regression analysis of the injury risk associated with fixed-site attractions showed no statistically significant trend.

It should also be noted that a single accident at Bullwinkle's Family Fun Center, in Medford, N.Y. on June 23, 2001, where a swing ride tipped over, caused injuries to 12 people (reported by USA Today). There were 10 injury records, on the date of the accident in the NEISS data that mentioned Bullwinkle's and this incident specifically. These ten records cause the national estimate of injuries to increase by 771 injuries. This single accident accounts for approximately 8% of the national estimate and 14% of the fixed site injuries.

5.6 Discussion

Analysis of the proximity of parks to NEISS sample hospitals before and after the 1997 sample redesign, revealed that some hospitals within 20 miles of major fixed site theme parks were deleted while others were added to the sample. The sample changes resulted in a net increase of 7 parks, within 20 miles of a sample hospital, having attendance in the top 50 for theme parks in the U.S. There is a net attendance increase of more than 29 million park attendees in the communities served by hospitals in the redesigned sample of 1997. Analysis of trends in amusement park injuries was limited to the years 1997 and later. Based on Exponent's analysis, the NEISS data indicate a total number of estimated injuries for the calendar year 2001 of about 9,035 emergency room-treated amusement ride-related injuries, with about 5,335 involving fixed-site rides and 3,700 involving mobile site rides. Fixed site injuries dropped 19% and total injuries dropped 15% from 2000. There were an estimated 16.7 injuries per million patrons at fixed-site parks. From 1997 through 2001, there were no statistically significant increases in fixed site injuries or total injuries. Further there was no significant trend in the risk of fixed-site injury defined as injuries per million patrons at amusement parks.

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6 Patterns and Risk of Injury at Six Flags Parks

6.1 Background

First-aide-station incident data from five Six Flags parks were analyzed for patterns in injury type and severity. The Six Flags parks were: 1) Great Adventure, New Jersey, 2) Great America, Chicago, 3) Six Flags over St. Louis, 4) Magic Mountain, Los Angeles and 5) AstroWorld in Houston. The attendance at the five parks in the sample represented an average of 25% of the attendance in all Six Flags parks over the three years examined.

The Six Flags first-aide-station data include all patrons who requested assistance at the in-park first-aide stations. Only injuries associated with park attractions were recorded. Injuries associated with water park rides or waiting in line were excluded from the analysis. Six Flags also supplied park attendance and roller coaster ridership data for the same parks. These data were used to evaluate the risk of injury for all park patrons and for roller coaster riders. Attendance numbers and first-aide-station injuries are presented in Table 6.1 and Table 6.2. Table 6.3 presents the number of each type of injury complaint by year.

Table 6.1 Attendance and sample percentage for analyzed parks and all Six Flags parks.

	1999	2000	2001	Total
AstroWorld		1,576,302	1,525,452	3,101,754
Great Adventure	3,781,848	3,236,246	3,434,911	10,453,005
Great America		2,681,774	2,685,048	5,366,822
Magic Mountain	3,127,117	3,276,157	3,011,463	9,414,737
Six Flags Over St. Louis		1,789,022	1,601,516	3,390,538
Sample Total	6,908,965	12,559,501	12,258,390	31,726,856
All Six Flags Park Attendance	41,386,000	40,884,000	42,350,000	124,620,000
Sample Percentage	17%	31%	29%	25%

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Table 6.2 Counts of all reported first-aide station treated injuries for five Six Flags parks by year.

Park	1999	2000	2001
AstroWorld	*	326	256
Great Adventure	168	279	260
Great America	*	412	432
Magic Mountain	345	459	396
Six Flags Over St. Louis	*	323	242

*Data not available

6.2 Patterns of Injury

Each park recorded injury data in a slightly different format. Data from AstroWorld, Magic Mountain, and Six Flags Over St. Louis contained narrative comments for each record, which provided additional information about the type and cause of the injury. Each of the parks varied in the categories used to classify an injury complaint. Exponent recoded the data applying consistent definitions of categories across the complaint injury data from the different parks. For example, records coded as swelling or bruising were combined into the hematoma category. The count of first-aide-station records from the five parks by complaint type and year as well as the total number and percent of each category of injury complaint across the three-year period are shown in Table 6.3.

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Table 6.3 Total count of first-aide station records by complaint type and year.

Injury Complaint	1999*	2000	2001	Total	Percent of Total Injuries
Contusions, Abrasions	112	587	468	1,167	29.9
Strain or Sprain	105	327	316	748	19.2
General Aches and Pain	122	321	279	722	18.5
Laceration	40	212	205	457	11.7
Unspecified Aches and Pains	63	44	67	174	4.5
Foreign Body	10	62	43	115	3.0
Nausea or Dizziness	5	30	28	63	1.6
Dental Injury	9	24	21	54	1.4
Hematoma	7	24	11	42	1.1
Unknown	10	25	7	42	1.1
Insect Bite or Sting	8	14	18	40	1.0
Nose Bleed	1	22	13	36	0.9
Syncope	2	11	22	35	0.9
Other	3	18	12	33	0.8
Headache		13	18	31	0.8
Avulsion	4	14	11	29	0.7
Burns, Not Specified	7	15	4	26	0.7
Dermatitis, Conjunctivitis	1	8	16	25	0.6
Dislocation	2	10	6	18	0.5
Fracture		9	4	13	0.3
Seizure	2	2	5	9	0.2
Abdominal Pain		3	6	9	0.2
Blister		3	4	7	0.2
Ear Ache		1	1	2	0.05
Hemorrhage			1	1	0.03
Total	513	1,799	1,586	3,898	-

*1999 data from two parks only

6.2.1 Injury Severity – Treated and Transported

With the exception of one park, AstroWorld, data included information about the disposition of patrons after they left the first-aide station. Injuries were categorized as to whether a patron returned to the park or went home, was transported to hospital or medical clinic, returned to work, or unknown. Table 6.4 presents the injury complaint totals by disposition. Table 6.5 displays the distribution of injuries with known dispositions for the four parks. Overall, of those park visitors who seek treatment at a first aid station, 93% have injuries that can be treated at the park without the need or desire for transport to some other medical facility.

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Table 6.4 Injury counts by disposition for four Six Flags parks.

Disposition	1999	2000	2001	Total
Returned to Park or Went Home	473	1,368	1,219	3,060
Transported to Hospital or Clinic	34	79	98	211
Unknown	6	26	13	45
Total	513	1,473	1,330	3,316

Table 6.5 Distribution of injuries with known dispositions.

Disposition	1999	2000	2001	Total
Park or Home	93%	95%	93%	94%
Transported	7%	5%	7%	6%

6.2.2 Injury Severity – Hospitalized

Each Six Flags park has a preferred hospital to which it transports patrons who desire additional medical treatment beyond that provided at first-aide stations. Six Flags Great Adventure used Centra State Hospital in New Jersey as its preferred provider. The Centra State Hospital was also one of the hospitals in the CPSC NEISS sample for the years 1990 through 2000. For 1992 through 2000, all injury complaint records for Great Adventure that indicated transport of a patron to a medical facility were compared to the data in the NEISS system. To the extent possible, the records were matched on accident date, gender, body part, injury diagnosis and information available in the narrative comment field of the NEISS data. Results are displayed in Table 6.6. Individual records in NEISS do not report identification information that links them to a specific hospital in the sample. It was not possible, therefore, to examine NEISS records specifically for Centra State Hospital to determine if there were instances in which an amusement park related injury in the NEISS data was not in the first-aide-station data of the park.

Table 6.6 Total injury counts with distributed unmatched records for Great Adventure transported patrons compared with records in the CPSC NEISS data, 1992-2000.

NEISS Disposition	Transported Injuries With Distributed Unmatched Records	Risk/Million Attendees
Treated and Released	67	2.13
Hospitalized	4	0.13
Total Transports	71	2.26

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Fifty-two of 71 first-aide station complaints at Six Flags Great Adventure involving transport to a medical facility were found to match records in the CPSC NEISS data. Of the 52 matching records, only three records indicated that the injury required an admission to the hospital. The three injuries were a broken thumb, a broken leg and a broken arm.

To adjust the estimate of the total number of hospitalized injuries for the unmatched records, a portion of the unmatched records was assigned to the hospitalized category based on the distribution of those for which dispositions were known. After redistributing the unknowns, it is estimated that from 1992 through 2000 a total of 67 transported patrons were treated and released and four patrons were required to stay overnight. Table 6.6 displays the totals with the unmatched records distributed on the basis of the matched records. Approximately, 5.8% of all transported patrons had injuries severe enough that they required an overnight stay at the hospital.

Six Flags Great Adventure had a total attendance of 31,357,588 patrons for the years 1992-2000. Using the injury counts after adjustment for unknowns, the transported injury rates were calculated to be 2.13 hospital emergency room treated and released injuries per million park attendees and 0.13 hospital-admitted patrons per million park attendees. This represents one injury requiring admission to a hospital per 7.7 million park attendees at Six Flags Great Adventure from 1992-2000.

6.3 Risk of Injury Associated with All Park Attractions

Using the total number of first-aide station complaints and the number of transported patrons injury risk can be calculated per million park patrons. Further, using the hospitalization rate information gained from matching the data from Great Adventure to the NEISS data the other parks can be analyzed to calculate a risk of serious injury requiring an overnight stay at the hospital. Table 6.7 displays attendance, injury totals and risks by disposition. There were an estimated seven transported-to-medical-facility injuries per million park patrons and one hospitalized injury per 2.6 million park patrons. The likelihood of a severe injury at an amusement park is very low.

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Table 6.7 Injury totals and rates for all park locations, all risk values reported per million park attendees.

Park	Total Park Attendance	Injury Complaints		Transported Patrons		Hospitalized Patrons[a]	
		Number	Risk	Number	Risk	Number	Risk
AstroWorld	3,101,754	582	188	*	*	*	*
Great Adventure	10,453,005	707	68	52	5	3.0	0.29
Great America	5,366,822	844	157	50	9	2.9	0.54
Magic Mountain	9,414,737	1,200	127	62	7	3.6	0.38
Six Flags Over St. Louis	3,390,538	565	167	50	15	2.9	0.85
Total	31,726,856	3,898	123	214	7[b]	12.4	0.43[b]

* Data could not be calculated because disposition data was not recorded at AstroWorld. All figures rounded after calculation

[a] Estimates calculated as 5.8% of all transported injuries. Rate calculated from analysis of nine years of Six Flags Great Adventure transported injuries. All figures rounded after calculation

[b] Risk calculations for transported and hospitalized patrons excludes park attendance data from AstroWorld.

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6.4 Risk of Injury Associated with Roller Coasters

An analysis was conducted of the injuries associated only with roller coasters, excluding kiddie coasters. Based on information available in the first-aide-station injury reports from the sample of five Six Flags parks, records were identified in which the injury was associated with a roller coaster. Within the category for roller coasters, injuries were further separated as to disposition (e.g., transported, returned to park). It was not possible to estimate the number of hospitalized injuries related to roller coasters. Roller coaster ridership information was provided by Six Flags for each park and year. The total rides for each roller coaster at each park were used to calculate a risk of injury per million rides. Table 6.9 displays the risk of a first-aide-station treated injury for roller coasters and the risk of a transported injury per million roller coaster rides.

Approximately 57% of injuries seen at first-aide-stations were related to roller coaster rides. The type and disposition of injuries associated with roller coasters is similar to all park injuries. Table 6.9 displays the number of roller coaster first-aide station complaints and the percentage of the total roller coaster injuries by injury type. The percentage of injuries transported to other medical facilities was the same for roller coaster related injuries (6%) as for all park injuries. Given that an injury occurs, roller coaster related injuries are no more likely to involve transport to a medical facility than those for non-roller coaster activities. There were an estimated 19 first-aide-station complaints and one transported-to-medical-facility injury per million roller coaster rides. The likelihood of injury involving roller coasters at Six Flags parks is very low.

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Table 6.8 Distribution of injury complaint types associated with roller coasters for five parks (approximately 118 million roller coaster rides).

Diagnosis	First-Aide Station Complaints Associated With Roller Coasters	Percent of Total First-Aide Station Complaints Associated with Roller Coasters
Strain or Sprain	546	24.6
Contusions, Abrasions	511	23.0
General Aches and Pain	417	18.8
Laceration	209	9.4
Unspecified Aches and Pains	135	6.1
Foreign Body	95	4.3
Nausea or Dizziness	46	2.1
Insect Bite or Sting	35	1.6
Syncope	27	1.2
Dental Injury	25	1.1
Hematoma	23	1.0
Headache	23	1.0
Nose Bleed	21	0.9
Unknown	20	0.9
Other	20	0.9
Dermatitis, Conjunctivitis	16	0.7
Avulsion	13	0.6
Dislocation	13	0.6
Seizure	8	0.4
Fracture	7	0.3
Abdominal Pain	5	0.2
Ear Ache	2	0.1
Blister	1	0.05
Hemorrhage	1	0.05
Total	2,219	100.00

Figures rounded after calculation.

Table 6.9 Injury counts and rates for roller coasters riders, all rates reported per million roller coaster rides.

Park	Roller Coaster Rides	Roller Coaster Injuries		Transported Roller Coaster Injuries	
		Number	Risk	Number	Risk
AstroWorld	8,405,009	299	36	*	*
Great Adventure	27,847,384	331	12	22	0.8
Great America	20,101,940	429	21	27	1.3
Magic Mountain	50,847,522	847	17	35	0.7
Six Flags Over St. Louis	10,911,128	313	29	31	2.8
Total	118,112,983	2,219	19	115[b]	1.0[b]

* Data could not be calculated because disposition data was not recorded at AstroWorld. All figures rounded after calculation.

[b] Risk calculations for transported and hospitalized patrons excludes roller coaster ride data from AstroWorld.

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6.5 Discussion

This series of analyses shows that the majority of injuries occurring at a sample of Six Flags parks are minor in nature in that they can be treated at the park first aide station. The types of injuries were primarily strains, sprains, and general aches and pains, contusions and abrasions. Further, 94% of all those treated at the first-aide stations continued their visit to the park or went home on their own.

CPSC publishes annual reports on injuries in fixed amusement parks using data from a sample of hospital emergency rooms throughout the United States. Estimates in the report indicate that approximately 2% of those treated in hospital emergency rooms for fixed-ride amusement parks are hospitalized. Based on nine years of data from Six Flags Great Adventure, we estimated that 5.8% of all transported injuries required an overnight stay. The difference in the rates may in part be due to patrons with minor injuries choosing to travel to a hospital or medical clinic on their own without notifying the Six Flags first-aide stations. Patrons with non-severe injuries not wishing to travel by ambulance after reporting to a first-aide station may also travel to the hospital or medical clinic on their own. These two practices would raise the percentage of hospitalized injuries in the first-aide station transported data. Exponent used the larger of these two percentages to estimate the number of hospitalized injuries for the four Six Flags parks included in this study. These data were then used to calculate rates of injuries per million park attendees. The injury rates at these parks and on roller coasters are extremely low. The analysis indicated that there was only one transported injury per million roller coaster rides.

The different sources of data (e.g., first-aide stations, hospital emergency rooms) and the different samples (e.g., national sample of hospitals, Six Flags parks) produce slightly different estimates of the risk of injury. The two sources are consistent with one another, however, in portraying the activity of attending a Six Flags amusement park as well as amusement parks nationwide as posing a low risk of injury. Riding roller coasters is also associated with a very low injury risk.

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APPENDIX 8

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Main Article

Long-term complications of bone-anchored hearing aids: a 14-year experience

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Abstract

Objectives: To report cases of long-term surgical complications, implant failure and revision surgery, within a large bone-anchored hearing aid programme.

Study design: Retrospective, case–cohort study.

Setting: Tertiary referral centre.

Patients: One hundred and sixty-five adults and children who had undergone a total of 177 bone-anchored hearing aid implantations.

Intervention: Diagnosis and explanation of adverse events and device failure.

Main outcome measures: Operative complications and survival analysis, surgical challenges related to revisions, and causes of failure.

Results: Twenty-one per cent of patients (3.4 per cent of those observed) suffered from skin reactions; this rate did not increase over time. Seventeen per cent had loss of osseointegration at a median interval of 6.3 months. Loss of osseointegration was observed more frequently in patients with a 3 mm compared with a 4 mm fixture ($p < 0.001$). Intra-operatively, the only complication was bleeding, occurring in 3 per cent of patients. Post-operative complications included: primary bleeding (2 per cent); severe skin reactions requiring intravenous antibiotics, cautery or grafting (8 per cent); thickening or overgrowth of skin requiring excision (8 per cent); failure of osseointegration requiring a new fixture (18 per cent); and graft necrosis requiring revision (1 per cent). In two patients, it was necessary to explore the area to remove overgrowth of bone. In 16 patients (10 per cent), the bone-anchored hearing aid had to be abandoned due to failure of osseointegration ($n = 4$), dissatisfaction with the aid ($n = 6$), intolerable pain ($n = 4$), hair growth around the abutment ($n = 1$) or recurrent infections ($n = 1$). In 12 of these patients, the bone-anchored hearing aid was removed surgically. Overall, 57 patients (34 per cent) underwent revision surgery.

Conclusion: Awareness of complications is becoming increasingly important in bone-anchored hearing aid programme. A substantial workload of device maintenance should be anticipated, and patients should be appropriately counselled beforehand. Ninety per cent of our patients chose to persevere with this form of hearing rehabilitation.

Key words: Implants and Prostheses; Hearing Aids; Deafness; Complications

Introduction

The principle of titanium implants within human bone originated from dental work (i.e. the 1966 Branemark implant system) and has shown long-term success.[1] In order to maintain good osseointegration (bonding) between the implant and the bone, it is of paramount importance to apply good basic clinical principles. This can be achieved through ensuring: gentle and meticulous technique during surgical installation; a direct connection between vital bone and titanium implants; the absence of interposed tissue between the fixture and the bone; an adequate period of healing; and proper distribution of stress over the implant.[1] It has been almost three decades since this technology was first applied to the temporal bone for the application of a bone-anchored hearing aid (BAHA) (in Gothenburg, Sweden, in 1977). In these initial procedures, a titanium screw was placed in the mastoid process and a transducer was attached to a skin-penetrating coupling. This allowed sound vibration to be transmitted to the cochlea via the implant and the skull bone, bypassing atresia or disease in the external and middle ear.[2–5]

The first official description of a BAHA was by Hakansson *et al.* (of Nobel Biocare, Gothenburg, Sweden) in 1985. This innovation in the rehabilitation

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of patients with impaired hearing had a high success rate initially.[2,6] The implantation of a screw directly into bone made it possible to obtain permanent, rigid, reaction-free penetration of the skin, without intervening soft tissues to attenuate sound transmission (especially in the high frequency range) or pain due to pressure and skin irritation, compared with conventional bone conduction hearing aids.[2–4,6–9]

The BAHA programme was established at the Countess of Chester Hospital in early 1991. Since then, this hospital has been the referral centre for the Merseyside region and parts of north Wales. We have experienced most of the early and late stages of this rapidly developing technique. The aim of this study was to evaluate the long-term results of osseointegration of BAHA implants in the mastoid process, with particular emphasis on the frequency and degree of adverse skin reactions close to the region of skin penetration.

Materials and methods

The case notes of all patients who had undergone BAHA insertion were retrospectively reviewed, and information regarding demographics, indication for surgery, previous hearing aids and audiograms was extracted. Any documented peri- or post-operative complication was recorded, and the total length of follow up was noted. Patients who had undergone fixture placement for an auricular prosthesis were excluded from the study.

The pure tone average (PTA) of the pre-operative bone conduction threshold in the operated ear was calculated at 0.5, 1.0, 2.0 and 4.0 kHz.

Results

We identified 167 patients who had undergone a total of 178 BAHA procedures between January 1991 and December 2004. Two patients who had been lost to follow up or had moved out of the geographical area soon after the operation were excluded from the study. There were 68 males and 97 females. The age of the patient at the time of operation ranged from four to 85 years, with a mean of 49.7 years and a median of 53.5 years. Twelve patients (two bilateral) were aged 16 years or under. Nine patients had a BAHA inserted on each side of their head at separate times (i.e. bilateral BAHA). Two patients had their BAHA changed from one side to the other. In most cases, the BAHA was fitted on the hearing side that had the best bone conduction thresholds; this was on the left side in 75 procedures and on the right side in 100 procedures.

Patients in this study underwent a BAHA fitting for the indications outlined in Table I.

One child and one adult with anotia had an abutment inserted alongside the fixtures for an artificial pinna, during the same operation. One hundred and five patients had undergone previous operations on the ear on the side in which the BAHA was inserted (Table II). The majority had undergone mastoid surgery for control of disease (90 per cent successfully) but were hearing aid users and could not maintain a dry cavity. Those who had undergone middle-ear surgery had associated otitis externa as the main indication for BAHA implantation, although one patient had persistent perforation. Patients who had undergone reconstruction of the external canal for hearing benefit or correction of a narrow canal (for chronic otitis externa) had restenosis. One patient had failed stapedectomy and required BAHA for unilateral sensorineural hearing loss (SNHL).

TABLE I

DIAGNOSIS OF 165 TREATED PATIENTS

Diagnosis	*n*	%
Chronic otitis media	112	64
Chronic otitis externa ± acquired stenosis	38	21
Congenital atresia	12	7
Single-sided neural deafness	4	2
Otosclerosis	5	3
Ossicular disease	2	1
Dissatisfaction with old hearing aid	3	2

The hearing loss in the operated ear was conductive on 55 occasions (54 patients), and mixed on 117 occasions (107 patients). A BAHA was fitted to a 'dead ear' on four occasions (four patients). In line with the original criteria for BAHA implantation,[3] most of our patients had a PTA threshold of 45 dB or better (Figure 1). Those with bone conduction better than 45 dB also fared well (11 patients had pre-operative bone conduction of 45–60 dB; only one abandoned their BAHA, due to persistent pain around the abutment). Six patients had a dead ear, four had unilateral SNHL, one had recurrent loss of osseointegration of a fixture originally fitted on the good hearing side, and one patient's audiologist recommended fitting another BAHA on the non-diseased deaf ear in order to increase spatial awareness.

Although most patients had used hearing aids previously, 15 had the BAHA as their first hearing aid (Table III). In the second half of this series, all patients had a two-month trial period with a bone conduction hearing aid prior to their BAHA fitting.

One hundred and sixty of the procedures were performed by a consultant (90 per cent) and the rest by specialist registrars. Due to technical reasons, we chose to perform the majority of procedures under general anaesthesia (83 per cent). The remainder was performed under local anaesthesia, at the patient's choice or due to unfitness for general

TABLE II

PATIENTS' PREVIOUS EAR SURGERY

Procedure	*n*
Mastoidecomy	78
Tympanoplasty or tympanotomy	18
Reconstruction of external canal*	7
Stapedectomy	1
Fenestration	1

*For congenital or acquired stenosis.

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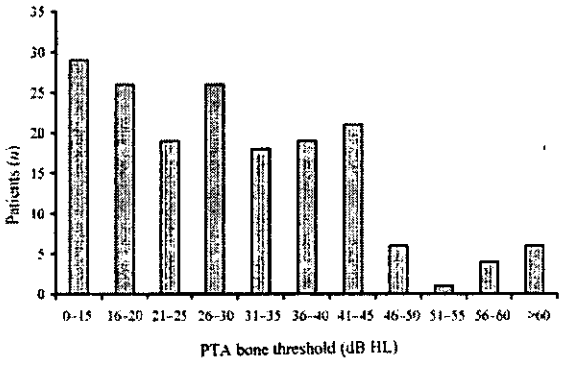

FIG. 1

Patients' pre-operative pure tone average bone conduction thresholds in the operated ear.

anaesthesia. However, this provided less operator control, particularly when drilling the bone. The majority of procedures ($n = 131$) were performed as day cases. In-patient stay was required when there were concerns over the patient's fitness or the distance of their home from the hospital. Three patients planned as day cases had to stay overnight because of bleeding.

The main problem encountered during the procedure was bleeding from the temporalis and sternocleidomastoid muscles. It was found that this was minimised if the muscles were divided with cutting diathermy. Bleeding from the bone occurred in five patients (3 per cent); this was controlled with bone wax to allow a further hole to be drilled in an adjacent site. In one case, there was a very small mastoid process and elevation of the sternocleidomastoid muscle resulted in incision of the internal jugular vein. This was sealed with a fibromuscular plug from the vastus lateralis and the operation was abandoned. The operation was subsequently completed with the placement of the fixture and the abutment somewhat more superiorly than usual. The dura was exposed on three occasions, but this did not prevent the insertion or the osseointegration of the flange fixtures.

Follow-up time ranged from three months to 161 months (13.4 years), with a mean of 50 months (4.2 years) and a median of 36 months (three years). The first post-operative visit was two weeks after the operation, at which the healing cap and sutures were removed and the condition of skin around the abutment was monitored. The next visit was around 2.5 months post-operatively, when the BAHA was attached. Patients were reviewed three months later (six months from the operation date) and thereafter at six-monthly intervals.

For 42 operations, incomplete healing of the graft was observed during the first follow-up visit. This was usually at the graft's anterior edge, as our flaps were posteriorly based. No treatment was required, and there was no delay to the provision of the hearing aid. However, partial failure of the graft was observed for three procedures; these grafts healed over within one month without further complication. In one case, there was total necrosis of the skin flap, which was closed by a rotation flap. This healed by primary intention and did not delay the provision of the hearing aid.

We recorded skin reactions around the abutment, using the system first described by Holgers *et al.*[10] Only symptomatic skin reactions were recorded (i.e. skin reaction type two or worse). Seventy-two per cent of our patients did not experience any symptomatic skin reactions. Skin reactions were categorised as early (i.e. within one year post-operatively), intermediate (one to three years) or late (more than three years). The majority of skin reactions tended to occur early (37/624 observations); of these, type two reactions were the commonest (26/37, 70 per cent). Skin reactions were less likely to occur as time progressed (intermediate reactions were noted in 12/403 observations (3.0 per cent) and late reactions in 12/646 observations (1.9 per cent)). Type two skin reactions were managed with local ointments and oral antibiotics. Type three skin reactions were observed in 11 patients, and were managed with silver nitrate cautery to the granulations in five cases; however, in six patients, granulation tissue was excised under general anaesthesia, followed by grafting in three patients. Two patients were admitted to hospital for intravenous antibiotic treatment due to severe infection of granulations. Type four skin reactions were observed in three patients during three clinic visits. Such a severe reaction necessitated temporary removal of the abutment. After one such experience, one patient decided to completely abandon their BAHA.

No BAHA complication showed an increasing rate of incidence with time.

Eighty-one per cent of patients did not suffer from loss of osseointegration at any stage (Figure 2). Loss of osseointegration occurred in 31 fixtures (24

TABLE III

PATIENTS' HEARING AID USAGE PRIOR TO BAHA

Aid type	Ears	
	n	%
Air conduction	93	53
Bone conduction	37	21
Air & bone conduction	11	7
None	15	9
Data unavailable	20	11

BAHA = bone-anchored hearing aid

TABLE IV

PERCENTAGE LOSS OF OSSEOINTEGRATION VERSUS PATIENT AGE

Reason	Occasions (*n*)
Poor sound quality	6
Pain at BAHA site	4
Loss of osseointegration	4
Recurrent infection	1
Uncontrolled hair growth	1

BAHA = bone-anchored hearing aid

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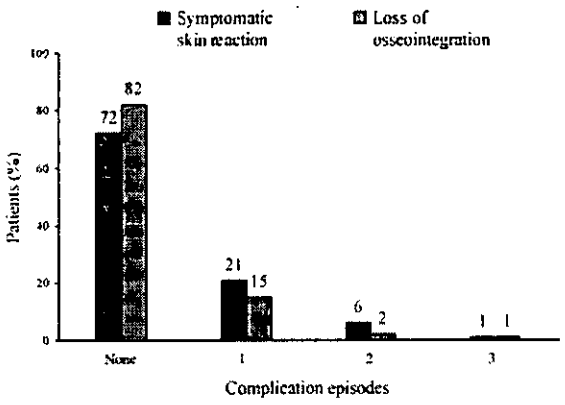

FIG. 2
Percentage of patients suffering episodes of complications.

spontaneous and seven traumatic cases), amounting to almost one-fifth of our population (18 per cent). Four patients decided to abandon their BAHA, while 27 patients requested reinsertion of the fixture (Table IV). Data for loss of osseointegration, stratified by age and fixture size, are shown in Table V. In total, the median interval from the time of operation to loss of osseointegration was 6.3 months.

The incidence of common complications (i.e. symptomatic skin reactions and loss of osseointegration) over the follow-up period is shown in Figure 2. There was no tendency for loss of osseointegration to increase with time. Loss of osseointegration did not increase with the age of the patient.

Thickening or overgrowth of skin and soft tissue around the abutment occurred in 15 patients, leading to an inability to fit the aid to the abutment. This required surgical removal of subcutaneous tissue. In two of these patients, there was also overgrowth of bone surrounding the flange fixture, which required removal of the excess bone by drilling.

Seven patients suffered persistent pain in the BAHA region. In four patients, removal of the abutment and the flange fixture was required.

In three patients, bleeding occurred within 24 hours of the operation, and in two cases the patient required admission. Recurrent bleeding around the abutment at a later date occurred in 23 cases. This was due to excessive rubbing of the area while cleaning, or due to the presence of loose, mobile skin.

TABLE V

FIXTURE FAILURE BY PATIENT AGE AND FIXTURE SIZE

Factor	Failed fixtures/total (n (%))
Patient age (yrs)	
<16	5/14 (36)
>16	26/162 (16)
Fixture size	
3	25/90 (28)
4	6/86 (7)

Yrs = years

Fifty-seven patients underwent a total of 73 revision operations (under general or local anaesthetic), as follows (some patients had more than one revision procedure): insertion of a new fixture after loss of osseointegration (29 patients, 34 procedures); removal of the abutment with or without the flange fixture (12 patients, 12 procedures); exploration of the abutment and excision of granulations or an abscess (four patients, six procedures); and removal of skin growth or soft tissue thickening around the abutment (14 patient, 21 procedures). Some of the patients in the last two groups required removal of bone and/or a skin graft.

The BAHA was abandoned in 16 patients (9.7 per cent). This occurred spontaneously following loss of osseointegration in four patients. The BAHA had to be removed in the remaining 12 patients.

Discussion

The introduction of the BAHA has enabled patients who cannot use conventional hearing aids to enjoy better hearing, due to the BAHA's safety, low incidence of complications and high efficacy in transmitting sound energy.[2–5]

In the earlier years of BAHA insertion procedures, surgeons were recommended to perform a two-stage procedure (described in detail elsewhere).[11] This technique was subsequently replaced with a one-stage procedure (described elsewhere),[2] which has been proved to be as effective.[12,13] In our series, the two-stage technique was applied in 17 procedures (17 patients), 83 per cent of which were performed before 1994. In the remaining 159 procedures (150 patients), a one-stage procedure was performed (two patients with bilateral BAHAs underwent both techniques).

In our early experience, we used a postauricular (Thiersch) graft for skin reconstruction at the BAHA site, as described by Tjellstrom.[12] Subsequently, we moved to using a split skin graft, harvested from the BAHA insertion area (using a hand-held dermatome), in a similar manner to that described later by Woolford *et al.*[14] As our experience developed, we began to use a local, split

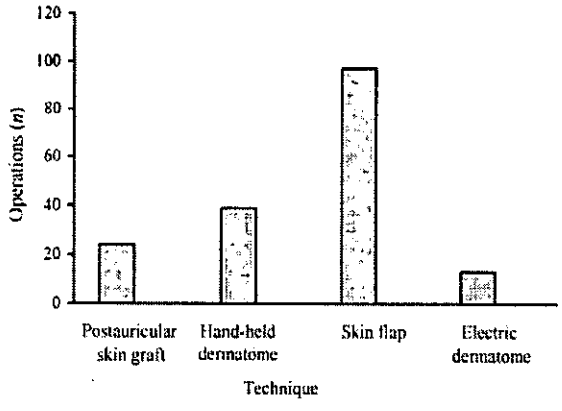

FIG. 3
Operative techniques used for bone-anchored hearing aid implantation.

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thickness skin flap technique, using a number 15 blade, which was becoming popular in the UK at that time (??, personal communication). More recently, the electric dermatome has been introduced in our department (Figure 3).

Previous reports comparing the original two-stage procedure with the more recent one-stage procedure concluded that the clinical results of the two techniques were statistically comparable.[11,13] Mylanus and Cremers showed that the frequency of adverse skin reactions following the two techniques was similar, 12 months after the operation.[13] Although the one-stage technique showed a higher incidence of early skin reactions (possibly due to early loading of the abutment), these authors mentioned that the results of this technique were encouraging as regards a reduced number of operations. However, they admitted that their follow-up time was too short to make a general statement about the possibility of replacing the two-stage technique.[13] We had exactly the same results in our first 12 months. However, after compiling data from a longer follow-up period, we observed that skin reactions in the two-stage procedure were more frequent four years after the operation, compared to a one-stage procedure (Figure 4). Although the significance of this finding is unclear (it should be noted that the number of patients under follow up (i.e. the denominator) declines with time in longitudinal studies, which magnifies the effect of those surviving in subsequent intervals (i.e. the numerator)), this finding generally supports the move towards a one-stage procedure. In our department, the one-stage technique was introduced in 1993, just two years after the BAHA programme was started.

The survival curves for the different techniques used for skin reconstruction are presented in Figure 4. For the two-stage technique, the initial results were good; however, deterioration tended to occur with time. Closure by skin graft resulted in fewer skin complications than skin flap closure. We also observed fewer skin reactions when the skin flap was raised using an electric dermatome, although the follow-up period was short.

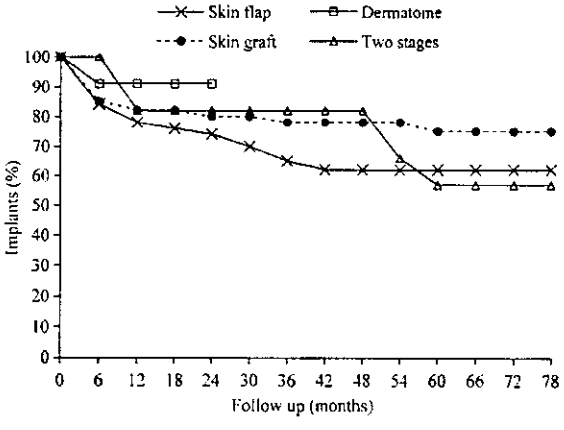

FIG. 4

Cumulative proportion of bone-anchored hearing aid implants remaining free from symptomatic skin reactions over the follow-up period (six-monthly assessment).

Inadvertent penetration of the internal jugular vein, encountered in our series, has been reported before. Similar to our management, this has been reported to be easily controlled by placing a muscle flap over the bleeding site.[15] In our series, the dura was exposed in three cases, but this did not lead to adverse events. One previous study reported a patient whose implant was in contact with the sigmoid sinus but caused no complication.[4] Inadequate bone thickness while drilling has also been mentioned as a hazard, especially in young children.[15] Thinness of bone should not hinder implantation, as in many cases the implant can still be made stable.[3] In our series, such a situation was encountered only once, in a nine-year-old child. In this case, we used a 3 mm fixture, which at the time of writing had lasted almost two years.

Our first post-operative evaluation of the graft was performed 10 to 14 days after the operation. Although we noted that a significant number had incomplete healing at that time, all had healed within one month with conservative treatment. This has also been observed by Proops,[15] who stressed that such an event was not a disaster as the skin heals well within the three months required for osseointegration to occur.[15]

In 96.2 per cent of the observations in our series, no symptomatic skin reaction was noted. Our results are similar to those of previous studies, which reported a rate of 96.6–98.3 per cent (these results included grade one reactions).[2,4] Extensive soft tissue reduction at the time of the operation was deemed necessary, as it was thought to lessen the incidence of skin reactions.[2] Seventy-two per cent of our patients did not experience a single episode of skin reaction during their follow up. Other studies have reported a rate varying from 68 to 81 per cent.[2,4,13,15]

In assessing skin reactions (Gothenborg classification by Holgers),[4–14] some authors have reported no apparent increase in the rate of skin reaction over time.[3,4,8,10] Hakansson *et al.*[3] used a score obtained by dividing the sum of the skin reactions (calculated according to their severity) by the total number of implants for each month of follow up. They found a range of 0.01 to 0.21 during the first 60 months, with no clear tendency to increase. They also calculated the score for implants that were followed for longer than 42 months, and found that this score was almost identical to the average result of all observations. Our results were quite similar; the range was 0.02–0.22 in the first 60 months, and the scores for implants followed for longer than 42 months were almost identical to the total average for all implants ($\pm$1.7 per cent).

Subcutaneous tissue around the BAHA implant can increase in thickness over time, requiring excision with or without grafting.[2] This observation was noted to be more apparent around puberty.[15] In our series, soft tissue reduction (excluding excision of overgrowth) was required in 10/176 cases (5.7 per cent).

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In our series, 31 patients (18 per cent) lost their BAHA implant. Out of these, 24 patients immediately requested replacement with a new implant. This is in concordance with other published series in which patients immediately requested a new implant when the first was lost.[4,15] However, other published series reported lower rates of implant loss. It should be noted that our series included seven traumatic displacements of the abutment, accounting for the higher overall rate of implant loss. Initially, the flange fixture and the abutment were separate. On 27 visits (22 patients), the attachment of the abutment to the flange fixture was observed to have become loose. The screw attaching these two pieces was tightened in the clinic. In four patients, there was loss of osseointegration, seen after tightening, which may have been either cause or effect. Since the introduction of the pre-mounted fixture (i.e. both the abutment and the flange fixture inserted as one unit) in late 2003, this procedure has not been required.

The overall loss of osseointegration following the one-stage procedure (25/159 observations) was less than that observed following the two-stage procedure (six of 17 observations). This was noted despite early loading of the flange fixture in the one-stage procedure. However, the significance of this observation is unclear, due to the substantial difference in group sizes. Only one study in the literature compared the two techniques, and found no differences regarding loss of osseointegration.[2]

- **This paper reports rates of long-term surgical complications, implant failure and revision surgery for a large bone-anchored hearing aid (BAHA) programme**
- **Thirty-one patients (18 per cent) lost their implant; of these, 24 immediately requested replacement with a new implant**
- **One in three patients will require some form of revision surgery during the lifetime of their BAHA implant**
- **A substantial workload for maintaining the device should be anticipated, and patients should be appropriately counselled beforehand**

We observed that loss of osseointegration does not increase with the age of the patient. As has been previously suggested,[4] this implies that osteoporosis in the mastoid process is not a factor leading to BAHA implant loss. It has been established that the length of the BAHA implant is related to its stability, as more threads distribute the load better.[4] In our series, it was noted that loss of osseointegration was more often seen with the 3 mm fixture. However, such loss occurred at a later stage (Table V).

Conclusions

Our experience with BAHA implants has been largely positive, and replicates the Swedish experience. However, it must be appreciated that one in three patients will require some form of revision surgery during the lifetime of their BAHA. A substantial workload for maintaining the device should be anticipated, and patients should be appropriately counselled beforehand.

One-stage surgery was associated with earlier skin reactions and two-stage surgery with later reactions. Skin grafts resulted in fewer skin reactions, compared with skin flaps, and the former are recommended. Dermatome surgery resulted in a promisingly low rate of skin complications. There was no significant increase in skin reactions over time. Loss of osseointegration may be reduced by using the 4 mm fixture and by adopting a one-stage technique. Intra-operative complications are mainly minor and predictable. Sixteen patients chose to abandon their BAHA. Despite this, 91 per cent of patients in our series continued to use their BAHA with satisfaction.[16]

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APPENDIX 9

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The Birmingham Pediatric Bone-Anchored Hearing Aid Program: A 15-Year Experience

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Objective: To evaluate the complication rates and outcomes of children who were fitted with a bone-anchored hearing aid (BAHA) on the Birmingham BAHA program.
Study Design: Retrospective case analysis of clinical records of all children implanted at Birmingham Children's Hospital since the beginning of the program in 1992 until February 2007.
Patients: A total of 182 children younger than 16 years old fitted with a BAHA. Of these children, 107 had a significant medical history.
Results: Surgery was performed as a 2-stage procedure in 174 children. The healing time was between 3 and 4 months in 112 (64%) cases. Single-stage surgery was performed in 8 cases. Implant failures were 14% of 230 loaded fixtures (32 fixtures lost in total). Multiple-fixture failures (18 fixture failures) occurred in 7 patients. Adverse skin reactions appeared in 34 (17%) patients during a 15-year follow-up period. Revision surgery was undertaken in 14 (8%) cases because of skin overgrowth around the abutment. Five of these cases required multiple surgical skin reductions.
Conclusion: The Birmingham Program has a high proportion of syndromic patients with complex medical problems. The fixture failure rate was found to be 14%. This included the multiple-fixture failures in children younger than 3 years old. There was 1 serious complication. The BAHA is a reliable and effective treatment for selected patients. Our program currently has 97% of its children wearing their BAHA on a daily basis with continuing audiologic benefit. **Key Words:** Bone-anchored hearing aid—Osseointegration—Pediatric.
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The use of osseointegrated implants for bone-anchored hearing aid (BAHA) retention is now a well-established practice since the device became commercially available in 1987 (1). There are many reports acknowledging the benefits of the BAHA both in audiologic terms and in its effects on patient well-being (2–5) The BAHA is a reliable and effective means of hearing rehabilitation.

In the adult population, the BAHA has been used primarily for chronic suppurative otitis media, chronic otitis externa, and failure with conventional aids. In the pediatric population, the BAHA has, in addition to the above, proven to be enormously useful in cases of congenital aural atresia and is an alternative to canal and middle ear reconstructive surgery (6,7).

In Birmingham, the first osseointegrated fixture for a BAHA was implanted on August 23, 1988 in the Birmingham Children's Hospital. The patient was a 15-year-old boy who had previously undergone bilateral mastoid surgery. It was almost 12 months before a second patient was implanted. This slow start was due to a combination of difficulties forming a multidisciplinary team with all the necessary specialties, in particular, audiology. The period between 1988 and 1992 saw sporadic BAHA surgery. Then, in 1992, a designated Birmingham pediatric BAHA program was set up with a multidisciplinary team composed of otolaryngologists, audiologists, an anaplastologist, a speech therapist, and an advanced nurse practitioner. Since this time, the program has grown, and it is now recognized as one of the largest in the U.K.

The aim of this study was to evaluate the complication rates and outcomes of children who were fitted with a BAHA on the Birmingham Pediatric BAHA Program since it began in 1992 until February 2007.

METHODS

This was a retrospective case analysis of all children aged 16 years and younger who received an osseointegrated fixture for a BAHA at the Birmingham Children's Hospital since 1992.

A total of 182 records were analyzed by 2 clinicians. Outcomes included indication for a BAHA, medical history, surgery, complications, and postoperative follow-up.

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All fixtures placed for auricular prosthesis were excluded from this patient cohort.

A small number of children had bilateral BAHA, and outcomes for the second side were also evaluated.

RESULTS

There have been 182 children younger than 16 years who have been implanted and fitted with a BAHA on the Birmingham program during the past 15 years. There were 102 female and 80 male patients.

Medical History

One hundred seven (59%) children had a significant medical history: There were 28 cases with Goldenhar, 26 children had Treacher Collins, 17 had unusual chromosomal deletions, 15 had Down syndrome, and 4 cases had Pierre-Robin sequence. The others included cases with Turners syndrome, CHARGE syndrome, and branchiootorenal syndrome (Table 1).

Indications for BAHA

One hundred seven children had a conductive or mixed hearing loss as a result of an underlying syndrome or abnormality. Of the remaining 75 cases with no significant medical history, 38 children had chronic middle ear disease.

Finally, there were 22 children who had isolated congenital atresia not associated with a recognized syndrome (Table 2). All cases had tried conventional air and/or bone conduction aids.

Two cases had traumatic injuries to the external ear, 1 burn accident and 1 road traffic accident. Both were unable to wear conventional aids.

TABLE 1. *Significant medical history*

Syndrome	n
Goldenhar syndrome	28
Treacher Collins syndrome	24
Down syndrome	16
Unusual chromosomal deletions	12
Pierre-Robin sequence	3
Turners syndrome	3
Crouzon syndrome	2
CHARGE association	2
Branchiootorenal syndrome	2
Fetal-alcohol syndrome	2
Asymmetric crying face	1
Pfeitter syndrome	1
Kabuki syndrome	1
Dubowitz syndrome	1
Klippel-Feil	1
Nagars syndrome	1
Alagilles syndrome	1
Marfans syndrome	1
Hunters syndrome	1
Cornelia de Lange	1
Smith Magennis syndrome	1
Di George syndrome	1
Winter-Tsukahara syndrome	1

TABLE 2. *Indication for BAHA*

	n
Congenital aural atresia	89
Congenital microtia	44
Chronic suppurative otitis media	38
Chronic otitis externa	6
Failure with conventional aids	3
Trauma to external ear	2

BAHA indicates bone-anchored hearing aid.

Since 2002, all patients undergoing BAHA assessment, irrespective of the underlying cause, had worn a BAHA Softband before surgery with good results (94 patients).

Side of Implant

The side of implantation was generally dictated by the cochlear function and patient and surgeon preference. There were 97 on the right and 51 on the left. Seventeen children had bilateral BAHA. Of these children, 4 had bilateral simultaneous implantation.

Age

The age at implantation ranged from 2.0 to 15.1 years. The mean age was 6.8 years. Thirty-nine children younger than 5 years had implants between 1992 and 2004.

Procedure

One hundred seventy-four children had 2-stage surgery. There were 2 senior otologists responsible for all the implant surgery on the Birmingham BAHA Program.

During the 15 years of the study, slight variations in the surgical technique and postoperative dressings were noted; however, the basis principles were unchanged.

The first procedure involved incision and elevation of the soft tissues, including the skin, subcutaneous tissues, and periosteum and insertion of 2 fixtures. In cases with thin bone or significant surgical concern, a third fixture was used. No skin reduction was included in this stage. Both 3- and 4-mm fixtures were used (Table 3). The second stage was performed between 12 and 51 weeks later (mean, 20 wk).

The standard healing time between the first- and second-stage procedures was 3 months in 112 children (64%). This period was increased to 5 to 6 months in 53 cases (30%) at the surgeons' discretion as a result of operative findings of "inadequate bone thickness." Social/family reasons resulted in a delay in second-stage surgery in 9 cases (5%).

The favored method of soft tissue management in Birmingham has always been either a local free split-thickness graft taken from the postauricular area or a thinned pedicled split-thickness flap.

The subcutaneous tissues were reduced, and a standard abutment (no larger than 5.5 mm) was placed on 1 chosen fixture.

The implant was placed in contact with the dura in 67 cases, and contact with the sigmoid sinus was reported in

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TABLE 3. *Surgical considerations*

	No. cases
3-mm fixtures	115
4-mm fixtures	67
Bone augmentation	34
Dura identified	67
Sigmoid sinus identified	11
Mastoid air cell identified	5
No operation notes	5

11 cases. Implants in contact with mastoid air cells were noted in 5 cases. The dura was not breached in any case.

A 1-stage surgical procedure was performed for 8 patients. All others had standard 2-stage surgery. A total of 411 fixtures were implanted during the 15 years of the pediatric program.

Fixture Failures

A total of 32 fixtures were lost during the 15-year period, giving a failure rate of 14% of the loaded fixtures. Twenty-five of these failures were in the group younger than 5 years, and all these fixtures were lost within the first 2 years. There were only 7 fixture failures in children older than 5 years (Table 4). Of the failed fixtures, 25 were 3 mm (78%). Of the remaining 7 failures, 4 (13%) were 4 mm. The remaining 3 cases did not have satisfactory documentation.

Nineteen fixture failures were associated with wound breakdown and significant skin reaction. Five children lost their fixtures as a result of trauma. There were incomplete records for the remaining case. With the exception of age, no association was identified between cases of fixture failure.

Skin Reactions

Holgers classification of skin reaction was first used in the documentation of postoperative skin reactions in 2001. Before this, it was a subjective record.

Adverse skin reactions appeared in 34 (17%) patients during a 15-year follow-up period. "Adverse" was standardized as a soft tissue problem requiring repeated visits to clinic for wound care, repeated silver nitrate cautery, or antibiotic therapy. Complete graft failure occurred in 7 cases; however no further surgery was necessary, and healing occurred by secondary intention.

Fourteen further cases required surgical skin revision. In this particular cohort, 2 children had 3 surgical reductions each during a 3-year period. An 8.5-mm abutment was used in 15 cases. One case of skin reaction was found to be the result of a rupture of an epidermoid cyst.

Follow-Up

The length of follow-up varied from 4 to 13 years. The first postoperative visit was between Days 4 and 8. Further follow-up at 3 months was performed by the audiologic team. Medical review was at 12 months' post-completion of surgery. An open follow-up appointment with the advanced nurse practitioner was available to all patients. In the formative years of the program, there were more follow-up appointments for each patient than in the latter years. Eighty children (44%) had been discharged to either their own local BAHA program or transferred to the Birmingham adult program at the time of the study.

BAHA Wearers (Success Rate)

One hundred seventy-six (97%) patients are still wearing their BAHA on a regular daily basis. There were 4 nonusers. Two of these children had abandoned their BAHA as a result of peer pressure and cosmesis issues. One child had repeated difficulties with the sound processor and opted to return to conventional aids, and the final child complained of pain and tenderness of the skin around the abutment when wearing the BAHA. However, clinical and radiologic examination revealed the abutment site to be healthy. Two cases remain unknown.

DISCUSSION

This study was a retrospective case analysis. Retrospective studies raise certain problems. First, the availability and quality of medical records during a 15-year period were not always ideal. Although all 182 records were analyzed, 4 cases had no record of implantation side, and 5 cases had missing operation data. In all 9 cases, the records were pre-1996.

The rationale for the management of many cases has not always been clear from the patient records. Availability of audiologic data was a particular problem in this study. Cross-referencing the operative procedures and dates with the operating ledgers was often necessary.

In the early years of the program, many children were referred from other regions within the U.K.; however, because more regional programs now have experience with BAHA, many of these children have continued their follow-up nearer their homes. This raised particular issues with long-term follow-up of the children. The record of late complications that may occur after discharge and the assessment of the current use of BAHA in patients now cared for in other BAHA centers was considered. These issues were dealt with by direct contact with the patient/carers by our advanced nurse practitioner who has kept in contact with the patient and family over the years.

Auricular prostheses require more than 1 fixture, and the site of implantation varies greatly. In addition, these children tend to have their prosthesis at an older age, and

TABLE 4. *Age and fixture failure*

Age, yr	No. cases	Loaded fixtures	Fixtures lost	Fixture failure rate, %
<3	14	23	9	40
3–5	25	40	15	38
5–10	75	88	7	8
>10	68	79	1	1

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so, their surgical considerations may vary considerably from those children having implantation for a BAHA alone. All fixtures for prosthetic prostheses were excluded from the study.

The Birmingham Children's Hospital is a tertiary referral hospital, and this is reflected in the high proportion and diversity of the medical conditions noted in our 182 cases.

The multidisciplinary team is crucial in the management of these patients. The addition of a plastic surgeon has recently complimented the Birmingham program. The anesthetist also has a vital role that is often underestimated. These children require 2 general anesthetics. Many of them may pose intubation difficulties (8).

In our study, the most common difficulty encountered during fixture insertion was thin calvarial bone. This was not just the result of the child's age but also on the fact that many had craniofacial abnormalities.

Developmental delay of the skull bones, including the mastoid, has been reported in Treacher Collins syndrome and, to a lesser extent, in Goldenhar syndrome, the 2 most common conditions in our series (9,10).

In 2 cases, the implantation was abandoned. One of these children now wears a BAHA; however, the second child has still not been successfully implanted. This child has Dubowitz syndrome, a rare autosomal recessive condition known to be associated with delayed bone maturation.

The surgical technique has been well described by Tjellström in 1990 (11). All children were under the care of 2 senior otologists. Most children had a 2-stage procedure. The techniques of local split-skin graft or pedicled split-skin graft were used in all patients. The main operative finding was thin calvarial bone. No records of actual bone depth were formally documented. Significant bleeding was encountered in 11 cases, but all were successfully managed by insertion of the fixture.

Sixty-seven children had documented dural exposure in our study. The dura was not breached in any case. Dura and sigmoid sinus exposure during BAHA surgery have been reported to be as high as 70% in the pediatric population (12,13).

Depressing the exposed dura did appear to restrict the length of the fixture to 3 mm, as has been reported by Papsin et al. (14) in 1997. However, those children who had exposed dura were implanted without any complications, and osseointegration did not seem to be compromised.

A 1-stage surgical procedure was performed in just 8 patients. Comparison of results between 1- and 2-stage procedures in children has not shown a significant difference in overall fixture failure rates. However, some of the data from these studies includes adult patients (15). There is evidence that a 2-stage procedure is associated with a lower rate of adverse skin reaction than single-stage surgery (1).

Some authors believe that a 1-stage procedure is successful if a 4-mm fixture is used (1). It has been suggested that 2 mm of cortical bone thickness is necessary for implantation for BAHA (16). In our series, predominantly 3-mm fixtures were used. Fixture failure rates have been reported as higher in the pediatric population as compared with the adults (15). Our study demonstrated an overall fixture failure rate of loaded fixtures of 14%. However, only 7 fixture failures were identified in children between the ages of 5 and 15 years.

Of the lost fixtures in our series, 78% were 3 mm. It is interesting that some previous studies have reported an increased failure rate with the shorter fixtures (17).

The lower failure rates in older children together with the apparent success of longer fixtures raises the interesting question of whether these children should have a sleeper fixture especially if a 4-mm fixture can be implanted without difficulty. This raises cost implications.

The Birmingham BAHA Program has previously implanted very young children (7). The youngest child was 2 years old at the time of implantation. In total, there were 39 children implanted before their fifth birthday. The fixture failure rate was high in this group (40%) (18).

Since 2002, no child younger than 3 years has been implanted on the program. This is a direct result of the introduction of the BAHA Softband. The child can wear the Softband until sufficient growth has occurred. Studies to date have shown the BAHA Softband to be a valuable means of aural rehabilitation in this very young group (19).

In our series, the overall fixture failure rate of loaded fixtures was 14%, reflecting a loss of 32 fixtures during the 15-year period. This is slightly higher than some similar studies in the literature (1,13,19–21). This may be a reflection of the large numbers in our study, the many syndromes complicating the fixture itself and its placement, and most importantly, the 39 children younger than 5 years. The pediatric BAHA team at Great Ormond Street has recently reported a similar adverse outcome rate in younger children (22).

Our fixture failure rate was 40% in children younger than 5 years old. These findings were consistent with other authors who included very young children (21). Interestingly, more recent reports in children younger cess rates to be comparable with older children (23).

Many studies reported complications from abutments used for a BAHA and auricular prostheses. It would appear that the fixture failure rate is higher for the BAHA (24,25). It has been speculated that the loading of a single implant is less favorable than multiple implants where all are connected to distribute the load more evenly (26). Of the 32 fixtures that failed in our series, 19 were associated with significant skin reactions. Increased soft tissue complications are well recognized in children (25). As the child grows, the fixture and abutment may become buried by new cortical bone. This occurred in 1 of our patients. The literature suggests that the rate of skin growth is equal in children and adults (27) However, children rely upon their family/carers for help with abutment hygiene. Perhaps this increases the child's risk of soft tissue complications. Furthermore, many of these children have a significant medical condition, many

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FIG. 1. Photograph illustrating the complete breakdown of the skin graft surrounding the abutment.

of which are associated with underlying behavioral and developmental delay. This would make maintenance of their BAHA more challenging.

Finally, older children have an increased risk of acne. They have an increased number of active hypertrophied sebaceous glands, making them more at risk for skin complications than the adult BAHA wearer.

Unfortunately, in the formative years of the Birmingham program, no objective classification was used until the introduction of the Holgers classification in 2001 (28). Before this, the documentation of skin reaction was very subjective, and this made exact calculations of skin reaction unclear.

Since the beginning of the Birmingham pediatric program, the advanced nurse practitioner has had a leading role in the management of the "wound" and today is largely responsible for the excellent skin results achieved. The follow-up and wound care are tailored to the individual need of the child. The first review is standard between postoperative Days 4 and 9.

Only 17% of the children had an adverse skin reaction during the 15-year period. "Adverse" related to a wound requiring more than 3 visits for redressing, repeated application of silver nitrate, or the need for systemic antibiotics. This would most likely equate to what is now termed Holgers Grade 3 or above.

A nonstandard longer abutment of 8.5 mm was necessary in 15 children. This seemed to reduce soft tissue reaction, and it overcame the problem of bony overgrowth that is seen in the pediatric population (20).

In the 7 cases of complete graft failure, no further surgery was necessary (Fig. 1). All 7 wounds healed with secondary intention, and the enfsd result was an excellent skin site around the abutment (Fig. 2).

Although the potential for increased skin reactions and excess bone formation has traditionally been considered higher in children, in our study, we found it was comparable with other recent pediatric studies (1,29,30) and actually less than some previous adult reports (30).

There has been interesting debate regarding the time to load the abutment. A limitation in pediatric BAHA practice is the long interval between surgery and loading of the sound processor. A recent study of 26 adult patients demonstrated no significant increase in osseointegration failure with a healing time of just 6.5 weeks before the abutment was loaded (30).

The length of time before the second stage was performed in our series varied depending on the operative findings and social/geographical issues. The range was 12 to 51 weeks (mean, 20 wk). Many children have traveled from southern Ireland and distant regions of the U.K. for their BAHA. One child had the second stage of his BAHA surgery 51 weeks later. The child and his parents had moved to Pakistan for 12 months.

There is concern regarding trauma in the pediatric BAHA population. There is no doubt trauma was important in our series; damage to the device and/or the abutment was common. There were 5 traumatic fixture failures and 1 more recent traumatic intracranial intrusion injury of the fixture (31).

Finally, direct comparison of our outcome measures with other published series from different institutions is difficult because of the great variation in the different study populations. In view of this, we concur with the rationale proposed by the Great Ormond Street BAHA Team in that the measure of success of any BAHA program should be a reflection of the number of successful BAHA wearers (14). In our program, there are currently 176 (97%) patients currently wearing their BAHA on a daily basis.

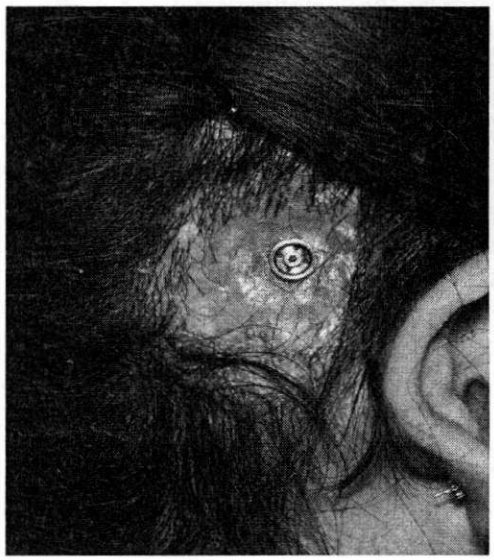

FIG. 2. The same abutment site illustrating the healing by secondary intention 14 weeks later.

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CONCLUSION

The BAHA is an effective means of aural rehabilitation that has also been shown to improve the overall quality of life of the child.

Although often described as "safe" and "simple," the procedure is not without risk as shown in this study. However, despite what may be for a minority of children a prolonged and perhaps difficult process, our program currently has 97% of its children wearing their BAHA on a daily basis. We feel this excellent success rate is a reflection of the multidisciplinary team; all members play such an active role in managing and supporting these children and their carers to minimize complications.

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APPENDIX 10

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Bone-anchored hearing aid A single-stage procedure in children

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ABSTRACT

Objective: The bone-anchored hearing aid (BAHA) is an essential part of the armamentarium of the modern otolaryngologist dealing with ear disorders. A two-stage approach for implantation in children is recommended by the manufacturers. In our practice we implant BAHA in children as a single procedure. We describe our technique and results.

Method: We performed a review of all children having a BAHA between 1997 and 2005. Surgery was performed by taking a post-auricular split skin graft and excising the underlying soft tissues. Drilling, tapping and fixture placement were performed as per the manufacturer's instructions. The skin graft was then sutured in place and perforated in its centre and the abutment placed. Ten to twelve weeks were allowed for osseointegration before the hearing aid attachment.

Results: Thirty children were implanted. Age at implantation ranged from 3 to 15 years (mean 9.1 and median 8.1 years). Main indications included recurrent otorrhoea, conductive hearing loss and aural atresia. Follow-up was at 4–6 weeks review initially, curtailing to 6 monthly reviews and then annual review. Early complications of skin infection occurred in two patients. Late complications such as skin hypertrophy and chronic infection occurred in two patients. Two patients lost the fixture due to trauma, both were subsequently reimplanted. There was no incidence of implant failure to osseointegrate. Twenty-eight children (93%) implanted wear their BAHAs.

Conclusion: Our results show that a single-stage technique is associated with a low rate of early complications, with no reports of fixture loss due to osseointegration failure.

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1. Introduction

The bone-anchored hearing aid (BAHA) is an essential part of the armamentarium of the otolaryngologist dealing with disorders of the ear. It is a bone-conduction hearing device secured to the skull by the process of osseointegration using a titanium fixture. The implant propagates sound directly to the inner ear through the bones of the skull, bypassing the impedance of the skin and subcutaneous tissues. It can be used to rehabilitate those with a conductive or mixed type of hearing impairment. Patients who are unable to wear a conventional hearing aid are the primary beneficiaries: in the paediatric population this is commonly patients with aural malformation or atresia.

Most surgeons implant BAHA in adults as a single-stage procedure. A two-stage approach for implantation is recommended by the manufacturers for children, because of fears of poorer osseointegration than compared to adults [1]. However, it has been our practice to implant BAHA in children as a single stage. The aim of this study is to describe our technique and present our early results in the support of single-stage surgery for paediatric BAHA insertion.

2. Methods

All children undergoing BAHA surgery in our unit are operated upon by a single surgeon (NKG). Their details are recorded in a database prospectively. We reviewed the clinical records of 30 children fitted with BAHA consecutively over a period from 1997 to 2005. We recorded patient demographics, indication for surgery, associated co-morbidity, initial and late complications, the long-term stability and audiologic thresholds.

2.1. Surgical technique

The first step in BAHA implantation is to mark the site. The ideal position is identified 5 cm behind and above the external auditory meatus (unless the child has microtia, when it is preferable to place the BAHA more posteriorly so as to avoid damaging the skin envelope for any possible future auricular reconstruction). After the area is shaved and cleaned, the site is then marked with methylene blue and infiltrated with 2% lignocaine with 1:80,000 adrenaline (Fig. 1). A split skin graft (in order to ensure hairless area

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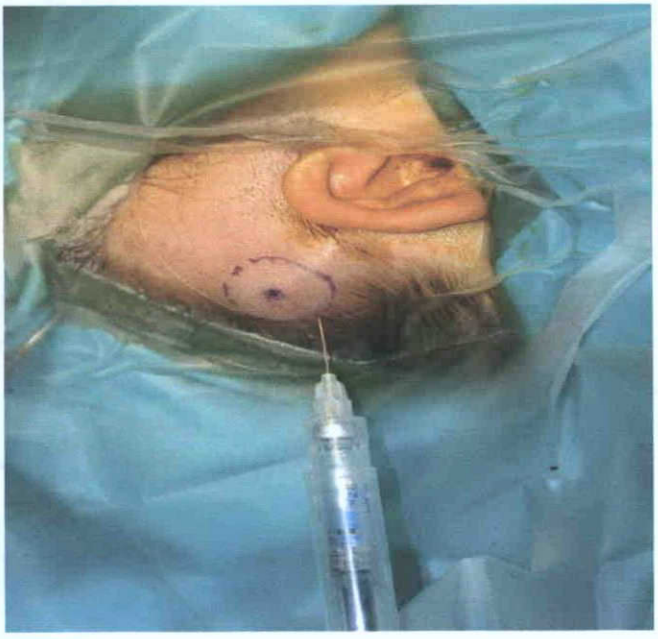

Fig. 1. Site marking and infiltration.

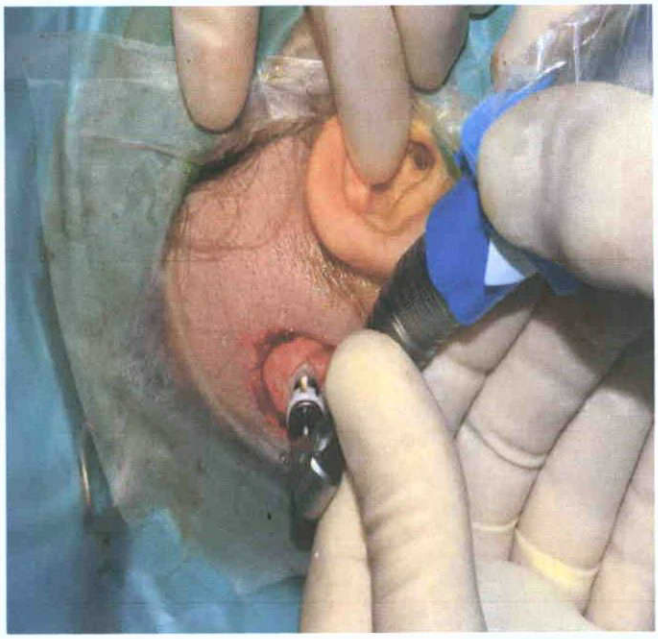

Fig. 3. Bone drilling.

for the implant) is taken from the site using a Silver's knife. Removal of soft tissue is carried out down to periosteum (Fig. 2). The area is drilled with a 3 mm burr, followed by a 4 mm burr if the thickness of bone allows (Fig. 3). At times the dura was exposed, but that did not alter the technique employed. The hole is tapped (all children in this series were implanted before the use of the self-tapping fixture was adopted). A single fixture is placed with no irrigation (Fig. 4). The split skin graft is placed over the fixture and sutured with 5/0 silk (Fig. 5). A 4 mm skin biopsy punch is used to perforate the centre of the skin graft. The abutment is placed onto the fixture. A healing cap is placed on the abutment and antibiotic ointment-impregnated ribbon gauze is wound around the abutment as a pressure dressing to stabilise the skin graft (Fig. 6). The dressing was removed and the wound reviewed at 2 weeks. At this stage training in caring for the implant for the child's carer is started by an audiologist with special interest in BAHA (AC). The wound is further reviewed at 4–6 weeks in the clinic, and the implant left to osseointegrate for 10–12 weeks before BAHA fitting. Thereafter, the patient is seen for review at 6 months and then annually.

3. Results

3.1. Patient group

Thirty children were implanted, 15 boys and 15 girls. Age at implantation ranged from 3 to 15 years (mean 9.1, median 8.1 years). Patients receiving BAHA had conductive and mixed hearing losses. In some patients there was co-existing problems such as recurrent otorrhoea in five patients, aural atresia/malformation in seven patients, and a bilateral cholesteatoma in one patient.

Fig. 2. Excision of subcutaneous soft tissue.

Fig. 4. Fixture placement.

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Fig. 5. Split skin graft placement.

Co-morbidities included Treacher-Collins syndrome (4), Goldenhaar syndrome (2), one each of VATER anomaly and Floating harbour syndrome, and two with undiagnosed dysmorphic syndromes. Aural atresia was an isolated finding in three patients.

3.2. Audiometric outcomes

We recorded pre-operative bone-conduction thresholds and air-conduction thresholds. The four frequency averages (over 500 Hz, 1 kHz, 2 kHz, and 4 kHz) were recorded with pure tone audiometry. The bone conduction was −5–40 dB [median 15 dB]. The pre-operative air conduction range was 25–75 dB [median 60 dB]. The post-operative aided thresholds were 0–20 dB in all but one of the patients. Speech discrimination scores were 100% at 40 dB, except for one patient in whom it was 75% at 35 dB.

Fig. 6. Dressing and healing- cap placement.

3.3. Technical outcomes

None of the patients had failure of osseointegration. Early complications occurred in two patients comprising infection at the abutment site that settled with topical antibiotic ointment. Late complications occurred 10 months after surgery in two patients, comprising skin hypertrophy in one patient and chronic infection in the other. These were managed with close observation, and topical antibiotic therapy, none of these patients required surgery. At the time of infection the BAHA was not used. Two patients had implant loss due to trauma; this happened with considerable force in both cases, one was hit with a frisby and the other was due to a fall from height in the playground. Both the incidents happened more than 5 years after implantation (both were reimplanted). Table 1 summarises these complications. Overall, there were no reported fixture losses in the early period up to 2 years. Twenty-eight (93%) children implanted currently wear their BAHA. Two do not, and this was due to preference for conventional hearing aids.

4. Discussion

The bone-anchored hearing aid (BAHA) has been in use since the late 1980s, it is a device secured to the skull by the process of osseointegration using a titanium fixture [2]. Patients who are unable to wear a conventional hearing aid are the primary beneficiaries: in paediatric practice this is commonly those with aural malformation or atresia. Patients in both the adult and paediatric group report a high level of satisfaction with their BAHAs [3,4]. Patients with craniofacial abnormalities although representing a unique problem also have a high compliance [5,6].

Bone-anchored hearing aids have both cosmetic and acoustic advantages over most conventional hearing aids. Dutt et al. reports the device to be of audiological benefit, to reduce otorrhoea, increase comfort, patient satisfaction and improved quality of life [7]. Our series illustrates effective hearing improvement with post-

Table 1

Age at implantation	Complication	
	Early	Late
3.5	Nil	Nil
3	Nil	Nil
13	Nil	Nil
12	Nil	Nil
13	Nil	Nil
4	Nil	Nil
11	Nil	Nil
12	Nil	Nil
16	Infection	Nil
6	Nil	Nil
2	Nil	Nil
6	Nil	Nil
8	Nil	Nil
6	Infection	Nil
10	Nil	Traumatic fixture loss
12	Nil	Nil
2.5	Nil	Nil
8.5	Nil	Traumatic fixture loss
14	Nil	Skin hypertrophy
10	Nil	Chronic infection
12.5	Nil	Nil
13	Nil	Nil
6	Nil	Nil
3.5	Nil	Nil
15.5	Nil	Nil
6.5	Nil	Nil
9	Nil	Nil
3.5	Nil	Nil
19	Nil	Nil
12	Nil	Nil

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operative aided thresholds 0–20 dB and speech discriminations scores to be 100% at 40 dB in the majority of patients (29 out of 30 patients). In other studies [8] the air–bone gap was within 10 dB of the pre-operative bone-conduction thresholds in 80% of patients and within 5 dB in 60% of patients.

The surgery for BAHA implantation involves a single-stage procedure under either local or general anaesthesia in adults. However, for children, a two-stage technique under general anaesthesia is recommended by the manufacturers and this is the technique employed by most centres [1]. It has been our practice to implant children as a single stage since 1997. We adopted this as a universal strategy for fitting all BAHAs, not influenced by individual skull thickness. The main advantage of this is the avoidance of a second anaesthetic for abutment fitting. This is especially important since some series have reported over grade 3 or 4 intubations in over a third of their children requiring BAHAs [9].

Our overall primary fixture loss rate was zero at our maximum follow-up of 8 years, which is very favourable for the single-stage strategy in children. In a comparable paediatric study the one stage technique was found to be safe and effective with a low complication rate [6]. In other paediatric series with two-stage implantation 5–10% of implants failed to osseointegrate [10,11] and late fixture loss occurred in 9–10% [12,13]. Thus, although the two-stage procedure also has a low complication rate, the single stage is more favourable since a second anaesthetic can be avoided in this group.

5. Conclusion

The BAHA provides a safe and effective means of rehabilitation of conductive or mixed hearing loss in the paediatric population. Our results show that a single-stage technique is associated with a low rate of early complications, particularly fixture loss. This is also reflected in other small series [14]. Our patients have a high level of satisfaction which is reflected in the high number of patients continuing to use the device.

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Main Article

Complications of bone-anchored hearing aid implantation

J C Hobson*, A J Roper†, R Andrew‡, M P Rothera*, P Hill‡, K M Green*†

Abstract

Introduction: Bone-anchored hearing aid implantations have been performed in Manchester for over 20 years. This study examined a range of variables that can occur during the implantation process, and the effect they may have on successful outcome.

Method: Retrospective study and literature review.

Location: Tertiary referral centre in central Manchester.

Results: Details of 602 bone-anchored hearing aid implantation procedures were retrieved from the departmental database. The overall complication rate was 23.9 per cent. The rate of revision surgery was 12.1 per cent.

Conclusion: This study involved a significantly larger number of patients than any previously reported, similar study. Possible reasons for differences in outcomes, and recommendations for best practice, are discussed.

Key words: Adult; Child; Hearing Aids; Hearing Loss; Postoperative Complications; Prostheses And Implants; Retrospective Studies; Surgical Wound Infection; Treatment Outcome

Introduction

Bone-anchored hearing aids (BAHAs) provide a means of hearing for those patients who, for a variety of reasons, cannot wear a conventional hearing aid. Bone-anchored hearing aids were first used in 1977, and have since been implanted in tens of thousands of patients.[1] They have been used in a variety of conditions, in patients with conductive, mixed or sensorineural hearing loss.[2]

The BAHA is based on the principle of osseointegration; a process by which metal integrates with bone.[3] This allows a titanium fixture to be inserted into the mastoid bone, to which an abutment and aid can be fitted. The BAHA transmits sound, processed by the hearing aid, to the cochlea via the cranium, therefore bypassing the tympanic membrane and ossicular chain and, by definition, any middle-ear pathology.

Bone-anchored heading aids have been in use in the Greater Manchester region for over 20 years. The indications for BAHA implantation have changed since the procedure was first developed in the 1980s.[2] The devices were first used in patients with conductive or mixed hearing loss due to a variety of pathology, particularly conditions resulting in a chronically discharging ear.[4] Another important indication is children and adults with congenital ear malformations.[5] These patients are unable to wear a behind-the-ear hearing aid, as the mould will not fit effectively in the ear. Other suitable conditions include otosclerosis, tympanosclerosis and previous ear surgery rendering the patient unable to wear a conventional hearing aid.[4]

More recently, BAHAs have been used in patients with unilateral sensorineural hearing loss, frequently after excision of acoustic neuromas; however, some have queried the evidence base for this indication.[6–8] The BAHA is implanted on the ipsilateral side and sound is transmitted transcranially to the functioning contralateral ear to give improved directional hearing and sound recognition.[9]

The aims of this study were to assess BAHA complication rates at the authors' institutions, and to compare these to nationally and internationally published data. There have been a number of studies reporting complications of BAHA implantation (see Table I), but none involving such a large number of patients as the present study.

We have developed a database of all patients who have undergone BAHA implantation since our programme started in 1984. This database contains details about the surgical procedure and the follow-up period, including complications and revision surgery. Not all records are complete, especially for earlier operations. Nevertheless, to our knowledge, this is currently the largest such database in

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TABLE I

SUMMARY OF PUBLISHED BAHA STUDIES

Study	Year	Institution	BAHA cases (*n*)	Complications (%)	Revision surgery (%)
Davids *et al.*[10]	2007	Hospital for Sick Children, Toronto, Canada	20	45	25
Gillett *et al.*[11]	2006	William Harvey Hospital, Ashford, UK	63	35	–
Goodyear *et al.*[12]	2004	Bradford Royal Infirmary, UK	80	59	18
House & Kutz[13]	2007	House Clinic, Los Angeles, California, USA	149	12.8	7
Kim *et al.*[14]	2005	A. Alfred Taubman Health Care Center, Ann Arbor, Michigan, USA	37	10	10
Kohan *et al.*[15]	2008	New York University School of Medicine, USA	32	25	13
Lloyd *et al.*[16]	2007	Great Ormond Street, Hospital for Children, London, UK	71	46	42
Lustig *et al.*[17]	2001	Johns Hopkins University, Baltimore, Maryland, USA	40	10	–
McDermott *et al.*[18]	2009	Birmingham Children's Hospital, UK	182	31	8
Monroy *et al.*[19]	2007	Rafael-Hospital Militar Central, Bogotá, Colombia	12	8	–
Proops[3]	1996	Queen Elizabeth Hospital, Birmingham, UK	188	10	–
Sheehan & Hans[20]	2006	Postal survey of UK & Ireland	43	49	–
Shirazi *et al.*[21]	2006	Loyola University Medical Centre, Baltimore, Maryland, USA	58	19	5
Wazen *et al.*[22]	2008	Silverstein Institute, Los Angeles, Florida, USA	218	18.8	5.8
Yellon[23]	2007	Children's Hospital, Pittsburgh, Pennsylvania, USA	15	53	13
Zeitoun *et al.*[24]	2002	University Hospital, Birmingham, UK	51	21	9

BAHA = bone-anchored heading aid; – = data not provided by authors

the UK, and it has allowed us to examine our BAHA complication rates.

We assessed four different factors to investigate whether they influenced outcomes: grade of surgeon, local or general anaesthetic, one or two stage procedure, and operative technique. The operative technique has changed over the years. Initially, the procedure was performed using a scalpel to raise the flap, thin it down and remove hair, whereas now a dermatome is commonly used to raise the skin flap.[25,26] Initially, the procedure was performed in two stages under a general anaesthetic. Now, most procedures are single-stage, performed if possible under local anaesthetic.[27]

Materials and methods

A list of all the patients who had undergone BAHA implantation in Central Manchester and Salford was compiled by the audit departments of the Manchester Royal Infirmary and Hope Hospital. This covered the period 1984–2008. Surgical indications, operative notes and follow-up details were then identified by examining the patients' medical records. We recorded the grade of the operating surgeon, whether the procedure had been performed under local or general anaesthetic, the operative technique, and whether the procedure had been performed in one or two stages. We compared published results to our own.

Additionally, a literature search was performed using the Medline, PubMed and Cochrane electronic databases, using the following medical subject headings: 'adult', 'child', 'hearing aids', 'hearing loss', 'postoperative complications', 'prostheses and implants', 'retrospective studies', 'surgical wound infection' and 'treatment outcome'. The search included all articles published in English up to 31 January 2009. Relevant references were used to identify other studies.

Six hundred and two BAHAs were implanted in 499 patients. Patients' ages ranged from four to 87 years. The procedures were performed by 32 different surgeons, mainly registrars rotating through the north west deanery training scheme. A consultant surgeon performed the operation in 284 cases.

Results and analysis

We found an overall complication rate of 23.9 per cent; this compares favourably with published rates of 8–59 per cent, as shown in Table I. The types of complications encountered are shown in Table II. The main complications were soft tissue overgrowth (48 patients), abutment site infection (31), abutment and fixture dislodgement (26) and trauma (six). Exposed bone (five patients), skull paraesthesia (five), persistent pain (four) and failure of osseointegration (four) were also encountered. Other rare complications included neuroma, and excess feedback due to weight gain. One patient had their BAHA removed in order to undergo radiotherapy, and one patient asked that the BAHA be removed as they did not perceive any benefit from the device (their hearing thresholds were at the minimum limit

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TABLE II

COMPLICATIONS ENCOUNTERED

Complication	Pts (*n*)	Frequency (%)
Soft tissue overgrowth	48	8
Skin infection	31	5
Abutment & fixture dislodgement	26	4
Trauma	6	1
Exposed bone at abutment site	5	<1
Skull paraesthesia	5	<1
Persistent pain at abutment site	4	<1
Failure to osseointegrate	4	<1
Granulation tissue at abutment site	3	<0.5
Persistent bleeding at abutment site	2	<0.5
Persistent feedback problems	2	<0.5
Neuroma at abutment site	2	<0.5
Keloid scar at abutment site	2	<0.5
Haematoma at abutment site	1	<0.5
Removed for pt to undergo RT	1	<0.5
Patient did not perceive any benefit	1	<0.5
Laryngospasm post-op requiring tracheostomy	1	<0.5
Total	144	23.9

Pts = patients; RT = radiotherapy; post-op = post-operatively

for a Compact BAHA, but they would not consider wearing a Cordelle device). All but one of the complications in our series was considered minor. One patient, a 45-year-old woman with Treacher Collins syndrome, developed laryngospasm which precipitated complete airway obstruction in the recovery room. Anatomical difficulties made reintubation difficult and so an emergency tracheostomy was performed, which was subsequently removed with no further sequelae.

Of the patients with complications, 73 required revision surgery (12.1 per cent), 38 for skin and soft tissue problems, 15 due to trauma or dislodgement of the fixture and abutment, and 14 for infection. Revision was also required for excessive feedback and failure to osseointegrate. Four BAHAs were removed at the patient's request: for pain in two cases, for failure to provide benefit in one case, and to enable the patient to undergo radiotherapy in the other case. These results are shown in Table III.

In order to determine whether any risk factors existed that were more likely to produce complications, various aspects of the operation were assessed in more detail. Statistical analyses were performed using Fisher's exact test (GraphPad software; La Jolla, California, USA) to investigate the different factors which may have affected the complication rate.

TABLE III

INDICATIONS FOR REVISION SURGERY

Indication	Pts (*n*)
Skin overgrowth or soft tissue problems	38
Trauma or dislodgement	15
Infection	14
Removed at patient's request	4
Feedback	1
Failure to osseointegrate	1
Total	73*

*Total revision surgery rate = 12.1 per cent

Implantation procedures were performed by three consultants and 29 specialist registrars. This appears to be a reasonably large number of operators, but actually equates to 1.5 registrars per year attached to the consultants who performed BAHA insertion. This is not an uncommon number in the context of a rotational training programme. In cases in which a trainee performed the surgery, a consultant present in the operating theatre during the procedure almost invariably supervised it. Of the patients who experienced complications, 84 (58 per cent) were operated upon by a consultant: the difference between consultant and non-consultant complications rates was statistically insignificant.

Three hundred and sixty-six procedures were performed at Hope Hospital and 236 at the Manchester Royal Infirmary. There was no statistically significant difference between the complication rates for either site.

In this series, local anaesthesia was used in 332 cases. General anaesthesia was preferentially used in children, and occasionally in adults if requested due to nervousness or intolerance of local anaesthesia. The type of anaesthetic used did not contribute significantly to the complication rate.

Initially, the insertion had been performed as a two-stage procedure. The first stage had involved choosing the site and placing the titanium fixture to allow osseointegration. The second stage, performed three months later when the fixture was uncovered, had checked for osseointegration; if this was satisfactory, soft tissue reduction had been performed and placement of the abutment undertaken. More recently, this method was still employed for younger children and adults with poor cognition, in order to minimise the risk of trauma during osseointegration.[4] However, the majority of our patients underwent a single-stage procedure. The complication rate was significantly greater in patients undergoing a two-stage procedure, compared with a single-stage procedure ($p < 0.0001$).

Prior to placement of the titanium fixture, a skin graft was taken to ensure a hairless area of skin around the fixture. Various grafting techniques have been described; in this series, a scalpel and a dermatome were the most commonly used instruments.[4,25–29] Grafts undertaken with a scalpel had a statistically significantly higher complication rate, compared with those undertaken with a dermatome ($p < 0.0001$). The senior author (MR) preferred to use a scalpel in order to retain the technique for use during insertion of bone-anchored auricular prostheses, but trainees mainly used a dermatome in order to minimise the complication rate and improve outcomes.

Discussion

The Manchester Bone Anchored Hearing Aid Programme has been implanting patients for over 20 years. A number of studies have reported the complications of BAHA implantation, but none have examined such a large number of patients as the present study.[4,10–24] Most studies have involved

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relatively small numbers of patients; previously published series have included between five and 188 subjects. Reported complication rates have ranged from 8 to 59 per cent, and reported revision rates from 5 to 42 per cent. Comparing such a heterogeneous group of data can be difficult; however, for interest, the weighted means of these studies were calculated[4,10–24], giving a combined complication rate of 24.90 per cent ($\pm$14.85 standard deviation) and a combined revision rate of 12.68 per cent ($\pm$10.5 standard deviation). The results are summarised in Table I.

Bone-anchored heading aid implantation is generally safe. Almost none of the published studies have reported any major complications or fatalities, although Scholz *et al.* have presented an interesting case report of a 42-year-old man who suffered a brain abscess after undergoing change to his bone-anchored implant.[30] This is a very rare complication, but noteworthy for its gravity. The present study encountered a case of laryngospasm, which was related to the increased anaesthetic risk of patients with craniofacial abnormalities. Thankfully, the outcome in this case was satisfactory. Most of the adverse outcomes seen in this and other studies comprised local reactions or problems with the implant itself.

The most common complication reported in the literature is an adverse skin reaction around the implant (generally, skin overgrowth or localised infection). The incidence of this complication varies from 7.5 to 37 per cent in the single centre studies.[13,16] However, Sheehan and Hans's postal survey of BAHA implantation in Down syndrome patients identified soft tissue complications in 49 per cent.[20] Most of these complications were successfully treated with antibiotics, although 1 to 2 per cent required surgical intervention, with some requiring removal of the BAHA fixture. More recently, steroid gel has been used to reduce skin overgrowth.[31]

In our study, traumatic damage to the BAHA was seen in 1 per cent of patients; perhaps unsurprisingly, this complication was more prevalent in studies involving a predominantly paediatric population. Lloyd *et al.* found that 26 per cent of their patients had experienced fixture loss at some point.[16] Davids *et al.* identified a greater incidence of traumatic fixture losses in children older than five years, compared with those under five.[10] Yellon made several recommendations in order to minimise the BAHA complication rate in the paediatric population: "(1) allow a six-month period between stages in children with thin skulls, (2) thin the flap with a scalpel when it is tented by healing fixture, or infiltrate the flap with local anaesthetic to balloon it, prior to using the dermatome for second stage cases, and (3) create an extremely thin flap to prevent cellulitis" and; the latter two recommendations could presumably be extrapolated to adult practice.[23]

In our series of BAHA patients, we encountered two previously unreported complications. One patient gained weight after BAHA implantation, resulting in the hearing aid coming into contact with the patient's scalp, causing feedback. This was easily managed by changing to a longer abutment. The second patient had a very thick scalp and the healing cap cut into the soft tissue. This too was managed conservatively.

- **Bone-anchored heading aids (BAHAs) provide a means of hearing for those patients who, for a variety of reasons, cannot wear a conventional hearing aid**
- **These devices have been in use for over 20 years**
- **Various institutions have published data regarding the safety of BAHA implantation**
- **In over 600 operations, we encountered only one serious complication: laryngospasm in a patient with craniofacial abnormality**
- **Minor complications were encountered in 23.9 per cent of patients, mostly soft tissue overgrowth and skin infections**
- **Revision surgery was required in 12.1 per cent of patients**
- **This study represents the largest published series to date; its complication and revision rates were similar to those of other identified series, which had combined, weighted means $\pm$ standard deviation of 24.90 $\pm$ 14.85 per cent and 12.68 $\pm$ 10.5 per cent, respectively**

We conclude that the BAHA is safe and effective in the rehabilitation of patients with conductive or mixed hearing loss, or with unilateral sensorineural hearing loss. Significant complications are uncommon after BAHA implantation; however, those that do occur may require local wound care, antibiotics or revision surgery.

Conclusion

This study involved a significantly larger number of patients than any other previously reported study. The overall complication rate in the current series was 23.9 per cent, and the revision rate was 12.1 per cent. These rates compare favourably with previously reported findings. The grade of surgeon, hospital site and anaesthesia type did not contribute significantly to the complication rate. However, performing the procedure in two stages rather than one, and using a scalpel rather than a dermatome for the skin graft, did appear to increase the complication rate significantly.

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APPENDIX 12

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Otolaryngology–Head and Neck Surgery (2008) 138, 662-666

ORIGINAL RESEARCH – OTOLOGY AND NEUROTOLOGY

Single-stage BAHA implantation in adults and children: Is it safe?

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OBJECTIVE: Most surgeons perform pediatric bone-anchored hearing aid (BAHA) implantation in two stages. This study examined the safety and efficacy of single-stage BAHA implantation in adults and children.

METHODS: Retrospective review of 32 ears: 18 pediatric (ages 6 to 13 years) and 14 adult patients who underwent single-stage BAHA surgery between 2002 and 2006.

RESULTS: A total of eight (25%) ears experienced complications. Overall, four (13%) ears required revision in the operating room. In the pediatric group, there were three (16.7%) ears with skin complications; two required operative revision. In the adult group, there were five (36%) ears with skin complications; two required operative revision.

CONCLUSIONS: In both adults and children, the single-stage technique for BAHA implantation is safe and efficient. All complications were related to skin reaction. Safety profiles for 1- and 2-stage surgery are similar, although the single-stage procedure is more cost effective, avoids a second procedure, and provides for earlier hearing rehabilitation.

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Implantation of the bone-anchored hearing aid (BAHA) was first successfully performed in Sweden in 1977 and reported in 1981 by Tjellström et al.[1] In 2002, the United States Food and Drug Administration approved BAHA for implantation in children as young as 5 years of age. Usually, BAHA surgery is a 2-stage process. First, a titanium fixture is implanted into mastoid bone. After a period of 3 to 4 months for osseointegration to occur, a skin-penetrating abutment is attached to the fixture, with external attachment of the sound transducer several weeks later.

In 1995, Tjellström and Granström[2] confirmed that in adults BAHA implantation was safe and feasible as 1-stage surgery, wherein the external abutment is attached to the fixture at the time of implantation. The Tjellström and Granström series reported a 2.5% rate of implant loss for both single-stage and 2-stage procedures. Accordingly, most surgeons today implant adult BAHAs in 1 stage.

Pediatric BAHA surgery, however, is usually a 2-stage procedure.[3] There have been few reports of complication rates after single-stage BAHA surgery, and no reports have explored outcomes with single-stage surgery in children. Single-stage surgery in children would obviate the need for a second scheduled operating room procedure, thereby avoiding a second anesthetic exposure as well as the logistical challenges to families of scheduling another surgical day. The aim of this study was to determine the safety and efficacy of single-stage BAHA surgery in children and adults.

METHODS

After institutional review board approval, a retrospective chart review was conducted that included all patients who underwent BAHA surgery performed by the senior otologist (D.K.). Although the focus of this study was on safety of single-stage surgery in pediatric patients, we also include a contemporary cohort of adult patients in order to place the pediatric results in context, which would otherwise be difficult given the wide range of reported complication rates in BAHA implantation.

A total of 32 single-stage BAHAs were implanted in 29 patients between January 2002 and January 2007. There were 18 implanted ears in 16 children, with a mean age of 9.4 years (range, 6 to 13 years). There were 14 implanted ears in 13 adults, with a mean age of 44.6 years (range, 30 to 74 years). Demographic data on patients implanted with the BAHA device are summarized in Table 1.

Causes of hearing loss are summarized in Table 2. Among children, the most common cause of hearing loss was microtia-atresia. In these cases, BAHA surgery was timed with the final stage of auricular reconstruction. Preoperative audiology confirmed that 15 of 16 children had bilateral intact auditory nerve function.

Among adults, the most common causes of hearing loss were idiopathic sensorineural hearing loss (SNHL) and Me-

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Table 1
Demographics of patients who undergo BAHA implantation

	Adults	Children
Mean age (range)	44.6 (30-74)	9.4 (6-13)
Male	6	11
Female	7	5
Right ear	4	11
Left ear	10	7
Total patients	13	16
Total ears	14	18

niere's disease–related SNHL. A purely conductive hearing loss was found in 5 of 13 adult patients.

All 32 single-stage BAHA procedures were performed as ambulatory surgery. Total surgical time including anesthesia time was less than 1 hour in all cases. All 18 pediatric cases were performed with the patient under general anesthesia. Local anesthetic with monitored anesthesia care was used in 12 of 14 adult cases.

The surgical technique for single-stage BAHA implantation has been well described.[4] All patients received perioperative antibiotics. The BAHA templates were used to plan the location of the skin flap, and the BAHA dermatome then used to elevate a superiorly-based skin flap. The soft tissue deep to the skin flap was then removed, which preserved the pericranium. The edges of the incision were undermined circumferentially and tacked to underlying periosteum with 4-0 vicryl. Periosteum was then removed at the site of the fixture, as localized with the BAHA template, and a spare fixture site was planned 1 cm inferior to the primary site.

In adults, 4 mm fixtures were used at both the primary and spare sites. In children, the preoperative CT scan was used to measure bone thickness and determine fixture length. Subsequent drillwork with the guide drill, countersink, and fixture-abutment complex was performed in sequence at the appropriate drill speed and torque. Irrigation and gentle soft tissue technique were used at all times.

A cover screw was then placed on the spare fixture, and the abutment was attached to the primary fixture. Finally,

Table 2
Causes of hearing loss

	Adults	Children
Unilateral microtia-atresia	2	11
Bilateral microtia-atresia	1	3
Idiopathic SNHL	5	1
Meniere's disease	2	—
Conductive hearing loss	2	—
Acoustic neuroma surgery	1	—
Crouzon's disease	—	1

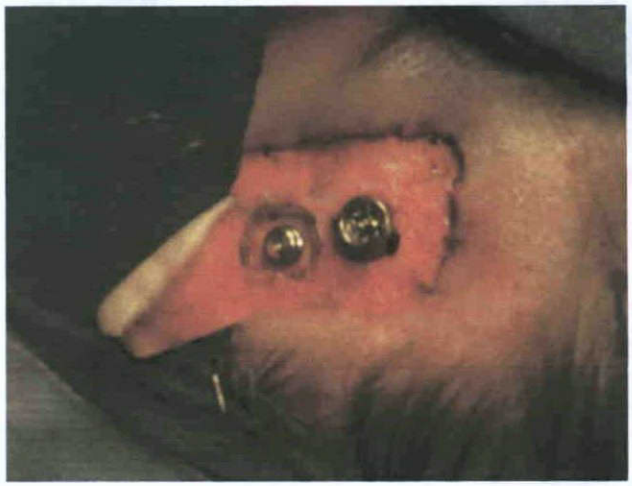

Figure 1 After installation of the titanium fixture with premounted abutment (*right*), a second "sleeper" fixture (*left*) is placed 1 cm inferior to the primary fixture. A cover screw is then applied to the spare fixture.

the skin flap was replaced, and the skin incisions closed with 5-0 rapidly absorbing suture. The BAHA skin punch was then used to bring the abutment through the skin, and xeroform gauze with the BAHA healing cap was then used to protect the abutment.

A spare "sleeper" fixture (Figs 1 and 2) was implanted in all patients with the exception of the first two adults and the first child in the series. Mean duration of follow-up in this series was 26.9 months: 24.2 months for children (range, 11.25 to 41 months) and 30.9 months for adults (range, 10 to 66 months).

All major and minor complications, including fixture loss (if due to failed osseointegration or traumatic extrusion), skin irritation or overgrowth, or site infection were recorded at postoperative visits. All patients are evaluated 1 to 2 weeks postoperatively, and then in 3 or 4 months, at which time the BAHA transducer device was provided (3 months in adults, 4 months in children). Patients are then seen in follow-up yearly. We did not include processor failure or malfunction as a complication. Postoperative audiologic testing was performed on an elective basis and was recommended only after the patients had become familiar with the BAHA sound processor.

Complication rates were reported in two forms: 1) the probability of complication (number of BAHA sites that experienced one or more complications divided by total number of BAHA sites), and 2) the incidence of complications (number of complications divided by total number of BAHA sites).

RESULTS

Complications are summarized in Table 3. A total of eight (25%) ears experienced single or multiple complications, all skin related. Because several ears experienced more than 1

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Figure 2 The skin flap is replaced and the titanium fixture-abutment complex brought through the skin.

complication, the total incidence of complications was 11 events in 32 ears, or 34.4%. Overall, four (13%) ears required revision of some kind in the operating room. At the end of the study period, all patients were regularly using the BAHA.

In the pediatric group, three (16.7%) ears experienced single or multiple complications, all skin related. One patient experienced two complications, for a total of four complications in 18 patients, which represented an incidence of complications of 22.2%. Two (11.1%) ears required one or more revisions in the operating room. Complications included one case of cellulitis, which responded to antibiotics and local wound care, and two sites with skin overgrowth, which both required revision in the operating room. One of these patients required a second revision for skin overgrowth over the abutment, which occurred because of poor hygiene and inconsistent use of the device. There were no cases of failed osseointegration, fixture extrusion, or skin graft loss.

In the adult group, there were five (35.7%) ears with single or multiple complications, all skin related. Several patients experienced more than one complication at the same site, for a total of seven complications in 14 ears or an incidence of complications of 50%. Two (14.3%) ears required single revision in the operating room. There were three cases of cellulitis, treated with antibiotics and local wound care; and four cases of skin overgrowth, two were revised in the office and two required a rotational flap under local anesthesia in the operating room. Two fixtures were lost after direct trauma but were not counted as complications because there was no evidence of failed osseointegration. In the first patient, a 3 mm fixture extruded after 22 months (following trauma with a hair dryer). Because a spare fixture had not been placed, a new 4 mm fixture was implanted in the operating room; there have been no further complications in 3 years. In the second patient, the fixture was lost on postoperative day 10 as a result of accidental head trauma. After a 3-month period, the spare 3 mm fixture was exteriorized in the office, and the abutment was attached, without any further sequelae over 2 years.

DISCUSSION

The definitive study of osseointegration after single-stage BAHA surgery was reported by Tjellström and Granström[2] at the Gothenburg University in Sweden in 1995. After 5 years of follow-up, 4 of 161 single-stage fixtures were lost, compared with 3 of 120 2-stage fixtures. This series did not include children. Most surgeons today routinely perform adult BAHAs in 1 stage.[3]

The adult cohort in our study experienced a 35.7% rate of one or more skin reaction complications: either cellulitis or skin overgrowth. This is slightly higher than the rates of skin complications in recent series: 7.5% to 23.3%.[5-8] Tjellström and Granström[2] did not identify a difference in skin complication rates between 1-stage and 2-stage operations. Skin reactions are believed to result from movement of the skin graft against the abutment. Poor hygiene and inadequate removal of hair follicles from the BAHA skin flap also predispose to irritation. It is therefore important to ensure that the fixture and abutment are stable and that the skin graft is sufficiently thinned and secured to underlying periosteum. To some degree, the variation in skin complication rates may be attributable to length of follow-up. When Tjellström and Granström[9] conducted an 8 to 16 year follow-up on the original 100 BAHA patients, a 32% rate of skin complications was found.

Children have been presumed by most surgeons to require a 2-stage approach. Despite relatively few studies of complication rates after BAHA surgery, limited data have suggested higher implant failure rates in children of 5.0% to 29.0%,[10-14] compared with 2.5% to 3.5% in large series of adults.[2,7,8] Additionally, Jacobsson et al[12] and Holgers et al[15] have reported higher rates of skin complications in children (5.1% vs 3.1%). Papsin et al[10] have reported a 16% rate of skin complications in children. Although there were no

Table 3
Complications experienced (adult and pediatric ears)

	Adults (n = 14)	Children (n = 18)
Skin flap cellulitis	3	1
Skin flap overgrowth	4	3
Failure of osseointegration	0	0
Ears with complications	4 (36%)	3 (17%)
Ears with return to OR	2 (15%)	2 (11%)

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fixture losses in our pediatric cohort, the rate of 1 or more skin complications was 16.7%.

The pediatric skull has a lower mineral content and higher water content than the adult skull, as well as thinner bone; the mean thickness at 5 years of age is only 2 mm. Accordingly, Granström and Tjellström[16] have reported that 70% of pediatric BAHAs are installed in direct contact with either the dura or sigmoid sinus. In this study the corresponding proportion was 90%. The dura and sigmoid sinus tolerate indentation by the fixture with rare adverse effects. This finding is not surprising given the extensive published medical literature on the safety of pediatric cochlear implants, which are often positioned against the dura and sigmoid sinus.

We provided pediatric patients with BAHA processors at 4 months after implantation, earlier than the 6 months that has traditionally been recommended. Fixture osseointegration is a gradual process that progresses over weeks to months and is dependent on many factors, including skull thickness, bone density, nutritional status, and atraumatic surgical technique at implantation. The process is slower in healthy children than in adults, and the extent of osseointegration required before safe usage of the BAHA processor has not yet been determined. It is unknown to what extent sound processor vibration adversely effects osseointegration.

Studies are currently underway examining the safety of early loading of the BAHA processor in adult patients, as early as 6 weeks postimplantation (Cochlear Corporation, personal communication). Considering emerging evidence in support of earlier use of the BAHA processor and with informed consent from the patients and families, our pediatric population was provided with BAHA processors at 4 months postimplantation. None of these patients experienced any adverse sequelae attributable to earlier loading of the processor. As more data are collected, we hope to provide all patients with the benefit of processor use as early as is safe after implantation.

To date, the largest series of pediatric BAHA outcomes have been reported by Papsin's group[17] at the Hospital for Sick Children in Toronto. This pediatric BAHA program has pioneered BAHA implantation in children younger than 5 years, as young as 14 months old. However, single-stage surgery is not commonly used; Papsin has advocated 2-stage surgery in most children, including all children younger than 9 years old, and in any child whose calvarium will not accommodate a 4 mm fixture.[10,17] Among 19 children who receive BAHAs in Toronto, only five patients with a mean age of 15 years had single-stage surgery; two of these patients required revision for skin overgrowth, and there were no fixture losses. In Papsin's series, children aged 6 to 13 (comparable to our pediatric cohort) were given a 4 to 6 month interval between stages.

Our results represent the second series and largest cohort to date of single-stage pediatric BAHA recipients. In contrast to Papsin, we have used single-stage surgery in children younger than 9 years old, and with 3 mm fixtures. Of 16 children in our series, 7 were younger than 9 years old, and 6 children were implanted with a 3 mm fixture. The youngest patient in our series who received single-stage surgery was 6 years old.

We note that during the time this series was accrued only one 2-stage BAHA procedure was performed, on a 5-year-old boy with Goldenhaar syndrome and hemifacial microsomia, whose calvarium was thinner than 2.5 mm. A 3 mm fixture was implanted and the second stage deferred for 8 months with no complications.

The BAHA system reliably restores hearing to near the bone conduction line,[18] and the transducer is adjusted to maximal efficacy. A postoperative BAHA soundfield audiogram essentially only reflects the amplification setting of the device. Accordingly, all patients who receive postoperative audiograms achieved closure of the air-bone gap to within 10 dB (data not shown). The efficacy of BAHA for auditory rehabilitation has been convincingly established in several large series.[2,4,19]

BAHA surgery is not complication-free, however, and a significant portion of patients will require revision surgery for either fixture loss or skin overgrowth. We advocate routine placement of a spare or "sleeper" fixture at the time of surgery, to be held in reserve in the event of fixture loss. In adults, if needed, the spare fixture can usually be exteriorized in the office. We are in the process of obtaining data for a cost analysis to compare routine placement of a "sleeper" fixture to as-needed insertion of a new fixture in the operating room in the event of fixture or fixture/abutment loss.

A recent outcomes and cost-effectiveness comparison between BAHA and atresiaplasty was reported by Evans and Kazahaya.[18] In this series of patients treated at the same institution (a major urban medical center, Children's Hospital of Philadelphia), BAHA patients achieved mean hearing gain of 31.8 dB, compared to 17.7 dB in atresiaplasty patients. Mean postoperative soundfield air conduction threshold was 17.5 dB in BAHA patients and 31.6 dB in atresiaplasty patients. In 2006, the total cost (operating room fees, surgeon's and anesthesiologist's fees, and postoperative clinical care fees) at the authors' home institution of an uncomplicated single-stage BAHA placement with 1 year of postoperative follow-up was estimated at $28,341, compared with $42,449 for 2-stage BAHA, and $51,505 for atresia surgery.

Any retrospective study of this type may potentially underestimate complication rates because complications can occur after the results are tabulated. This study should be interpreted in the context of 26.9 months mean follow-up. In addition, especially in an active pediatric population, there are likely to be minor skin irritations and abrasions that are self-treated by the patient or parents which are never reported to the physician.

Nevertheless, our results do support the feasibility and safety of single-stage surgery in children with thin calvaria, even if only a 3 mm fixture can be accommodated. Our complication rate was actually higher in the adult group. To

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some degree, we attribute our higher success in children to a high percentage of patients with microtia. Their parents were accustomed to caring for the reconstructed auricle and were more likely to provide meticulous wound care to the titanium abutment and skin graft. Our results suggest that with appropriate wound care and hygiene, a low rate of skin and implant complications can be attained with single-stage surgery.

Single-stage surgery allows for more efficient hearing rehabilitation in the appropriately selected patient. It obviates the need for second-stage surgery with its attendant anesthetic exposure, and time and financial costs for patients, families, and the health care system. If the processor is provided at 4 months postimplantation, single-stage surgery also slightly shortens the critical period of hearing loss in school-age children.

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AUTHOR CONTRIBUTIONS

Darius Kohan, study design, writer; **Luc GT Morris,** study design, data collection, statistical analysis, writer; **Thomas Romo III,** study design, supervision.

FINANCIAL DISCLOSURE

None.

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APPENDIX 13

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Main Article

Updated surgical experience with bone-anchored hearing aids in children

S Lloyd, J Almeyda, K S Sirimanna, D M Albert, C M Bailey

Abstract

Background: We present the results of a retrospective review of children undergoing implantation with bone-anchored hearing aids (BAHAs) at the Great Ormond Street Hospital for Children.

Methods: The case notes of 71 children undergoing BAHA placement at the Great Ormond Street Hospital for Children between December 1990 and August 2002 were reviewed. Outcome measures included hearing thresholds, incidence of fixture loss, skin reaction and need for revision. Quality of life outcomes were also measured.

Results: Eighty-five ears had been implanted. Fifty-four per cent of children had experienced no complications, 42 per cent had required revision surgery and 26 per cent had experienced fixture loss at some point. Young age at implantation was associated with an adverse outcome. Trauma and failure of osseointegration had been the commonest reasons for failure. A skin reaction around the abutment had occurred at some point in 37 per cent of children but had persisted for longer than six months in only 9 per cent; this had been associated with fixture loss. The use of fixture site split skin grafts had reduced problems with skin hypertrophy and hair overgrowth. Hearing thresholds when using BAHAs had been comparable to those when using bone conduction hearing aids. However, BAHAs had significant additional benefits in terms of sound quality, ease of use and overall quality of life.

Conclusion: Bone-anchored hearing aids provide significant benefits over other types of hearing aid, both audiologically and in terms of quality of life. Careful selection of candidates and meticulous follow up are required in order to minimize complications.

Key words: Implants and Prostheses; Otological Surgical Procedures; Hearing Aids; Children

Introduction

It is now over 25 years since the introduction of extra-oral, osseointegrated implantation.[1] Over this period, the technique has become widely accepted as the 'gold standard' for management of conductive hearing loss in patients with microtia, using bone-anchored hearing aids (BAHAs). The technique may also be used to treat other forms of conductive hearing loss (for example, otosclerosis or active chronic otitis media) when more traditional methods of hearing rehabilitation have failed.[2] Similarly, placement of osseointegrated fixtures has become one of the techniques used for prosthetic reconstruction in a number of locations in the head and neck region, not least the external ear.

The technique relies upon the propensity of titanium to become firmly bonded to bone, as well as its resistance to corrosion and non-toxicity.[3] The presence of a stable cutaneous–implant interface is also important. In particular, a thin, firmly attached, hair-free skin border around the implant is vital for success.[4]

The benefits of BAHAs over traditional bone-conduction hearing aids have been well documented.[5,6] Benefits include improved sound quality, reduced discomfort and improved cosmesis.[7,8] These benefits are particularly pertinent to the paediatric population. It has become evident, however, that this particular group of patients has specific requirements regarding cochlear implantation if long-term success is to be achieved.[9–13]

In 1997, our centre published results for the first 32 children undergoing placement of BAHAs at the Great Ormond Street Hospital For Children.[9] Since then, many more children have undergone implantation. This paper presents the more recent experience of BAHA implantation at our centre, which has a purely paediatric caseload.

Materials and methods

Local ethical committee approval was obtained prior to commencement of this study.

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All children who had undergone BAHA fitting between December 1990 and August 2002 were identified from the databases of the departments of otolaryngology and audiology. This included those who had been involved in the previous study.

The case notes for each child were reviewed. The following background information was recorded: date of birth, sex, indications for BAHA, associated medical conditions, associated craniofacial abnormalities, previous hearing aid use and requirement for auricular reconstruction. The following information regarding surgical technique was recorded: side, dates at which each stage was performed, grade of surgeon, type of skin graft, number of holes drilled, number of fixtures inserted, length of screw, dural exposure and abutment type. The following audiological data were recorded: type of aid fitted, and pre- and post-operative bone- and air-conduction hearing thresholds at 0.5, 1, 2 and 4 kHz. The duration of follow up was also recorded, together with any relevant complications.

Subsequently, each child was mailed three validated questionnaires examining quality of life (QoL) issues following implantation. These were: the Glasgow children's benefit inventory (a general post-operative QoL instrument); the Glasgow hearing aid difference profile (which measures the change between two different types of hearing aid in terms of: hearing difficulty in certain situations, proportion of time that the hearing aids are used, benefit gained from the new aid compared with the old, and level of satisfaction with the new aid compared with the old); and the Nijmegen BAHA QoL instrument (which measures BAHA-specific QoL issues such as effectiveness of aiding, sound quality, visibility and ease of use). Each child (or parent) was asked to return the questionnaires to the Great Ormond Street Hospital for Children, together with a signed consent form, in a stamped addressed envelope.

The surgical methods used for implantation have been described elsewhere.[1] Each child had undergone a two stage procedure. The first stage had involved insertion of the flange fixture screw. The second stage, several months later, had involved application of a skin graft and insertion of the abutment (which attaches to the screw and allows attachment of an appropriate hearing aid). Entific Medical Systems (Cochlear, Weybridge, UK; previously Nobelpharma Auditory System) hearing aids had been used in all cases. Children had been reviewed at three weeks, three months, six months and every six months thereafter. At follow up, skin reaction around the abutment had been recorded according to Holgers' classification (Table I).[10]

Statistical analysis was carried out when appropriate. The Student *t*-test was used for quantitative data. The chi-square test was used for categorical data.

TABLE I

CLASSIFICATION OF SKIN REACTION[10]

Score	Description
0	No irritation
1	Slight redness
2	Red and moist tissue, no granulation tissue
3	Red and moist tissue with granulation tissue
4	Revision of skin penetration necessary

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Results

During the study period, 41 boys and 30 girls had undergone primary implantation. Fourteen children had also had the opposite ear implanted (secondary implantation) at some point, making a total of 85 ears implanted. Figure 1 illustrates the age distribution of children undergoing primary implantation. The mean age at primary implantation had been 8.7 years (standard deviation (SD) 3.7 years) with a range of 3.6–17.2 years. The mean age at secondary implantation had been 12.1 years (SD 3.0 years). The mean follow-up duration had been 4.5 years (SD 3.4 years). Seventy-nine per cent of stage one and stage two procedures had been performed by the senior authors (DMA and CMB), 19 per cent of stage one and stage two procedures had been performed by senior trainees, and in 2 per cent of cases the operating surgeon had not been documented.

The indications for implantation are shown in Table II. Sixty-one children had had microtia. The majority of these children had had an associated craniofacial abnormality, the most common being Treacher Collins syndrome (mandibulofacial dysostosis). Nine of these children had undergone attempted middle-ear reconstruction prior to receiving their implant. Four of these had suffered on-going, active chronic otitis media. A further eight children had suffered primary, active chronic otitis media.

Fifty-two and 17 ears had had 3 mm and 4 mm fixtures inserted, respectively. The length of the screw had not been recorded for 11 ears. Five ears had had a 3 mm and a 4 mm fixture implanted. In 55 per cent of cases, dura had been exposed at the base of the drill hole. After 1995, each child had undergone insertion of an additional 'sleeper' fixture during the primary procedure. The mean interval between the first and second stages had been 6.8 months (SD 14.1 months). Figure 2

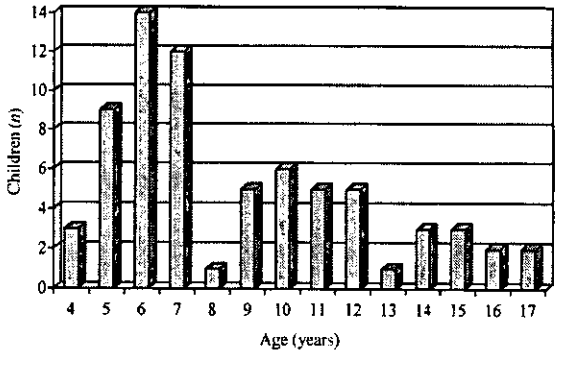

FIG. 1

Distribution of age at primary bone-anchored hearing aid implantation.

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TABLE II

INDICATIONS FOR BAHA INSERTION

Diagnosis	Patients (n)
Microtia	
Treacher Collins	24
Isolated bilateral atresia	22
Cleft lip and palate	4
Goldenhars	4
Pfeiffers	3
Cloverleaf skull	1
Downs	1
Nager	1
18q	1
Active chronic otitis media	
Non-syndromic	2
Klippel Fiel	1
Treacher Collins	1
Branchio-oto-renal	1
Russel–Silver	1
Downs	1
Sticklers	1
Other	
Recurrent otitis externa	1
Ossicular chain fixation	1
Total	71

BAHA = bone-anchored hearing aid

illustrates the types of skin graft used. In latter years, the graft had invariably been obtained by raising a split skin graft from the skin overlying the fixture site.

Table III lists the complications and outcomes experienced. Fifty-four per cent of children had not developed any complications. Forty-two per cent of children had required revision surgery at some point (25 per cent had required a single revision).

Twenty children had experienced fixture loss (22 episodes in total). Nine children in this group had been syndromic, compared with 11 who were non-syndromic. The mean age at implantation in those children experiencing fixture loss had been 7.8 years (SD 4.0 years), compared with a mean age of 9.6 years (SD 3.5 years) in those who had not lost fixtures ($p = 0.05$). Boys made up 70 per cent of those patients experiencing fixture loss, compared with 57 per cent of those who had not lost their fixture. This difference was not statistically significant ($p < 0.1$). Fixture loss had occurred within one year of implantation in 65 per cent of cases. Delayed fixture loss had predominantly resulted from trauma. There was no significant difference in fixture loss rates between children with 3 mm implants and those with 4 mm implants ($p < 0.5$).

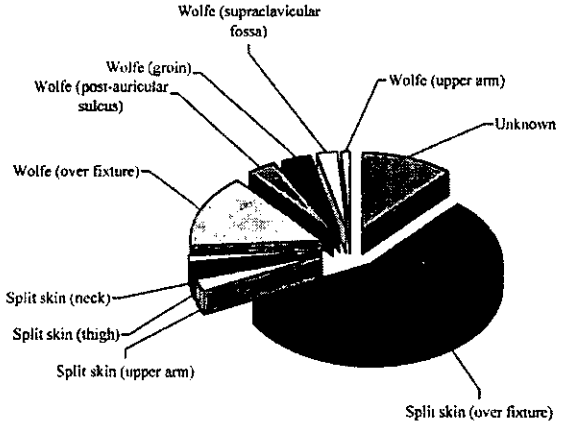

FIG. 2

Types of graft used for stage II bone-anchored hearing aid implantation.

Thirty-seven per cent of children had suffered a skin inflammation scoring two or more at some point during the follow-up period, but 91 per cent of these had settled by the next appointment. There was no significant difference in skin reaction between the different types of skin graft used. However, those children who had had split skin grafts taken from the fixture site were less likely to develop hypertrophy of the graft than those who had had full thickness Wolfe grafts or split skin grafts taken from other areas (11 *vs* 36 per cent, respectively; $p < 0.01$). For both groups, 80 per cent of the children who had developed thickening of the skin graft required revision surgery.

Of those children who had undergone contralateral BAHA insertion after the initial implant: five had been due to the initial BAHA being in an inappropriate position to allow auricular reconstruction or bone-anchored auricular prosthesis placement; two had experienced failed osseointegration on the initial side; three had developed chronic infection around the abutment; two had developed skin and bony overgrowth around the abutment; and one had developed bony overgrowth alone. In one child, the reason for contralateral implantation was not documented.

Three children had subsequently stopped wearing their BAHA. The first child had developed a progressive sensorineural hearing loss which became unaidable with a BAHA. The second child played sport frequently and had found the BAHA a hindrance; he had also undergone two stage two revisions because of skin overgrowth. The third child had been accepted into the programme in its early stages, but, after implantation, he temporarily went back to his air conduction aids and realized that he heard better with them. A single child had undergone implantation but never used an aid because of failed osseointegration.

The children's mean aided thresholds had been 33 dBA before and after implantation. This is higher than one would expect for a population with predominantly conductive hearing loss. The reasons for this are twofold. Firstly, normal or near normal aided thresholds had been recorded as 'threshold < 30 dBA', and these were taken as 30 dBA for this calculation in the majority of notes. Secondly, there had been a number of patients with a mixed hearing loss.

The number of QoL questionnaires returned was extremely low. Thirteen Glasgow children's benefit inventory questionnaires and 12 Glasgow hearing aid difference profile questionnaires were returned. Eleven Nijmegen BAHA QoL questionnaires were returned. This represented a response rate of 16.9 per cent.

With regard to the Glasgow hearing aid difference profile, nine children had noticed a reduction in

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TABLE III

COMPLICATIONS OF BAHA IMPLANTATION*

	Loose abutment	Loss of abutment	Loss of fixture	Bony overgrowth	Skin overgrowth	Hair growth
n	25	15	22	12	22	2
Mean onset (months)	22.6	11.3	25.5	62.5	45.1	22.0
Median onset (months)	12.0	10.0	6.0	56.5	35.0	1
Range of onset (months)	2–99	2–27	2–62	4–96	2–104	1–38
SD (months)	25.9	9.2	31.9	40.9	37.9	26.2
Reason						
Unknown	1	0	5	NA	NA	NA
None	19	1	3	NA	NA	NA
Trauma	2	8	5	NA	NA	NA
Infection	3	6	3	NA	NA	NA
Failed OI	NA	NA	6	NA	NA	NA
Outcome						
Abutment tightened	25	NA	NA	NA	NA	NA
Revision stage II	0	15	NA	6	13	2
BAHA resited	NA	0	13	0	1	0
BAHA opposite ear	NA	0	3	4	3	0
Awaiting revision	0	0	5	1	3	0
No intervention	0	0	1	1	2	0

*$n = 85$. SD = standard deviation; OI = osseointegration; NA = not applicable; BAHA = bone-anchored hearing aid

hearing difficulty, comparing their BAHA with a bone conduction hearing aid (significant at the 0.01 level). There had also been an increase in the amount of time the BAHA was used, compared with the bone conduction hearing aid (significant at the 0.01 level). Nine of the children wore their BAHA all the time, compared with six children who wore their bone conduction hearing aid constantly. The other three children used their BAHA more than three-quarters of the time. Two children who had worn their bone conduction hearing aid less than a quarter of the time went on to wear their BAHA constantly. Ten of the children reported an overall benefit from the BAHA compared with the bone conduction hearing aid. Similarly, 10 children reported that they were more satisfied with the BAHA than with the bone conduction hearing aid.

Of the 10 children returning the Nijmegan questionnaire, almost all reported that their BAHA was more effective in quiet and noisy environments than their bone conduction hearing aid. The BAHAs also provided better sound quality, were less visible and were easier to handle than bone conduction hearing aids. The improvement in sound quality was regarded as the most important benefit. Four children with chronically discharging ears noticed an improvement in the amount of discharge. Only four of the children regarded cleaning the BAHA abutment site as a burden.

Regarding the Glasgow children's benefit inventory, almost none of the children reported a worsening of QoL following BAHA insertion. Many of the children reported that their QoL was much better following BAHA insertion. This was particularly true for the following domains: overall QoL, progress and development, and learning.

Discussion

The majority of children in this series had undergone successful insertion of their BAHA. Fifty-four per cent had experienced no difficulties during the post-implantation follow-up period. The vast majority of those who had developed complications required revision surgery at some point.

Twenty-eight per cent of children required re-implantation because of fixture loss. This figure is higher than that reported by most other published paediatric series (Table IV), despite the staged insertion process.[10–16] A number of series included children who had both BAHA and bone-anchored auricular prostheses, and it was not possible to separate the data for these two groups in some. However, in those series in which the BAHA data were presented separately, the overall trend was towards a lower fixture loss rate in the bone-anchored auricular prosthesis patients compared with the BAHA patients. The overall fixture loss rates were therefore skewed. Once this was taken into account, a number of series had results that were broadly similar to those of the present series.

The lower fixture loss rates in the bone-anchored auricular prosthesis population may be because these devices are not subject to the severe vibratory loading that the BAHA fixtures are subject to.

TABLE IV

COMPARISON OF BAHA FIXTURE LOSS IN PUBLISHED PAEDIATRIC POPULATIONS

Author	Year	Fixture loss (%)	Population (*n*)
Jacobsson *et al.*[15]	1992	6	16
Stevenson *et al.*[16]	1993	29	7
Papsin *et al.*[9]	1997	15	32
Béjar-Solar *et al.*[11]	2000	9	11
Tietze & Papsin[12]	2001	5	19
Granstrom *et al.*[13]	2001	10*	100
Zeitoun *et al.*[14]	2002	20	31

*Bone-anchored hearing aids (BAHAs) and bone-anchored auricular prostheses; no specific BAHA figures.

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Fixture loss did not appear to be related to syndromic status or to the sex of the child. However, the age of the child at primary implantation was important, with those implanted at a younger age being more likely to lose their implant than older children.

The age distribution of the present study population was similar to that of other published paediatric BAHA populations.[10–16] However, a number of units implant children as young as two years. This department does not implant children younger than four years of age because of the increased risk of fixture loss in younger children.

In contrast with other series, the length of the fixture screw did not appear to affect the rate of fixture loss.[17] However, shallow cortical bone thickness has previously been shown to result in a higher probability of fixture loss. In this population, the high proportion of patients with exposed dura at the base of the drill hole reflected the high number of children with thin cortical bone. This may have contributed to the high rate of fixture loss. Occasionally, a child may have undergone prior computerized tomography of the skull, and, in these cases, the imaging can be used to assess cortical bone thickness. However, bone thickness measured by this technique is a poor reflection of actual bone thickness encountered intra-operatively. A bone augmentation technique has been described by Granström and Tjellström.[18] In this procedure, an Expanded-polytetrafluoroethylene (e-PTFE) membrane is placed under the flange of the fixture in order to stimulate bone growth.

All but one of the children whose fixtures had failed to osseointegrate had had stage one of their surgery performed by the senior authors.

This study did not examine the behavioural aspects of the population, but these may play a significant role in fixture survival.

Further research to produce more robust aids and implants may reduce the number of fixtures lost due to trauma. In this series, this was a significant cause of delayed fixture loss.

The high rate of fixture loss in this population highlights the importance of inserting a reserve ('sleeper') fixture during the first stage of BAHA insertion.

It should be noted that some series in the literature do not show any benefit from staged implantation.[17] In view of this, and in view of the lower failure rate in the older age group, there is an argument for single-stage implantation in older children who would accept a 4 mm fixture.

The rates of peri-abutment skin reactions seen in this series compare favourably with those in other published series.[10–16] The development of such a reaction does not appear to be related to the type of graft used. However, children who had split skin grafts from the fixture site, as described by Woolford *et al.*,[19] showed a lower propensity for skin hypertrophy compared with children who had other graft types. This may relate to difficulties in the thinning or depilation of Wolfe grafts. Local split skin grafts also have the clear advantage of no donor site morbidity.

The hearing thresholds obtained with the BAHA were not significantly different to those obtained with a bone conduction hearing aid, but this may reflect the method of documentation used in our department. However, the literature has shown a 10–20 dB additional benefit with BAHAs compared with bone conduction hearing aids.[5,20] In addition, there is strong evidence that the hearing threshold itself is only one of several aspects important in hearing rehabilitation. For example, improved sound quality, comfort, ease of use and aesthetics are all proven benefits of BAHAs compared with bone conduction hearing aids.[7,8] They also have an impact on overall quality of life.[21]

The broader benefits of BAHAs over more traditional aids, particularly quality of life issues, were addressed by this study, although the poor response rate to the questionnaires makes it difficult to draw useful conclusions regarding these issues. However, for those children returning questionnaires, it is clear that BAHAs have significant hearing benefits over bone conduction hearing aids. Bone-anchored hearing aids not only produced more effective amplification but also improved speech recognition, sound quality and ease of use.

- **This paper presents the results of a retrospective review of children undergoing implantation with bone-anchored hearing aids at the Great Ormond Street Hospital for Children**
- **Outcome measures included hearing thresholds, incidence of fixture loss, skin reaction and need for revision**
- **Young age at implantation was associated with an adverse outcome. Trauma and failure of osseointegration were the commonest reasons for failure**
- **Bone-anchored hearing aids provide significant benefits, compared with other types of hearing aid, both audiologically and in terms of quality of life. Careful selection of candidates and meticulous follow up are required to minimize complications**

Importantly, respondents universally preferred the BAHA to the bone conduction hearing aid, and this was reflected in an increase in the amount of time the children wore their BAHA. Some useful suggestions were made by respondents, including production of a waterproof version of the BAHA and of a smaller, slimmer aid which would be less prone to knocks. Further prospective data collection would be useful in the assessment of these issues. Despite the poor questionnaire response rate, it was clear from the follow-up data that almost all respondents continued to use their aids even following revision surgery, and this is undoubtedly a reflection of the benefits obtained from BAHAs.

Bone-anchored hearing aid surgery clearly benefits children with certain types of conductive

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hearing loss, but careful patient selection is vital, as is the age at which implantation is performed. Similarly, recent modifications to the surgical technique and to the implants themselves have led to better outcomes and greater ease of use. In particular, the use of split skin grafts from the fixture site and the change from the bayonet to the snap coupling abutment have been particularly beneficial. However, regular and on-going care of BAHAs is of the utmost importance, not only by hospital staff but by the children and their parents. Similarly, rigorous follow up of patients is paramount to enable early identification and correction of problems.

Conclusions

Bone-anchored hearing aids are a safe and effective way of rehabilitating hearing for patients who are unable to use traditional hearing aids. However, implantation in the paediatric population requires careful consideration if results are to be optimized.

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APPENDIX 14

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The bone-anchored hearing aid in children: A surgical and questionnaire follow-up study

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OBJECTIVES: **The main objectives were to evaluate the surgical techniques and problems seen in children with bone-anchored hearing aids (BAHA) as well as to determine the children's attitudes toward BAHA.**

STUDY DESIGN: **A retrospective study of 41 children with unilateral BAHA was conducted. Surgical recordings were investigated and a questionnaire was distributed.**

RESULTS: **Surgery was performed as a 2-stage procedure. Available bone thickness was measured in 29 patients and found to be on average 2.5 mm. Thin temporal bone necessitated bone augmentation in 8 patients. Of the implants, 70.5% were installed in contact with the dura or the sigmoid sinus. Implant failures were seen in 9.1% and adverse skin reactions appeared in 7.6% of the patients. Twenty-seven patients responded to the questionnaire, 19 were still BAHA users. Overall, these patients were very content with their BAHAs.**

CONCLUSION: **BAHA is a good alternative in children despite limited thickness of the temporal bone.** (Otolaryngol Head Neck Surg 2005;132: 559-565.)

In 1977, a new technique to establish bone-anchored hearing aids (BAHAs) by use of osseointegrated implants was developed in Gothenburg, Sweden.[1] The aim was to improve the rehabilitation of patients with conductive type of hearing loss. This technique has now been in use in both adults and children for more than 26 years. According to the manufacturer's information, more than 15,000 patients worldwide are fitted with unilateral BAHA today, most of these adult patients. BAHA is used in adults with chronic suppurative middle ear infections or recurrent infections in the external auditory meatus, which enable them to use conventional air conduction aids placed altogether or partly in the ear canal. In children, however, the most common reason for receiving a BAHA is congenital ear malformations in which the BAHA replaces a conventional bone conductor (CBC).

Congenital malformation of the ear with impaired hearing early in life can cause problems later in life with social integration due to impaired ability to learn speech and language. This in turn greatly influences the individual in his or her choice of education and work in the future. Surgical reconstruction of the congenital malformation of the ear is difficult and the results are often poor.[2-5] Before deciding on reconstructive middle ear surgery, the child is thus supplied with a bone conductor. The CBC works by pressing a steel band with the hearing device to the temporal bone. The use of CBCs has some important disadvantages such as discomfort due to the high pressure needed to maintain contact between the conductor and the mastoid, poor sound quality, and esthetic disadvantages in wearing a highly visible aid that is usually headband-mounted.

During the years 1978-1999, 41 children were fitted with BAHA in Gothenburg. The objective of this study was to achieve more specific information about what problems there are in a population of younger patients. This group is known to have a soft and immature bone, appositional growth of the temporal bone, skin overgrowth of the abutments, and cleaning problems in adolescence. A closer follow-up and control of this patient population is especially important with respect to the long-term results. Another aspect of this study was to determine the children's attitude toward the BAHA and to decide to what extent they use the device today.

MATERIALS AND METHODS

Surgical Recordings

All children (aged 16 years or younger) who had osseointegrated implants inserted for rehabilitation with a BAHA between 1978 and 1999 were retrospectively evaluated regarding implant surgery. Age at sur-

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gery, age at follow-up, gender, type of malformation, and syndromic belonging were investigated. Indications for insertion of osseointegrated implants, number of inserted implants, number of surgical procedures, bone thickness, and specific surgical problems at the site of implantation were studied. The surgical procedure was generally performed in 2 steps, as described by Tjellström,[6] and involved gentle handling of the soft tissue and bone. At the first-stage operation, the skin over the implant site was incised, continuing through the subcutaneous tissue and periosteum. A hole was drilled in the temporal line, 55 mm behind and 30 mm above the external ear canal under profuse irrigation with saline solution. Into this hole, a 3.75-mm diameter threaded flange fixture of 3 or 4 mm length (SEC 001, SEC 002; Entific Medical Co., Gothenburg, Sweden) was inserted. The bone thickness was measured peroperatively in 29 of the included patients with a millimeter-graded dental probe. In children with limited bone thickness, bone augmentation was undertaken with expanded, polytetrafluoroethylene membranes (standard e-PTFE membranes; OV4, OV6, Gore & Associates AB WL, Mölndal, Sweden) as described earlier.[7] The soft tissue was thereafter sutured and the implant was allowed to integrate in the bone for a period of 3 to 4 months. At the second-stage operation, standard titanium abutments for the BAHA (SHCB 179; Entific Medical Co.) were adapted on the fixtures and the skin penetration prepared as described earlier.[6] Two to 3 weeks after the second operation, the patients were fitted with the hearing aid (HC 200, 300 or 360, Entific Medical Co.). The patients were seen in the outpatient clinic at follow-up periods at 3- to 6-month intervals, stability of the implants was checked and the skin penetration site cleaned and adjusted. Skin reactions around the implants were classified according to the clinical scoring system of Holgers et al,[8] where 0 = no irritation, 1 = slight redness, 2 = red and moist, 3 = as in 2 but also granulation tissue formed, and 4 = skin irritation of such a degree that the abutment has to be removed.

Questionnaire Study

Of the 41 children supplied with a BAHA, 31 could be traced for a follow-up questionnaire. The questionnaire was answered by the children themselves, if they were old enough (>8 years); otherwise, they were helped by their parents to answer the questions. The questionnaire consisted of 24 questions to evaluate the children's opinion and usage of the BAHA (Table 1). The children were asked what types of BAHA they have been wearing and what kind of BAHA they used at the time of the questionnaire and to what extent. The children were asked about the use of other types of hearing devices, e.g., alarm clocks. They also evaluated the function and sound quality of the BAHA in different situations. Questions about skin infections and problems with osseointegration of the titanium implant and with the abutment were asked. The patients also answered if they are content with the availability of the doctor if needed and the possibility of service of the BAHA if broken. They were encouraged to comment on failures in the rehabilitation and suggest improvements.

Table 1. The questionnaire. All subjects who participated in the study were Swedish citizens. The questions were sent out in the Swedish language. The interpretations of the questions are presented here.

1. What type of BAHA are you using today?
2. Did you use a conventional air conduction hearing aid before?
3. Did you use a conventional bone conduction hearing aid before?
4. Do you use any other hearing devices?
5. For how long have you had your titanium implant?
6. How many different kinds of BAHA have you tried?
7. How many days per week do you use your BAHA?
8. How many hours per day do you use your BAHA?
9. How often do you change the batteries?
10. Try to describe your feelings about the BAHA concept on a tenth grade scale 1 is very content and 10 is very discontent.
11. How would you rate your BAHA in following situations, scored in following way: very satisfactory, quite satisfactory, passable, not very satisfactory, and very unsatisfactory.
    A. Listen to a teacher in quiet surroundings
    B. During conversation with one or many persons in quiet surroundings
    C. Listen to a teacher in noisy surroundings
    D. During conversation with one or many persons in noisy surroundings
    E. Listen to music
    F. Listen to the TV/radio
    G. Phoning
12. Has your language changed after you got your BAHA?
13. Does it trouble you to have an implant through your skin?
14. Have you had skin infection by the implant site?
15. Have you needed surgery because of skin infection?
16. Have you been treated in any other way because of skin infection?
17. Is cleaning hard?
18. How often do you clean around the implant site?
19. Has the osseointegration ever failed?
20. Have you needed another titanium implant installed?
21. Has the abutment ever loosened?
22. Are you able to replace the plastic part yourself?
23. Do you feel that you have had the contact that you think necessary with your treating doctor?
24. Do you get the service you need for your device?

BAHA, bone-anchored hearing aid.

Statistics

The Fisher's exact test has been used in this study.

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RESULTS

There were 41 patients included in the study of which 25 were boys and 16 were girls. The most common reason to supply the children with unilateral BAHA was different types of bilateral malformation of the ear, often as a part of a syndrome. Five patients had malformation of the ear combined with other malformations such as malformation of the heart, oesophagus atresia, syndactylia, renal aplasia, and anal atresia. Of the patients, 38 had bilateral ear symptoms, and 3 patients had unilateral symptoms. Age of the patients at the time of surgery was on average 8.4 ± 4.6 years (mean ± SD). Age at follow-up varied from 2 to 37 years, mean 14.8 ± 8.3 years (mean ± SD). Two patients were supplied with bilateral BAHAs, whereas the other patients had unilateral BAHA. Eight patients had the combination of BAHA and bilateral bone anchored episthesis (BAE), and 1 patient had BAHA and unilateral BAE. The right side of the skull was generally chosen for BAHA installation (n = 26), whereas 13 had the BAHA installed on the left side. Further details of the patients are shown in Table 2.

Surgical Recordings

A total of 44 implants were inserted. All implants were of the Brånemark type, of which 20 were 3 mm long, 20 were 4 mm long, and 4 had an unknown length. All implants were inserted in the parietal or temporal bone. In 29 patients, the bone thickness was measured during surgery and was found to vary from 1 to 4 mm, mean 2.5 ± 0.8 mm (mean + SD; Fig 1). In 24 of the 44 drilled holes (54.5%), the implants were in contact with the dura and in 7 of 44 (16%) the implants were in contact with the sigmoid sinus. In no case was the dura or the sinus injured during surgery. 39 of the operations were performed as a two-stage procedure. The time from first- to second-stage surgery varied from 3 to 13 months, with a mean of 4.9 ± 2.0 months (mean ± SD). Three operations were performed as a 1-stage procedure. Eight patients had bone augmentation because of limited bone thickness at first stage (<2.5-mm bone). At the second-stage surgery, available bone had increased by 1.2 ± 0.3 mm (mean ± SD). Unilateral BAHA wearers received 1 standard abutment. During the observation time of 21 years, 4 implants were lost (9.1%). These were lost after 3 weeks (1), 1 year (2), and 2 years (1), and none were lost later. All the lost implants were 3 mm long. The bone thickness was only measured peroperatively in 1 of the patients who lost his implant and found to be 3 mm. None of the patients with lost implants had undergone bone augmentation due to limited bone thickness. Skin reactions were documented at the patient's follow-up visits under a 21-year period of time. 92.4% of 539 observations were completely reaction free (grade 0). Adverse reactions were seen in 41 instances, of which 4.0% were of grade 1, 1.8% were of grade 2, and 1.6% were of grade 3. The incidence of adverse reactions was distributed evenly over the follow-up period.

Revision surgery was undertaken in seven patients (17.1%). The reason for revision was a shorter distance between the skin surface and the abutment. Subcutaneous tissue reductions were undertaken, and excess bone growing on the implant and abutment was reduced. No revisions were necessary in children earlier than two years after implant installation.

Questionnaire Study

The questionnaire was distributed by mail to 31 patients out of 41. Ten patients were excluded from the questionnaire study, 4 of whom did not speak Swedish as their natural language and 6 of whom had an unknown address. Of the 31 included patients, there was a total of 27 responders (87%) to the questionnaire. Of the responders, 23 replied by mail and 4 were interviewed on the telephone. Of the responders, 15 were male and 12 were female. The responders ages varied between 2 and 37 years of age at the time of the evaluation and the younger (<8 years) patients had help by their parents to answer the questionnaire.

Eight of the respondents did not use the BAHA at the time of the questionnaire survey. In 4 of these patients, the reasons for not using BAHA were related to implant failures. One of the patients had reconstructive surgery done, thus the patient is no longer in need of a hearing aid. One child was supplied with a BAHA for relapsing external ear canal infection. The disease has now healed and the child wears a conventional air conductive device. One child was not yet fitted with the BAHA at the time of the study but is osseointegrated for fitting later, and, finally, 1 child complained of acoustic feedback from the BAHA. The remaining 19 respondents use their BAHAs regularly. Of these, 18 use their BAHA daily and 1 patient uses it 5 to 6 days per week. Most of the children use their aid 8 to 15 hours daily (12 patients), 6 patients use it more than 15 hours daily, and 1 patient uses it 4 to 8 hours daily. Battery consumption varies greatly, and the patients change batteries from once a week to once every 2 months.

Of the children using BAHA, 15 had used a conventional bone conduction hearing aid before and 2 had been wearing a conventional air conduction hearing aid. One patient had been wearing an air as well as a bone conduction hearing aid before and 1 patient did not answer the question. On the whole, the children

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Table 2. Data on the included patients

No.	Sex	Age (y)	Diagnosis	Type of malformation	Syndrome
1	F	1.5	COM		
2	M	5	EM	Microtia + ear canal atresia	Treacher Collins
3	M	3	EM	Microtia + ear canal stenosis	Otorenal syndrome
4	F	2	EM	Microtia + ear canal atresia	
5	M	2	EM	Ear canal stenosis	
6	M	5	COM		
7	M	13	EM	Microtia + ear canal atresia	Treacher Collins
8	F	13	EM	Microtia + ear canal atresia	Treacher Collins
9	F	4	EM	Ear canal atresia	
10	M	15	EO		
11	F	4	EM	Microtia + ear canal atresia	Treacher Collins
12	M	11	EM	Microtia + ear canal atresia	Hemifacial microsomi, esophagus + colonatresia, renal aplasia
13	M	10	EM	Ear canal atresia	
14	M	6	EM	Middle ear malformation	Treacher Collins
15	F	1.5	EM	Microtia + ear canal atresia	Treacher Collins
16	F	4	EM	Microtia + ear canal atresia	
17	F	7	EM	Microtia + ear canal atresia	
18	F	12	EM	Microtia + ear canal atresia	
19	M	10	EM	Microtia + ear canal atresia	Treacher Collins
20	F	13	EM	Microtia + ear canal atresia	Treacher Collins
21	M	13	EM	Microtia + ear canal atresia	
22	M	2	EM	Microtia + ear canal atresia	Treacher Collins
23	F	11	EM	Ear canal atresia	
24	F	16	EM	Microtia + ear canal atresia	Thalomid embryopathy
25	F	4	EM	Microtia + ear canal atresia	Syndactylia
26	M	11	COM		Hunters
27	M	6	EM	Microtia + ear canal atresia	Diabetes embryopathy
28	M	3	EM	Ear canal atresia	Crouzon
29	M	5	EM	Ear canal stenosis	Pfieffer
30	F	7	EM	Middle ear malformation	
31	M	4.5	EM	Ear canal atresia	Crouzon
32	M	6	EM	Microtia + ear canal atresia	Esophagus + analatresia, heart + renal malformation
33	M	5	EM	Microtia	
34	M	10	EM	Microtia + ear canal atresia	Treacher Collins
35	M	12	EM	Microtia + ear canal atresia	
36	M	9	EM	Microtia + ear canal atresia	
37	F	5	COM		
38	M	15	COM		
39	M	3	EM	Ear canal atresia	Pfeiffer
40	M	15	EM	Microtia + ear canal atresia	Treacher Collins
41	F	7	EM	Microtia + ear canal atresia	Treacher Collins

F, female; *M*, male; *Age*, age at the time of operation; *COM*, chronic otitis media; *EO*, recurrent ear canal infection; *EM*, ear malformation.

seem very content with their BAHAs, even though they feel that the function of the BAHA varies in different situations (Fig 2). One of the questions asked was if the patients avoided using the BAHA in any situation and the most common responses were that they avoid using their BAHA in very noisy environments, when wearing a hat, or when practicing sports, especially swimming. Of the BAHA users, 12 patients or their parents think their language has improved, whereas 7 patients think it is unchanged after being fitted with BAHA.

In the questionnaire there were questions included regarding complications with BAHA. The most common problem was skin infection around the implant site and that had occurred in 13 of the patients. The infection was treated surgically in 3 cases and medically in 8 cases with different kinds of antibiotics locally or/and systemically. A way to avoid infections is to clean often around the implant site and 14 of the patients clean daily, although 5 patients think cleaning is hard. Three of the patients also find it hard to have an implant

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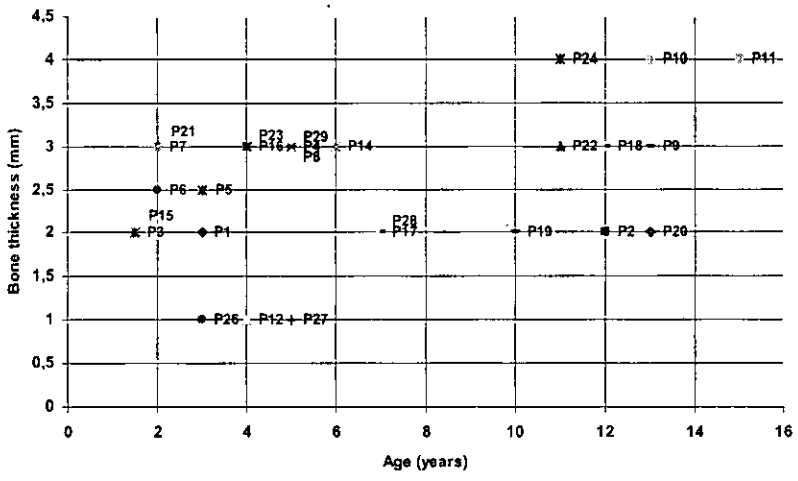

Fig 1. The measured temporal bone thickness in 29 of the BAHA fitted children (P1–P29). The bone thickness increases in general with increased age in patients even though differences occur especially in syndromic patients. Each patient was measured only once with a millimeter-graded dental probe during first stage surgery for BAHA.

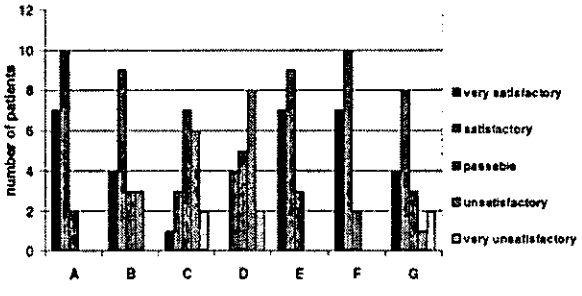

Fig 2. The children's opinions of the BAHA in different listening environments. (*A*) Listening to a teacher in quiet surroundings. (*B*) Conversation with one or many persons in quite surroundings. (*C*) Listening to a teacher in noisy surroundings. (*D*) Conversation with one or many persons in noisy surroundings. (*E*) Listening to music. (*F*) Listening to the TV/radio. (*G*) Phoning.

penetrating the skin mostly because hairs get stuck in the abutment. Another complication is loosening of the abutment, which has occurred in 5 of the patients. One patient even lost his titanium implant due to a trauma and has been reoperated.

The patients also evaluated if their contact with the center supplying the BAHA was satisfactory. Of the patients, 17 felt they had the contact they needed with the treating doctor and 15 of the patients were also pleased with the service contact if there was trouble with the device.

The patients were also encouraged to write down any other opinion they had about BAHA and what could be changed to make it function even better. The most frequent comment was that it was hard wearing a hat or helmet when using a BAHA because of acoustic feedback. Some patients also commented on the service, that they could not get the spare parts they needed when required.

DISCUSSION

The first child we implanted was a 13-year-old girl with Treacher Collins syndrome (mandibulofacial dysostosis). Before the implantation, she had undergone multiple-staged surgeries for ear canal and middle ear reconstruction with poor hearing results. She had worn a CBC during childhood and was able to compare the sound of the CBC with the BAHA. The implantation was successful. She still uses the same fixture that was implanted 25 years ago, has had 1 revision surgery because of skin overgrowth, and has tested 6 different types of BAHAs. At the age of 38, she is still a satisfied BAHA user.

In earlier studies, we compared the BAHA with reconstructive middle-ear surgery as well as conventional types of bone-conduction hearing aids.[3,5] It seems that persons with severe ear malformations are more difficult to reconstruct by ear canal and middle ear surgery. These would be mainly the syndromic patients, which are rated 5 to 6 according to the Jahrsdoerfer scale.[2] Especially in these syndromic children with bilateral ear malformations, the BAHA has been proven to be useful.[3,5] Reports from other centers of the world using the osseointegration concept for hearing rehabilitation are similarly positive.[9,10]

Based on the positive experience from adolescent BAHA users,[11] we have therefore gradually implanted younger children, not knowing the lowest age limit for osseointegration surgery. A careful selection procedure has been an important tool to choose the appropriate time for implantation. Parents of children with ear malformations have met with other patients who were already

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implanted, for information, exchange of opinions and decision according to a protocol described.[12] All children implanted were previously supplied with conventional bone conductors from early childhood, CT scanning of the temporal bone was performed preoperatively, and audiometry and brain stem evaluation was used to evaluate the cochlear function. Still, most parents needed a long time to come to a decision regarding implant surgery, often 2-4 years. Actually, those children implanted at one-year of age were all children to parents who themselves already were BAHA-wearers; i.e. children of hereditary syndromic patients. It is otherwise our opinion that implantation in this very young age group should be restricted, and the most suitable period for BAHA implantation would be at 2 to 4 years of age. Most commonly, the right side of the skull was chosen for implantation. Reasons for choosing the left side was related to the cochlear function of the ears, lack of bone available on the right side, or the patient's preference. The surgery was mostly carried out as a 2-stage procedure, although in 3 cases the surgery was performed as a 1-stage procedure. The youngest child in this series who had a 1-stage procedure lost his implant during follow-up. After this incident, we have not performed 1-stage surgeries in younger patients. In 2 patients 3-stage surgeries were performed because the amount of bone at the first stage was too limited. A grafting procedure was then undertaken, and implant surgery was postponed.

Implant failures were relatively low at only 4 of 44 (9.1%). All of the lost implants were 3 mm long, which proposes a better survival of the longer fixtures even though it is not significant according to Fisher's exact test ($P = 0.1060$). This is in accordance with implant failures in adults[13] but slightly higher with earlier reports from us on children.[14,15] Even higher implant failures in the pediatric population have been reported.[10] In this study, however, there were several losses due to trauma as well. Several of our patients have had traumatic incidents, but very few to such a degree that the fixtures were lost. Adverse skin reactions in this young material were also of the same magnitude as in the older group.[13] Earlier reports show a tendency that patients with bone-anchored ear prostheses score higher than BAHA wearers,[16] which could be explained by easier cleaning properties of just using one abutment.[14]

The thickness of the temporal bone is critical for implant integration but could be well recorded during implant surgery. If a 3-mm long fixture should be inserted, a minimum of 2.5 mm of temporal bone would be needed. This temporal bone thickness was the mean of the measured temporal bones of 29 patients. In patients younger than 4 years of age, the temporal bone thickness is often reduced[14] and one must, as a surgeon, be aware that precautions must be taken to use bone augmentation to be able to install an implant properly. We have described such a bone-augmentation technique.[7] With e-PTFE membranes, appositional bone can be directed to grow under the flange of the fixture. The technique seems promising because it can be made together with standard fixture and abutment placement, and does not change therapy planning. It is our opinion that BAHA can be used also in children despite a limited bone thickness of the temporal bone.

A questionnaire was included in the study to evaluate the children's opinion and usage of the BAHA. Generally the children seemed very content with the BAHA and used it most of their awake time. The BAHA seemed to work better in quiet surroundings than in noisy surroundings, as do most hearing aids. Most children thought it worked quite satisfactory or very satisfactory while listening to a teacher in a quiet surrounding and while listening to music or the TV/radio. Most of the patients also thought it worked quite satisfactorily or very satisfactorily while phoning, although 3 patients commented on that it did not work with cell phones. The device seemed to work less well while listening to a teacher or speaking with one or more persons in a noisy surrounding. The answers to the questions concerning the function of the BAHA varies greatly though from satisfactory to very unsatisfactory between the children. The children though do seem to favor the BAHA in comparison with the CBC.

CONCLUSION

BAHA has the same function pattern, frequency of implant failures, and skin reactions in children as in adults. BAHA should therefore be prescribed to children with maximal conductive hearing loss and good cochlear function otherwise suitable for BAHA.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 15

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Section 07: 510(k) Summary

Records processed under FOIA Request #2013-2881; Released by CDRH on 09-08-2015

510(k) Summary: Otomag Bone Conduction Hearing System

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

Submitter: Sophono, Inc.

Establishment Registration Number: 3008514292

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Date Prepared: July 27, 2010

Name of Device: Otomag Bone Conduction Hearing System

Common Name: Bone Conduction Hearing System

Classification Name: Hearing Aid

Device Classification:

- Classification: II
- Classification Panel: Ear, Nose and Throat
- Regulation Number: 874.3300
- Product Code: LXB

Predicate Device:

Otomag Bone Conduction Hearing System, Unmodified Version – K100193

Xomed Audiant Bone Conductor - K855059 / K861971

Device Description:

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

The Otomag System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag System for individual patient hearing loss.

Technological Characteristics:

The technological characteristics of the version of the Otomag Bone Conduction Hearing System are equivalent to those of the predicate device. Items that are identical between the modified version and the predicate are:

- Overall Device Performance
- Fundamental Technology (bone conduction)
- Software

Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Through non-clinical performance testing and evaluation, the identified technological differences do not raise new questions of safety and effectiveness.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;

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- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patients using the Alpha 1(M) configuration of the device, which utilizes a magnetic implant, should not undergo magnetic resonance imaging (MRI) without having the implant removed prior to scanning.

Performance Standards:

The design of the Otomag Bone Conduction Hearing System conforms to the following voluntary standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
- AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI/ANSI ST8:2008, Hospital steam sterilizers
- AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products – Requirements for products labeled "STERILE"
- AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization
- AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications

Non-Clinical Performance Testing:

The Otomag Bone Conduction Hearing System has been subjected to extensive safety, performance testing, and verification / validation. Testing of the Otomag Bone Conduction Hearing System included various device performance tests and software validation tests designed to ensure

that the device meet all of its functional specifications and is fit for its intended use. Tests have also been performed to ensure the device complies with industry and safety standards. The testing information presented in this submission demonstrates the device's performance is substantially equivalent to the predicate devices.

Conclusion:

Based on the non-clinical performance testing, the modified version of the Otomag Bone Conduction Hearing System is as safe and effective and considered to be substantially equivalent to the predicate Otomag device cleared in K100193 and the Audiant cleared K855059 and K861971 and that the differences between the three devices:

- Do not raise any new issues of safety and effectiveness
- Do not amount to a change in the "fundamental scientific technology" of the device with regard to the Otomag predicate K100193
- Do not present any adverse health effect or safety risks to patients when used as intended.