

OCT 17 2000

K002913

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Entific Medical System summary for the Headband for BAHA.

SUBMITTER'S NAME: Entific Medical System
ADDRESS: P.O. Box 16024
SE-412 21 Göteborg
Sweden
CONTACT PERSON: Constance Bundy
TELEPHONE NUMBER: 612-574-1976
FAX NUMBER: 612-571-2437
DATE OF SUBMISSION: September 15, 2000

1. Identification of device

Proprietary Name: Headband for BAHA
Common Name: Headband for Bone Conduction Hearing Aid
Classification Status: Class II per regulations 874.3300
Product Codes: LXB

2. Equivalent devices

Entific Medical System believes the Headband for BAHA is substantially equivalent to the headband used with the Second Ear Bone Conduction Hearing Aid, cleared for marketing under 510(k) K953872.

3. Description of the Device

The BAHA is a bone conduction-type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA is based on a bone conduction technology. Sound is transmitted directly through the bones of the skull to the cochlea, bypassing the middle ear.

The BAHA is usually connected to a fixture pillar, which has been surgically placed in the bone behind the ear. Use of the headband allows the BAHA to be held against the skin behind the ear. With the headband, there is no fixture pillar implanted. See B.3 System Diagram. BAHA with headband consists of the same components as the BAHA Classic 300 and Cordelle II minus the components necessary for the surgical attachment.

4. Intended use

The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive

losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

5. Technological characteristics, comparison to predicate device.

Comparison table

Characteristic	Predicate device: Second Ear – Bone Conduction Hearing Aid	Headband for BAHA
Material	Medical Grade Plastic	Peek
Intended Use	Moderate to severe conductive hearing losses. Particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.	Same
Power requirement	4.8 VDC Nickel-Metal-Hybride Battery	R675 Zink Air – BAHA Classic 300 Nickel-Metal-Hybride 9V 6F22 – BAHA Cordelle II
Max gain	57dB	33 dB – BAHA Classic 300 55 dB – BAHA Cordelle II
Frequency response	150 Hz – 8 KHz	125 Hz – 8 KHz
Manufacturer	Wordcomp International	Entific Medical Systems
Classification code	LXB	Same
K-number	K953872	Pending

7. Conclusion

It is the conclusion of Entific Medical System that the Headband for BAHA is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2000

Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
6470 Riverview Terrace
Minneapolis, MN 55432

Re: K002913
Trade Name: Headband for BAHA
Regulatory Class: II
Product Code: 77-LXB
Dated: September 15, 2000
Received: September 18, 2000

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

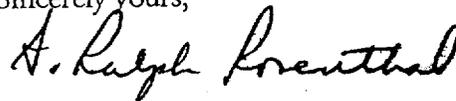
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Constance G. Bundy

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

B. INDICATIONS FOR USE

510(k) Number K002913

Device Name: Headband for BAHA

Indications for Use:

The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over the Counter Use _____

Karen Palmer
(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K002913

ENTB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 12/12/05

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): 1002913/A1

To: Division Director: EN/DOCD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

Change in Content
CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: *[Signature]*

Date: 12/16/05

Draft #2 : 9/8/99

Draft #3: 1/3/00

Draft #4: 3/1/03

(PMC)
12/22

1002913/A'

Cochlear

Cochlear Americas
 400 Inverness Parkway
 Suite 400
 Englewood, CO 80112 USA
 Telephone 303 790 9010
 Facsimile 303 792 9025
 www.cochlear.com

DEC 12 11 09 AM '05

December 8, 2005

Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center (HFZ 401)
 9200 Corporate Blvd.
 Rockville, MD 20850

RE: Cochlear Americas' Regulatory Contacts

PMA Numbers: P840024, P890027, P970051, P000015

**510K Numbers: K945154, K955713, K984162, K992872, K002913, K011438,
 K021837, K042017**

IDE Numbers: G920119, G990155, G000213, G020272, G030210, G040122

Dear Sir or Madam:

At Eric Mann's request, I'm writing to advise you that Dr. Anne Cosgriff is no longer employed by Cochlear Americas and that she should not be listed as the company's official regulatory contact.

At present, Cochlear Americas holds four, FDA-cleared, Pre-market Approval Applications and eight 510K Applications. Please note that the 510K clearances were obtained by Entific Medical Systems, A.B., of Gothenburg, Sweden, which is now a wholly owned subsidiary of Cochlear Limited. Cochlear Americas is also the sponsor of six active Investigational Device Exemptions.

Two regulatory managers, Deb van den Honert and myself, manage the company's PMA/510K products and IDE-controlled studies. The official contact for each product/study is listed below, for the Agency's convenience.

Product/IDE Study	PMA/510K/IDE#	Regulatory Manager/Contact
Nucleus 22 Channel Cochlear Implant System (Adults)	P840024	Patti Arndt
Nucleus 22 Channel Cochlear Implant System (Children)	P890027	Patti Arndt
Nucleus 24 Cochlear Implant System	P970051	Patti Arndt
Nucleus 24 Auditory Brainstem Implant System	P000015	Patti Arndt
Vista-Fix Craniofacial Rehabilitation System	K945154	Deb van den Honert

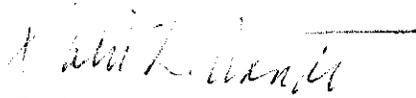
Hear now. And always

Food and Drug Administration
 Center for Devices and Radiological Health
 December 8, 2005
 Page 2

BAHA System – Adult Indication	K955713	Deb van den Honert
BAHA System - Pediatric Indication	K984162	Deb van den Honert
BAHA System – Cordelle Speech Processor	K992872	Deb van den Honert
BAHA System – Headband	K002913	Deb van den Honert
BAHA System – Bilateral Indication	K011438	Deb van den Honert
BAHA System – Single-sided Deafness Indication	K021837	Deb van den Honert
BAHA System – Divino Speech Processor	K042017	Deb van den Honert
Nucleus 24 Percutaneous Cochlear Implant	G920119	Patti Arndt
Nucleus Freedom Hybrid Cochlear Implant	G990155	Deb van den Honert
Penetrating Auditory Brainstem Implant	G000213	Deb van den Honert
Nucleus Research Platform 8	G020272	Patti Arndt
Asymmetrical Hearing Loss	G030219	Patti Arndt
Nucleus System 4 Cochlear Implant	G040122	Patti Arndt

Should you have questions regarding this information, please don't hesitate to contact me at 303-524-7162, or Deb van den Honert, Regulatory Manager, at 303-524-6792.

Yours sincerely,



Patti L. Arndt, CCC-A
 Regulatory Affairs Manager
 COCHLEAR AMERICAS



OCT 17 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
6470 Riverview Terrace
Minneapolis, MN 55432

Re: K002913
Trade Name: Headband for BAHA
Regulatory Class: II
Product Code: 77-LXB
Dated: September 15, 2000
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Page 2 - Ms. Constance G. Bundy

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Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

B. INDICATIONS FOR USE

510(k) Number K002913

Device Name: Headband for BAHA

Indications for Use:

The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over the Counter Use _____
(Per 21 CFR 801.109)

Karen Pollock
(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K002913

J

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Karen Baker

Subject: 510(k) Number K002913

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices NA

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

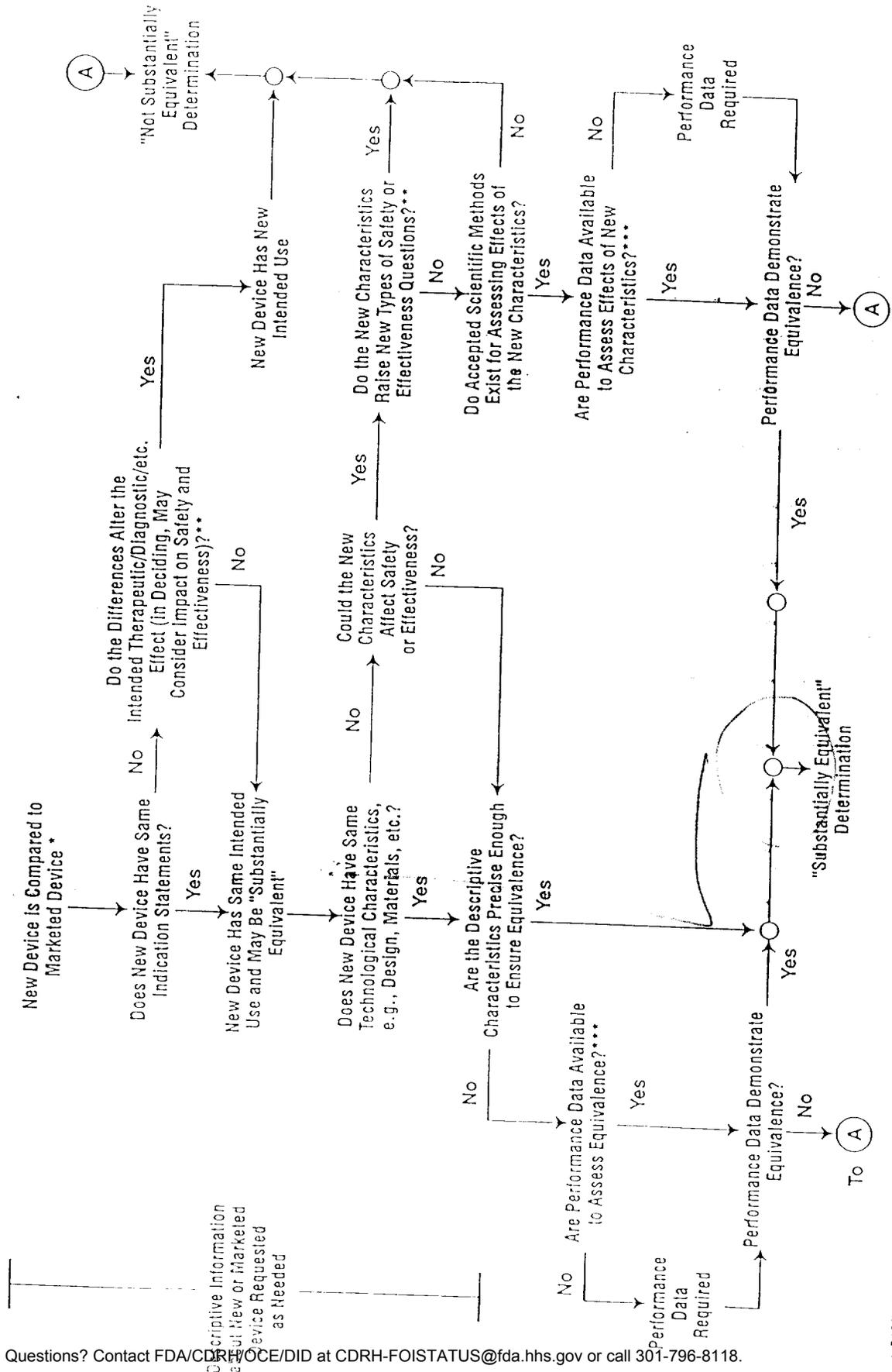
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

874.3300 77LXB

Review: Harold (Branch Chief) ENTB (Branch Code) 10/16/09 (Date)

Final Review: David M. Whipple for OED (Division Director) 10/16 (Date)

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



** This Decision is Normally Based on Descriptive Information Alone, But Limited Additional Information is Sometimes Required.
 *** Data M... in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

* 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.

Document # K002913

Company Name: Entific Medical Systems
P.O. Box 16024
SE-41221 Göteborg
Sweden

Contact Person: Constance Bundy
C.G. Bundy Associates
6470 Riverview Terrace
Minneapolis, MN 55432
612-574- 1976
FAX 612-571-2437

Device Name: Headband for BAHA

CLASSIFICATION NAME: Headband for Bone Conduction Hearing Aid

COMMON NAME: Headband for Bone Conduction Hearing Aid

PRODUCT TO WHICH COMPARED: (510(k) NUMBER IF KNOWN)

K955713 – BAHA Classic 300
K992892 – Cordelle II

INTENDED USE STATEMENT: The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

Submission Provides:

Comparative Specifications:	yes
Comparative Lab Data:	no
Summary of Animal Testing:	no
Summary of Clinical Testing:	no
510(K) Summary:	yes

GENERAL INFORMATION SUMMARY

Life-Supporting or Life-Sustaining:	no
Is it an Implant?	no
Software Driven:	no
Sterility:	no
Single Use: (repeated use by same patient)	no
Home or prescription use:	yes
Drug or Biologic product:	no
Device a kit:	no

K002913, page 2.

	YES	NO
1. IS PRODUCT A DEVICE?	x	- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	x	- IF NO STOP
3. SAME INDICATION STATEMENT?	x	- IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?		- IF YES STOP, NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	x	- IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?		- IF YES GO TO 8
DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	x	- IF NO GO TO 10 - IF YES STOP
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?		- IF YES STOP, NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?		- IF NO STOP, NE - IF NO, REQUEST DATA
10. PERFORMANCE DATA AVAILABLE?		
11. DATA DEMONSTRATE EQUIVALENCE?		

A. Device Description:

The BAHA is a bone conduction type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA is based on a bone conduction technology. Sound is transmitted directly through the bones of the skull to the cochlea bypassing the middle ear.

The BAHA is usually connected to a fixture pillar, which has been surgically placed in the bone behind the ear. Use of the headband allows the BAHA to be held against the skin behind the ear. With the headband, there is no fixture pillar implanted. The BAHA with headband consists of the same components as the BAHA Classic 300 and Cordelle II minus the components necessary for the surgical attachment.

B. Device Materials and Toxicity

The headband is made of (b)(4) which is the same material used in the predicate devices. This material contacts skin only.

C. Comparative Specifications

Comparisons are made between the subject and each of the cited predicate devices. These comparisons include intended use, technological characteristics, power requirements, gain and frequency response.

K002913, page 3.

D. Physical Properties and Performance Testing

The physical properties are well described. No performance testing is provided. There is a statement indicating that the wearer will experience a reduced sound signal compared to a wearer of the BAHA that is attached to the surgically implanted abutment.

E. Clinical Testing

No clinical testing is provided.

F. Sterilization

The device is not sterile.

G. Device Labeling

Sample labeling is provided.

H. 510(k) Summary or Statement

A 510(k) Summary is provided.

SUMMARY: The headband for the BAHA bone conduction hearing aid is an accessory that allows a patient to use the device without having the surgically implanted abutment procedure. It is a low risk device that gives the user a non-surgical option.

RECOMMENDATION:

The Headband for the BAHA is substantially equivalent to other headband devices used to assist in securing bone anchored hearing aids to the head. This reviewer has no questions regarding the safety or effectiveness of the headband.

CFR# 874.3300
Product Code 77-LXB
CLASS II



Karen H. Baker, MSN, RN
Nurse Consultant/ENTB

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name: <u>K002913</u>						K	
Submitter (Company): <u>Entific Medical System</u>							
Items which should be included <i>(circle missing & needed information)</i>						✓ IF ITEM IS NEEDED AND IS MISSING	
SPECIAL		ABBREVIATED		TRADITIONAL			
		YES	NO	YES	NO	YES	NO
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)		GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5	
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS ✓ IF ITEM IS NEEDED							
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)							
		NA		YES		NO	
		SPECIALS		ABBREVIATED		TRADITIONAL	
		YES	NO	YES	NO	YES	NO
		AND IS MISSING					
a) trade name, classification name, establishment registration number, device class						✓	
b) OR a statement that the device is not yet classified		FDA-may be a classification request; see coordinator					
c) identification of legally marketed equivalent device		NA			✓		
d) compliance with Section 514 - performance standards		NA			N/A		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)					N/A		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)					N/A		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					✓		
v) performance (bench, animal, clinical) testing		NA			N/A		
vi) safety characteristics		NA			N/A		
m) If kit, kit certification					N/A		
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) STATEMENT - INTENDED USE AND INDICATIONS FOR							
		* If no - STOP not a special					

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*				* If no - STOP not a special
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

<p>inapplicable requirements or deviations noted below</p>		
<p>iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed</p>		
<p>iv) An identification, for each consensus standard, of any requirements that were not applicable to the device</p>		
<p>v) A specification of any deviations from each applicable standard that were applied</p>		
<p>vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference</p>		
<p>vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations</p>		
<p>d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards</p>		

5. Additional Considerations: (may be covered by Design Controls)						
<p>a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:</p>					<p>NA</p>	
<p>i) component & material</p>					✓	
<p>ii) identify patient-contacting materials</p>					✓	
<p>iii) biocompatibility of final sterilized product</p>					✓	
<p>b) Sterilization and expiration dating information:</p>					NA	
<p>i) sterilization method</p>					↓	
<p>ii) SAL</p>					↓	
<p>iii) packaging</p>					↓	
<p>iv) specify pyrogen free</p>					↓	
<p>v) ETO residues</p>					↓	
<p>vi) radiation dose</p>					NA	
<p>c) Software validation & verification:</p>					↓	
<p>i) hazard analysis</p>					↓	
<p>ii) level of concern</p>					↓	
<p>iii) development documentation</p>					↓	
<p>iv) certification</p>					↓	

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: 10/4/00

Reviewer: Karen Baker
 Concurrence by Review Branch: David M. Whyle
 for JZS!

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

September 19, 2000

ENTIFIC MEDICAL SYSTEMS INC. 510(k) Number: K002913
 C/O C.G. BUNDY ASSOCIATES, INC. Received: 18-SEP-2000
 6470 RIVERVIEW TERRACE Product: HEADBAND FOR BAHA
 MINNEAPOLIS, MN 55432
 ATTN: CONSTANCE G. BUNDY

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
 Consumer Safety Officer
 Premarket Notification Staff
 Office of Device Evaluation

16 002 913

Entific Medical System

September 15, 2000

510(k) Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RE: Traditional 510(k) Notification for the Entific Medical System Headband for BAHA.

Attached are two (2) copies of a 510(k) Notification submitted in accordance with 21 CFR 807, Subpart E, for the Headband for BAHA.

Entific Medical System is seeking clearance to introduce the Headband for BAHA into commercial distribution in the U.S. The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

This submission contains confidential commercial and trade secret information and we respectfully request maximum protection provided by the law. This submission has been prepared for Entific Medical System by C. G. Bundy Associates, a regulatory consulting group. Should you require further information, please contact Constance Bundy, C. G. Bundy Associates.

Sincerely,

Constance G. Bundy

Constance G. Bundy
Direct dial: 612-574-1976
Fax: 612-571-2437
C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Minneapolis, Minnesota 55432

14 SEP 19 13 41
16 002 913

Handwritten initials and numbers: *AK*, *EN*, *11*, *13*

Traditional 510(k)
Premarket Notification

Entific Medical System
Headband for BAHA

September 15, 2000

Submitted by:
C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Minneapolis, Minnesota 55432
Direct dial: 612-574-1976
Fax: 612-571-2437
Email: cgbundy@attglobal.net

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SECTION 1. GENERAL INFORMATION

A. GENERAL INFORMATION

SUBMITTER'S NAME: Entific Medical System
ADDRESS: P.O. Box 16024
SE-412 21 Göteborg
Sweden
CONTACT PERSON: Constance Bundy
TELEPHONE NUMBER: 612-574-1976
FAX NUMBER: 612-571-2437
DATE OF SUBMISSION: September 15, 2000

- a) Proprietary Name: Headband for BAHA
- b) Common Name: Headband for Bone Conduction Hearing Aid
- c) Classification Status: Class II per regulations 874.3300
Product Codes: LXB
- d) Establishment Registration Number: 9038368
- e) Addresses:
Manufacturing:
P.O. Box 16024
SE-412 21 Göteborg
Sweden

(b)(4) Confidential and Proprietary
Information

Sterilization Facility:
N/A

- f) Reason for Submission: Entific Medical System wishes to introduce an accessory to their existing hearing aid models, BAHA Classic 300 and BAHA Cordelle II, K955713 and K992892 respectively.
- g) Substantial Equivalence: Entific Medical System believes the Headband for BAHA is substantially equivalent to the headband used with the Second Ear Bone Conduction Hearing Aid, K953872.

B. INDICATIONS FOR USE

510(k) Number K002913

Device Name: Headband for BAHA

Indications for Use:

The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

(Please do not write below this line - continue on another page if needed)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over the Counter Use _____

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Entific Medical System summary for the Headband for BAHA.

SUBMITTER'S NAME: Entific Medical System
ADDRESS: P.O. Box 16024
SE-412 21 Göteborg
Sweden
CONTACT PERSON: Constance Bundy
TELEPHONE NUMBER: 612-574-1976
FAX NUMBER: 612-571-2437
DATE OF SUBMISSION: September 15, 2000

1. Identification of device

Proprietary Name: Headband for BAHA
Common Name: Headband for Bone Conduction Hearing Aid
Classification Status: Class II per regulations 874.3300
Product Codes: LXB

2. Equivalent devices

Entific Medical System believes the Headband for BAHA is substantially equivalent to the headband used with the Second Ear Bone Conduction Hearing Aid, cleared for marketing under 510(k) K953872.

3. Description of the Device

The BAHA is a bone conduction-type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA is based on a bone conduction technology. Sound is transmitted directly through the bones of the skull to the cochlea, bypassing the middle ear.

The BAHA is usually connected to a fixture pillar, which has been surgically placed in the bone behind the ear. Use of the headband allows the BAHA to be held against the skin behind the ear. With the headband, there is no fixture pillar implanted. See B.3 System Diagram. BAHA with headband consists of the same components as the BAHA Classic 300 and Cordelle II minus the components necessary for the surgical attachment.

4. Intended use

The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive

losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

5. Technological characteristics, comparison to predicate device.

Comparison table

Characteristic	Predicate device: Second Ear – Bone Conduction Hearing Aid	Headband for BAHA
Material	Medical Grade Plastic	Peek
Intended Use	Moderate to severe conductive hearing losses. Particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.	Same
Power requirement	4.8 VDC Nickel-Metal-Hybride Battery	R675 Zink Air – BAHA Classic 300 Nickel-Metal-Hybride 9V 6F22 – BAHA Cordelle II
Max gain	57dB	33 dB – BAHA Classic 300 55 dB – BAHA Cordelle II
Frequency response	150 Hz – 8 KHz	125 Hz – 8 KHz
Manufacturer	Wordcomp International	Entific Medical Systems
Classification code	LXB	Same
K-number	K953872	Pending

7. Conclusion

It is the conclusion of Entific Medical System that the Headband for BAHA is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

B. TRUTH AND ACCURACY CERTIFICATION, ENTIFIC MEDICAL SYSTEM – HEADBAND FOR BAHA

I certify that, in my capacity as Regulatory Consultant to Entific Medical Systems, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

Constance G. Gundy

Regulatory Consultant to Entific Medical System

September 15, 2000
Date

SECTION 3. PROPOSED LABELING

A. LABELING

Please refer to Appendix A.

B. INSTRUCTIONS FOR USE

Please refer to Appendix B.

SECTION 4. DEVICE DESCRIPTION

A. INTENDED USE

The BAHA with headband is intended for patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

B. DEVICE DESCRIPTION

B.1 Introduction

The BAHA is a bone conduction-type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA is based on a bone conduction technology. Sound is transmitted directly through the bones of the skull to the cochlea, bypassing the middle ear.

The BAHA is usually connected to a fixture pillar, which has been surgically placed in the bone behind the ear. Use of the headband allows the BAHA to be held against the skin behind the ear. With the headband, there is no fixture pillar implanted. See B.3 System Diagram. BAHA with headband consists of the same components as the BAHA Classic 300 and Cordelle II minus the components necessary for the surgical attachment.

The BAHA with headband is intended for the same patient categories as Second Ear: Patients who suffer from moderate to severe conductive hearing losses. BAHA with headband may be particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

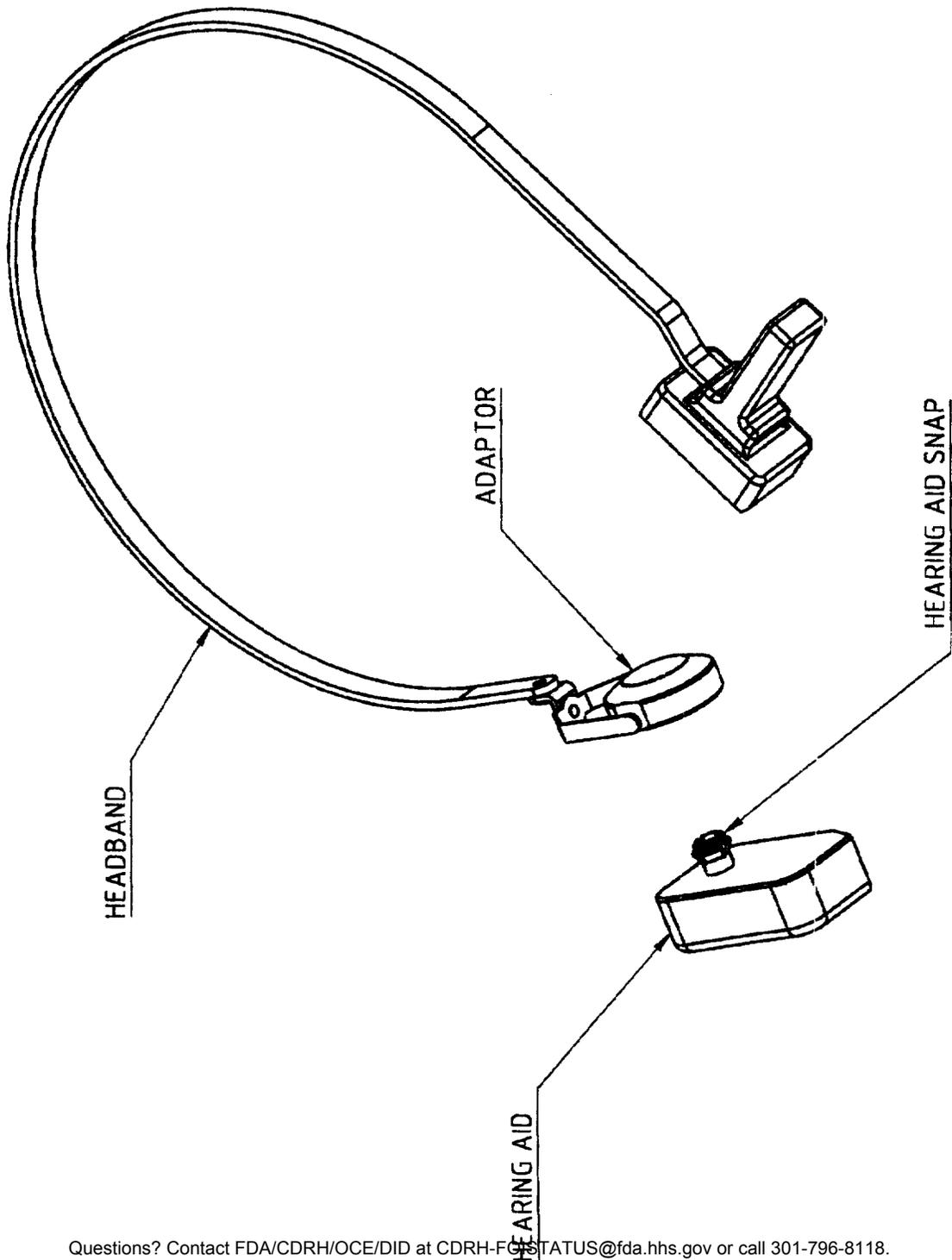
The BAHA Classic 300 with headband and the BAHA Cordelle II with headband are identical to those two devices without the headband.

The headband is designed to press the hearing aid against the skin behind the ear. The at-the-ear level of the hearing aid is connected to an adapter made of Peek and the actual band is made of stainless steel.

Packaging:

The headband will be sold separately from the hearing aid and will be packaged in a protective plastic bag.

B.3 Diagram





SECTION 5. COMPARATIVE INFORMATION

A. COMPARATIVE TABLE

Characteristic	Second Ear – Bone Conduction Hearing Aid	Headband for BAHA
Material	Medical Grade Plastic	Peek
Intended Use	Moderate to severe conductive hearing losses. Particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.	Same
Power requirement	4.8 VDC Nickel-Metal-Hybride Battery	R675 Zink Air – BAHA Classic 300 Nickel-Metal-Hybride 9V 6F22 – BAHA Cordelle II
Max gain	57dB	33 dB – BAHA Classic 300 55 dB – BAHA Cordelle II
Frequency response	150 Hz – 8 KHz	125 Hz – 8 KHz
Headband	Yes	Yes

Conclusion: The headband as used with the BAHA Classic 300 and Cordelle II (cleared through the 510(k) process) introduces no additional safety and effectiveness concerns and is substantially equivalent to the headband used with the Second Ear hearing aid.

SECTION 6. BIOCOMPATIBILITY ASSESSMENT

The part that is in contact with the skin, the adapter, is made of (b)(4) (b)(4), which is the same material that has been cleared in K925766 and K944964:

(b)(4) Confidential and Proprietary Information



SECTION 7. STERILIZATION INFORMATION

This section is not applicable to this device.

SECTION 8. SOFTWARE VALIDATION/ VERIFICATION

This section is not applicable to the device.

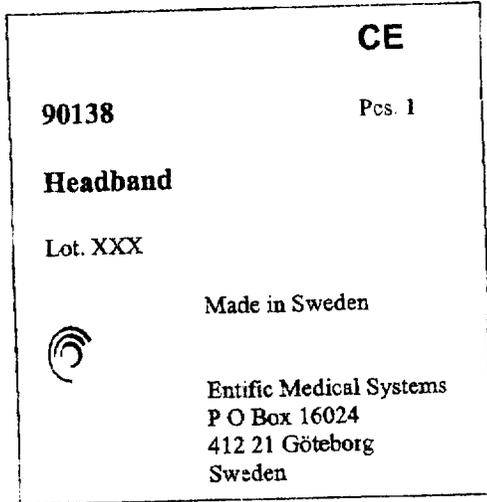
SECTION 9. SPECIFIC STANDARDS AND GUIDELINES

This section is not applicable to the device.

APPENDIX A

LABELING

Product label



APPENDIX B

USERS MANUAL & INFORMATION ON BAHA HEARING AIDS

User's Manual

Dansk • Deutsch • English • Español
Français • Italiano • Nederlands
Português • Suomi • Svenska

BAHA® Headband



Entific Medical Systems AB, Box 16024,
SE-412 21 Göteborg, Sweden
Tel: +46-31-733 37 00, Fax: +46-31-335 88 60,
E-mail: info@entific.se

www.entific.com



www.entific.com

Bitte beachten: Tragen Sie den BAHÄ-Bügel während des Fixierungsprozesses nicht direkt über der Implantationsstelle der Fixier- oder der Diskonusselle, da sonst die Entfernung des Implantates beeinträchtigt werden kann.

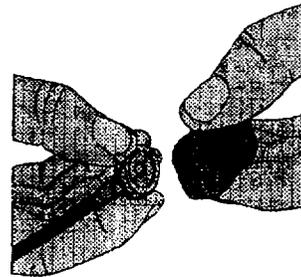
Bitte beachten: Tragen Sie den BAHÄ-Bügel nur ein empfangt der Träger bei ersten BAHÄ-Hörsystems Hörerfolg eines fest installierten BAHÄ-Bügel mit dem Vergleich mit dem und Fixtur (Implantat) nicht über die Disarzhilse durch die Haut geführt, Tonsignal wird hierbei Das Knochenleitungshören. Das toneller und Weise wie ein konventioneller

Der BAHÄ-Bügel funktioniert auf die gleiche Art und Weise wie ein konventioneller

Das Knochenleitungshören. Das Tonsignal wird hierbei durch die Haut geführt, nicht über die Disarzhilse und Fixtur (Implantat) Vergleich mit dem Hörerfolg eines fest installierten BAHÄ-Bügel mit dem empfängt der Träger bei ersten BAHÄ-Hörsystems Hörerfolg eines fest installierten BAHÄ-Bügel nur ein reduziertes Tonsignal.

Bitte beachten: Tragen Sie den BAHÄ-Bügel während des Fixierungsprozesses nicht direkt über der Implantationsstelle der Fixier- oder der Diskonusselle, da sonst die Entfernung des Implantates beeinträchtigt werden kann.

ENTIFIC



Dansk Deutsch

English	Espanol	Francais	Italiano
<p>The BAHA Band works in the same way as a conventional bone conductor as the sound signal has to travel through the skin instead of via the abutment and fixture. Therefore the wearer will receive a reduced sound signal compared to a wearer of the BAHA sound processor itself.</p> <p><i>Please note: Do not wear the BAHA Band directly over the fixture or over the abutment during the healing period as this may jeopardise osseointegration.</i></p>	<p>The BAHA Band works in the same way as a conventional bone conductor as the sound signal has to travel through the skin instead of via the abutment and fixture. Therefore the wearer will receive a reduced sound signal compared to a wearer of the BAHA sound processor itself.</p> <p><i>Please note: Do not wear the BAHA Band directly over the fixture or over the abutment during the healing period as this may jeopardise osseointegration.</i></p>	<p>Le serre-tête BAHA fonctionne de la même manière qu'un ostéophone classique : le signal sonore traverse la peau et non pas le pilier et la fixation. Pour cette raison, le porteur perçoit un signal sonore réduit comparé au signal sonore perçu avec une prothèse auditive BAHA.</p> <p><i>Remarque: Ne placez pas le serre-tête BAHA directement sur la fixation ou le pilier pendant la période de guérison, car ceci pourrait compromettre l'assoi-</i> <i>gration.</i></p>	<p>BAHA Band funziona allo stesso modo di un apparecchio convenzionale per via ossea, in quanto il segnale sonoro deve attraversare la cute anziché essere trasmesso dall'abutment e dalla fixture. Quindi l'utilizzatore riceverà un segnale sonoro ridotto rispetto ad un utilizzatore del BAHA vero e proprio.</p> <p><i>N.B.: Non applicare BAHA Band direttamente sulla fixture o sull'abutment durante il periodo di guarigione, poiché ciò potrebbe compromettere l'osteointegrazione.</i></p>
Nederlands	Portugues	Suomi	Svenska
<p>De BAHA Draagbeugel werkt op dezelfde manier als een conventionele beengeleider; het geluidssignaal moet zich namelijk door de huid heen verplaatsen. Wordt het BAHA toestel op de opbouw geplaatst, dan gaat het geluid via de schroef direct over het bot. Met de draagbeugel zal derhalve een minder sterk geluidssignaal worden ontvangen dan met het BAHA toestel bevestigd op de opbouw.</p> <p><i>Let op: Draag de BAHA beugel niet rechtstreeks op de schroef of de opbouw tijdens de inheiligingsfase. Dit kan de osseointegratie in gevaar brengen.</i></p>	<p>A Banda BAHA funciona do mesmo modo de um condutor ósseo convencional, em que o sinal sonoro é transmitido através da pele, em vez de através do pilar e do implante. Por esta razão, o utilizador recebe um sinal acústico reduzido, quando comparado com o sinal recebido de um processador de som BAHA normal.</p> <p><i>Nota: Não colocar a Banda BAHA directamente sobre o implante ou o pilar, durante o período de cicatrização, de modo a não prejudicar a integração do tecido ósseo.</i></p>	<p>BAHA Band toimii samalla tavalla kuin tavallinen luuhun kiinnitettävä johdin, siinä äänisignaali kulkee ihon läpi, ei välkkeen ja ruuvien läpi. Siksi käyttäjä vastaanottaa alhaisemman äänisignaalin kuin varsinaisen BAHA-kuulokojeen käyttäjä.</p> <p><i>Huomautus: Älä käytä BAHA Band -laitetta suoraan ruuvia tai kiinnikkeen päällä paranemisen aikana, sillä se saattaa vaarantaa osseointegraation.</i></p>	<p>BAHA® huvudbyggen fungerar på samma sätt som en konventionell benleciare eftersom ljudsignalen måste passera genom huden, istället för genom distansen och fixturen. Ljudet kommer därför att upplevas som svagare.</p> <p><i>Observera: Sätt inte bygeln direkt över fixturen eller distansen under läknings tiden då detta kan äventyra osseointegrationen.</i></p>

Records processed under FOIA Request #2016-4260; Released by CDRH on 07-25-2016.

BAHA® Classic 300

The BAHA® system has been used to successfully treat nearly 10,000 patients world-wide who have either a conductive hearing loss due to bilateral atresia or chronic suppurative otitis media. The system is based on osseointegration and the principle of hearing through bone conduction.

The BAHA® Classic 300 model features excellent patient comfort and gives high quality and reliable sound transmission. It is easily connected to the implanted titanium fixture by means of a snap coupling. The coupling has an overload release function for the patient's safety.

The unit is equipped with a tone switch (N, L and E) and an electrical input designed for connecting external equipment such as FM hearing systems, IR systems, Walkman, TV etc.

The Classic 300 is available in three colours; black, beige and grey and is delivered in a kit including the sound processor, abutment cover, battery, cleaning brush, safety line and user's manual.

Audiological indications*:

Pure tone average bone conduction threshold of the indicated ear should be better than or equal to 45 dB HL (measured at 0.5, 1, 2, 3 kHz).

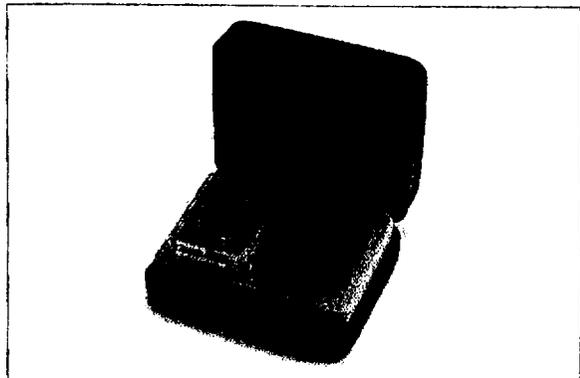
Accessories

Several accessories such as a telecoil unit, audio adapter and directional microphone unit are available for the Classic 300.

**For more detailed information regarding indications and technical data, please see the Audiological manual.*

Technical data*

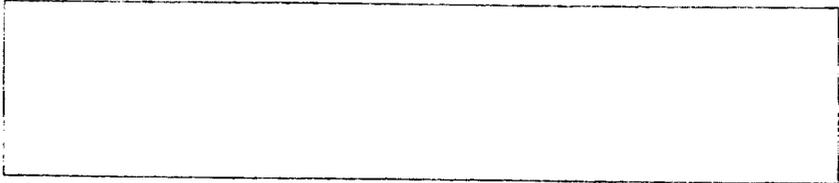
Battery type	675
Current consumption	0.7 mA (in silence), 3.5 mA (at 60 dB SPL, 1600 Hz)
Frequency range	300 - 6500 Hz
Peak OH at 60 dB SPL	113 dB rel 1µN
Harmonic distortion (THD)	Below 3% above 600 Hz
Equivalent input noise	24 dB SPL
Size (L x W x H) and weight	34 x 22 x 10 mm, 14 g incl. battery
Electrical input	85 dB rel 1µN
Sensitivity (1 kHz)	1600 Hz
Input impedance	18kΩ



Ordering Information

Ordering numbers for:
 908 110 0 BAHA Classic 300, beige
 908 111 0 BAHA Classic 300, black
 908 112 0 BAHA Classic 300, grey
 908 676 0 Snap coupling w. gold screw
 908 703 0 Cleaning brush
 908 009 0 Torque wrench
 908 011 0 Torque driver (imp)
 908 022 0 Torque driver (imp)
 Please note: A protective cap is needed for the snap coupling 908 676 0

For further information and orders; please contact your local office:



Entific Medical Systems AB, P.O. Box 16024, SE-412 21 Göteborg, Sweden,
 Tel: +46-31-733 37 00, Fax: +46-31-335 88 60. E-mail: info@entific.se

www.entific.com

2006 03.01
 915063 Standard Tryckener AB ISO 14001 CERT. 145087. Printed in Sweden

10. BAHA® Classic 300

Technical Data	
Battery voltage	1.1 - 1.5 V
Current consumption	0.7 mA (in silence) 3.5 mA (at 60 dB SPL, 1600 Hz)
Frequency range	300-6500 Hz
Peak OFL at 80 dB SPL	113 dB rel. 1µN
Peak OFL at 60 dB SPL	103 dB rel. 1µN
Harmonic distortion (THD ₆₀)	Below 3% above 600 Hz
Equivalent input noise	24 dB SPL
Battery type	675
Colour	Black, beige or grey
Weight	14 g (incl. battery)
Size (l × w × h)	34 × 22 × 10 mm
Electrical input sensitivity (1 mVms)	85 dB rel. 1µN, 1600 Hz
Electrical input equivalent to an acoustic input of 70 dB SPL	10 mV, 1600 Hz
Input impedance	18 kΩ

Description of device

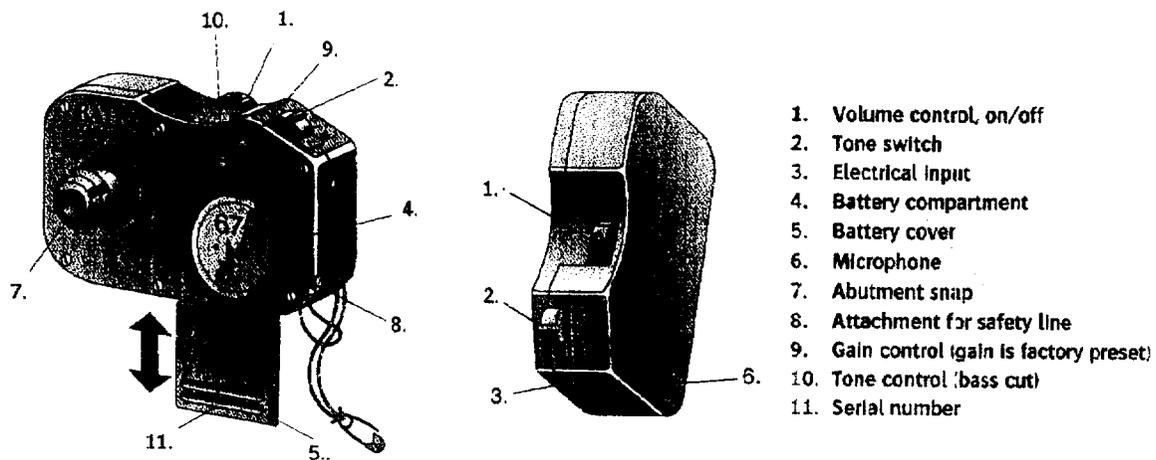


Figure 12. BAHA® Classic 300. For a more detailed description of the main components, please see the "User's manual for BAHA® Classic 300".

BAHA® – THE NATURAL ALTERNATIVE

12. BAHA® Cordelle II

Technical data	
Measurements are at reference settings.	
Battery voltage	7.5 - 9.5 V
Battery type	9V, IEC 6F22
Current consumption	1.4 mA (in silence) 11 mA (at 60 dB SPL, 1500 Hz)
Frequency range	250-6500 Hz
Peak OFL at 90 dB SPL	132 dB rel. 1µN
Peak OFL at 60 dB SPL	116 dB rel. 1µN
Harmonic distortion (THD ₆₀)	Below 3% above 500Hz
Equivalent input noise	24 dB
Telecoil sensitivity (10 mA/m)	102 dB rel. 1µN at 1600 Hz
Electrical input sensitivity (1 mV _{RMS})	103 dB rel. 1µN at 1600 Hz
Electrical input equivalent to an acoustic input of 70 dB SPL	4 mV _{RMS} 1600 Hz
Input impedance	2 kΩ
Transducer	
Colour	Black, beige or grey
Weight	20 g
Size (l x w x h)	29 x 23 x 10 mm
Body worn unit	
Colour	Black
Weight	88 g incl. battery
Size (l x w x m)	90 x 34 x 26 mm

Description of device

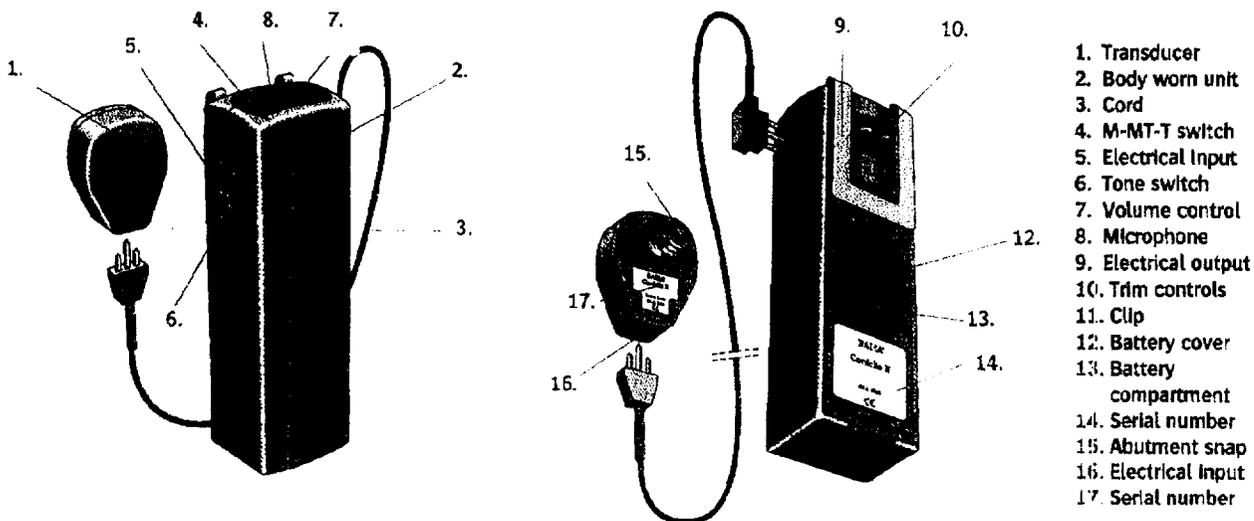


Figure 15. BAHA® Cordelle II. For a more detailed description of the main components, please see the "User's manual for BAHA® Cordelle II.

APPENDIX C

COMPARATIVE PRODUCT MATERIAL



U.S. Food and Drug Administration - Center for Devices and Radiological

Other 510(K) Listing MAUDE PMA Classification

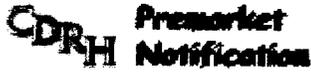
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Device Classification Name	HEARING-AID, BONE-CONDUCTION
Regulation Number	874.3300
510(k) Number	K953872
Device Name	SECOND EAR BONE CONDUCTION HEARING AID WORDCOMP INTERNATIONAL COMMUNICATION GR (WICG)
Applicant	1000 BUNNETT AVENUE SUITE 450 CONCORD, CA 94520
Contact	DAVID W SCHLERF
Product Code	LXB
Date Received	08/17/1995
Decision Date	04/12/1996
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Ear Nose & Throat
Review Advisory Committee	Ear Nose & Throat
Statement/Summary/Purged Status	Summary only
Type	Traditional

(Database Updated August 7, 2000)



U.S. Food and Drug Administration - Center for Devices and Radiological

- Other
- 510(K)
- Listing
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- PMA
- Classification

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Device Classification Name	PUNCH, SURGICAL
510(k) Number	K955713
Device Name	NOBELPHARMA BONE ANCHORED HEARING
Applicant	NOBELPHARMA USA, INC. 777 OAKMONT LANE SUITE 100 WESTMONT, IL 60559
Contact	MARY EDWARDS
Product Code	LRY
Date Received	12/18/1995
Decision Date	08/09/1996
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	Ear Nose & Throat
Statement/Summary/Purged Status	Summary only
Type	Traditional

(Database Updated August 7, 2000)

Pre-market Notification

NOV 24 1998

K992872

Summary of Safety and Effectiveness

A. Name and Address

The Summary of Safety and Effectiveness is being submitted by Entific Medical Systems Inc., 3944 N. Hampton Drive, Powell, Ohio 43065 (formerly part of Nobel Biocare USA, 22895 East Park Drive, Yorba Linda California 92887). The contact person for this submission will be Betsy A. Brown, the regulatory specialist for Entific Medical Systems Inc. Ms. Brown can be reached at the following:

B.A. Brown & Associates
8944 Tamaroa Terrace
Skokie, Illinois 60067
Tel# 847-677-8944
Fax# 847-677-0177

B. Name of Device

This device is generally known as a bone-anchored, bone-conduction hearing aid with a body worn unit, and has the trade name "Branemark Bone-Anchored Hearing Aid (BAHA™) Cordelle II System". This submission is to allow the BAHA Cordelle II System to be used in patients 5 years old or older.

C. The Predicate Product

The predicate products used in this Premarket Notification are the Branemark Bone-Anchored Hearing Aid (BAHA™), K955713 and K984162, the Branemark System® Bone Anchored Craniofacial Prosthetic Attachment System, K945154 and other bone conduction hearing aids.

D. Description of the Device

The Branemark Bone-Anchored Hearing Aid (BAHA™) Cordelle II System includes a titanium fixture which is placed in the temporal bone just behind the ear, an abutment, various accessories necessary for the placement and use of the fixture/abutment pillar, a sound processor which is attached to the abutment and a body worn unit which has two potentiometers that control threshold knee and loudness boost and a tone control switch.

Pre-market Notification

E. Intended Use of the Device

The Branemark Bone-Anchored Hearing Aid (BAHA™) Cordelle II System is intended to be used as a bone-anchored, bone-conduction hearing aid. The device is indicated for use in patients who have conductive hearing loss and can still benefit from sound amplification. Also indicated are patients with mixed hearing loss with average bone conduction thresholds in the indicated ear better than 45dB HL. The nominal output from the BAHA Cordelle II is on average 13 dB stronger than the Classic 300 (measured at 0.5, 1,2,3 kHz). The Cordelle II is recommended for patients having the same indications for the Classic 300 but where the Classic 300 is "too weak". (Patients with bone conduction thresholds better than 45dB HL will be expected to improve, but may not achieve levels in the normal range. Patients with a bone conduction threshold where each standard measured frequency threshold is less than 25 dB HL can be expected to have restored hearing levels in the normal range.) The patients indicated for this device must also be unable to use conventional air conduction hearing aids or undergo ossicular replacement surgery because of one of the following:

1. Chronic otitis media (COM); or
2. Congenital malformation (CM) of the middle/external ear; or
3. Other acquired malfunctions of the middle or external ear canals which preclude the wearing of a conventional air conduction hearing aid.

Additional indications to be met by perspective BAHA candidates:

1. Patients (either by themselves or with the aid of others) must be able to maintain the abutment/skin interface of the BAHA. Therefore, careful consideration must be given as to the patient's psychological, physical, emotional and developmental capabilities to maintain hygiene. In the case of children part, but not all, of that responsibility falls on the parent or guardian.
2. For children and patients with congenital malformation, sufficient bone volume and bone quality must be present for a successful fixture implantation. Alternative treatment such as conventional bone conduction hearing aids, should be considered for patients having a disease state that might jeopardize osseointegration.

Pre-market Notification

Contraindications:

1. Speech discrimination scores of the indicated ear less than 60% at elevated sound pressure levels (SPL) during standardized tests.
2. Patients who are developmentally delayed or who suffer from drug abuse. (This includes children who have behavior problems or who have parents who are not able to keep the implanted area clean.)
3. Age less than 5 Years.
4. Patients who already have a BAHA™ (i.e. no bilateral implants.) The BI-CROS attachment to the BAHA should be used for this purpose.

F. Comparison of Technological Characteristics

The technological characteristics between the attachment system, the sound processor and the respective predicate products are substantially identical and no additional questions regarding safety and effectiveness exist.

Substantial Equivalence

The **Branemark Bone-Anchored Hearing Aid (BAHA™) Cordelle II** is a sound processor system which consists of two units; a transducer and a body worn unit. The body worn unit has two potentiometers which control threshold knee and loudness boost and a tone control switch.

Transducer

The transducer is an at-the-ear level sound processor which uses a direct connection to the skull bone without intervening skin and soft tissue. The transducer is attached to a snap coupling titanium abutment, which is fastened to a titanium flange fixture using a gold screw. The transducer is connected to a body worn unit via a cord with electrical output and input connectors.

Body Worn Unit

As noted previously the body worn unit has two potentiometers which control the threshold knee and loudness boost. The unit is also equipped with an electrical input to receive signals from a "Walkman" FM/IR system. When the electrical contact is connected it overrides the telecoil signal.

Pre-market Notification

Body Worn Unit (continued)

The body worn unit has a tone switch which controls the frequency response. The switch can be set in three different positions. N= Normal, which gives the widest frequency response. H= High frequency emphasis (reduction of low frequency sounds). L= Low frequency emphasis (reduction of high frequency sounds). The tone switch is effective for all inputs (microphone, telecoil, electrical).

The two trim controls marked LB and TK can be adjusted with a small screwdriver by the patient's audiologist. The LB adjusts the gain for loud sounds and the TK adjusts the gain for soft sounds.

The body worn unit is equipped with a clip so you can attach the unit to the patient's clothing (i.e. shirt/blouse pocket...).

Abutment Snap

There is an abutment snap which is mounted to the transducer. It is designed to snap into the abutment and hold the transducer securely in place.

Abutment Insert

The function of the abutment insert is to act as a guide for the abutment snap. It makes it easier to connect the transducer to the abutment. It also protects the inside of the abutment from dirt.

Abutment and Abutment Screw

The abutment is a replaceable percutaneous connection between the fixture and the external sound processor which is partially or totally submerged into soft tissue. The abutment is made of titanium and is fastened to the fixture via an internal an abutment screw.

Abutment Cover

When the transducer is not in place you can attach the abutment cover on the abutment to make it look more aesthetically pleasing. One can attach the cover by pressing it into place on the abutment.

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Fixture

The fixture is a threaded titanium screw which is implanted into the temporal bone and intended to provide permanent bone anchorage as a means to attach the sound processor.

Cover Screw and Healing Cap

The cover screw and healing cap are temporary components utilized only during the healing periods post surgical placement of the titanium fixture. The cover screw is used during the first healing period and is attached to the fixture and covered with the soft tissue during the healing of the bone and soft tissue. The cover screw covers the upper part of the internal threads of the fixture. Thus, the cover screw will preclude bone and soft tissue from growing into the site where the abutment will be placed. The healing cap is used during the second healing period and covers the abutment surface. These components are used only during the healing stages of the surgery and remain in place for three to four months and one to two weeks respectively.

The Branemark Bone-Anchored Hearing Aid BAHA®™ Cordelle II System is substantially equivalent to the Branemark Bone-Anchored Hearing Aid BAHA™, K955713, K984162 and to the Branemark System® Bone-Anchored Craniofacial Prosthetic Attachment System (BA-CPAS), K9445154 for the following:

1. The BAHA Cordelle II System has the same intended use as the predicate products
2. The BAHA Cordelle II System has the same identical technological characteristics as the predicate products
3. The BAHA Cordelle II System has the same identical surgical technique as the predicate products
4. The BAHA Cordelle II System has similar manufacturing processes; and same packaging and sterilization process as the predicate products

Therefore, based on the facts presented above, we believe the BAHA™ Cordelle II System is substantially equivalent to the predicate products and respectfully request the concurrence of the Agency.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Ms. Betsy A. Brown
Regulatory Specialist for Entific Medical Systems
B. A. Brown & Associates
8944 Tamaroa Terrace
Skokie, IL 60076

Re: K992872
Trade Name: Branemark Bone-Anchored Hearing Aid (BAHA) Cordelle II
Regulatory Class: II
Product Code: 77LXB
Dated: July 28, 1999
Received: August 26, 1999

Dear Ms. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

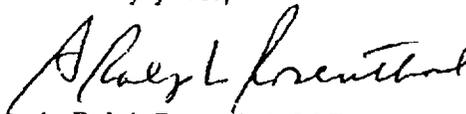
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): # 992872

Device Name: Branemark Bone Anchored Hearing Aid (BAHA™) System Cordelle II System

Indications For Use:

This device is to be used by patients who have a conductive hearing loss and can still benefit from sound amplification. Also indicated are patients with mixed hearing loss with average bone conduction thresholds in the indicated ear better than 45dB HL. The nominal output from the BAHA Cordelle II is on average 13 dB stronger than the Classic 300 model (measured at 0.5, 1, 2, 3 kHz). The Cordelle is recommended for patients having the same indications for the Classic 300 but where slightly stronger amplification is needed than what is delivered by the Classic 300 model. (Patients with bone conduction → thresholds better than 45dB HL will be expected to improve, but may not achieve levels in the normal range. Patients with a bone conduction threshold where each standard measured frequency threshold is less than 25 dB HL can be expected to have restored hearing levels in the normal range.) The patients indicated for this device must also be unable to use conventional air conduction hearing aids or undergo ossicular replacement surgery because of one of the following:

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(Please do not write below line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

Karen J. Zahra
(Division Sign-Off)
Division of Otolaryngologic Devices

510(k) Number K999872

K992872

Contraindications:

1. Speech discrimination scores of the indicated ear less than 60% at elevated sound pressure levels (SPL) during standardized tests.
2. Patients who are developmentally delayed or who suffer from drug abuse. (This includes children who have behavior problems or who have parents who are not able to keep the implanted area clean.)
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