



MAR 7 - 2005

K050275 page 1 of 2

SPECIAL 510(k) SUMMARY
for the INION OTPS™ Biodegradable Pin / device modification

MANUFACTURER

Inion Ltd.
Lääkärintäti 2
FIN-33520 Tampere

Contact Person

Hanna Marttila
Regulatory Affairs Director
Lääkärintäti 2
FIN-33520 Tampere
Phone: +358 3 2306 600
Fax: +358 3 2306 691
Hanna.Marttila@Inion.fi

DEVICE NAME

Trade name: Inion OTPS™ Biodegradable Pin
Common/Usual Name: Pin, Fixation

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification Panel: Orthopedic
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY

PREDICATE DEVICE

Inion OTPS™ Biodegradable Pin (K031712)

CONFORMANCE WITH PERFORMANCE STANDARDS

No applicable mandatory performance standards exist for this device.

THE REASON FOR Special 510(k)

Currently the Inion OTPS™ Biodegradable Pins are manufactured by extrusion followed by grinding and cutting. This special 510(k) is submitted to additional manufacturing method by injection moulding followed by cutting.



page 2 of 2

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Previously 510(k) cleared Inion OTPS™ Biodegradable Pin (K031712) is manufactured by extrusion followed by grinding and cutting. With this special 510(k) we inform for additional manufacturing method by injection moulding followed by cutting. Injection moulded Inion OTPS™ Biodegradable Pins are identical in all the other aspects with the predicate pins except this manufacturing method. Material recipe with copolymer composition is identical. Only difference is that the molecular weight is slightly higher with the extrusion recipe than with the injection moulding recipe.

EQUIVALENCE TO MARKETED PRODUCTS

Injection moulded Inion OTPS™ Biodegradable Pins are essentially identical with the previously 510(k) cleared extruded/machined Pins. Raw material composition with the both devices is identical except slightly lower molecular weight with the injection moulding recipe when compared to the extrusion/machining recipe. Degradation by-products are biocompatible, with no short - or long-term safety concerns. There are no new risks associated with use of the injection moulded Inion OTPS™ Biodegradable Pins as compared to the predicate device.

Injection moulded Inion OTPS™ Biodegradable Pins are substantially equivalent to predicate device used in maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts as shown by the verification testing and do not raise any new questions on safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 - 2005

Ms. Hanna Marttila
Director, Regulatory Affairs
Inion Ltd.
Lääkärintäti 2
FIN-33520 Tampere
Finland

Re: K050275
Trade/Device Name: Inion OTPS™ Biodegradable Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: February 3, 2005
Received: February 7, 2005

Dear Ms. Marttila:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

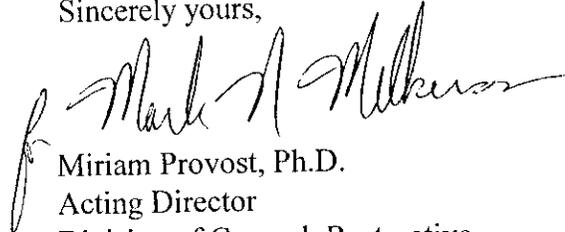
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Hanna Marttila

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", with a stylized initial "P" on the left.

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: Inion Ltd.

510(k) Number: *K050275*

Device Name: Inion OTPS™ Biodegradable Pin

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Contraindications:

The Inion OTPS™ Biodegradable Pin should not be used in fractures and osteotomies of diaphyseal bone or in cases with insufficient quality or quantity of bone. Other contraindications are active or potential infections, patient conditions including limited blood supply, and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse).

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH/Office of Device Evaluation (ODE)

for Mark H. Mathers
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

K050275

Page 1 of _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 2/7/11

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K050275/A2

To: Division Director: OF/DSORD

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.

Change ownership

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).

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: 

Date: 2/11/11

POS

DLK 2/11/11

3/2/11



COPY

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

K050275 / A2

FDA CDRH DMC. 28 January 2011

FEB - 7 2011

Received

LETTER TO FILE – INION OY

Transfer of ownership of 510(k) clearances

Please be informed that effective December 29, 2010 the ownership of the following 510(k) clearances has been transferred as follows:

FROM:

Establishment name: Inion Oy
Address: Lääkärintäti 2
33520 Tampere, Finland

TO:

Establishment name: Beijing Naton Technology Group Co. Ltd.
8-2-1201, Yuan Yang Feng Jing
No. 15 Deshengmen West St. Haidian Dist,
Beijing 100082, China

TRANSFERRED 510(k) CLEARANCES:

Please see next page.

Sincerely,

Kati Marttinen
QA/RA Director
Inion Oy



List of 510(k) clearances, where ownership has changed:

| | |
|---|--|
| Inion Anchron™ and Inion Anchron Plus™ Biodegradable Anchor System | K051362 K062782 |
| Inion BioRestore™ Bone Graft Substitute | K070784 K070998 K090177 |
| Inion CPS® 1.5/2.0/2.5 Biodegradable Fixation System | K010352 K013039 K020266 K022981 |
| Inion CPS® Baby 1.5 Biodegradable Fixation System | K010351 K033194 K051341 K052444 |
| Inion GTR™ Biodegradable Membrane | K033074 |
| Inion Hexalon™ Biodegradable ACL/PCL Screw | K021280 K060393 K071464 |
| Inion OTPS™ Biodegradable Mini Plating System | K023887 |
| Inion OTPS™ 2.5/2.8/3.1 Screws | K043142 |
| Inion OTPS™ Biodegradable Mesh Plating System | K031961 |
| Inion OTPS™ Biodegradable Fixation System | K030900 K062617 |
| Inion OTPS Biodegradable Pin | K031712 K050275 |
| Inion OTPS™ Biodegradable Distal Radius Plate | K052624 |
| Inion CPS/OTPS FreedomPlate™ | K063410 |
| Inion Spinal Graft Containment System (Inion S-1™ and Inion S-2™) | K071810 |
| Inion S-1™ Anterior Cervical Fusion System for Graft Containment | K051821 |
| Inion Trinion™ Biodegradable Meniscus Screw | K031714 |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 - 2005

Ms. Hanna Marttila
Director, Regulatory Affairs
Inion Ltd.
Lääkärintäti 2
FIN-33520 Tampere
Finland

Re: K050275
Trade/Device Name: Inion OTPST™ Biodegradable Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: February 3, 2005
Received: February 7, 2005

Dear Ms. Marttila:

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.

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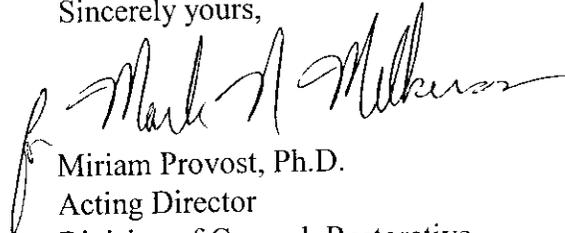
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Hanna Marttila

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: Inion Ltd.

510(k) Number: *K050275*

Device Name: Inion OTPS™ Biodegradable Pin

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Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH Office of Device Evaluation (ODE)

for Mark H. Milken
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

5/2/2016 *K050275*

Page 1 of _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

February 08, 2005

INION LTD.
LAAKARINKATU 2
TAMPERE,
FINLAND 33520
ATTN: HANNA MARTTILA

510(k) Number: K050275
Received: 07-FEB-2005
Product: MODIFICATION TO:
INION OTPS
BIODEGRADABLE PIN

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), 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 May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". 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. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) 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 www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA 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
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

February 08, 2005

INION LTD.
LAAKARINKATU 2
TAMPERE,
FINLAND 33520
ATTN: HANNA MARTTILA

510(k) Number: K050275
Received: 07-FEB-2005
Product: MODIFICATION TO:
User Fee ID Number: 17146
BIODEGRADABLE PIN

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), 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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier (e.g., Fed Ex, UPS, etc.)

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

| | | |
|---|---|---|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET | | PAYMENT IDENTIFICATION NUMBER (b)(4) Confidential and Proprietary Information Write the Payment Identification Number on your check. |
| Completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment: | | |
| <ol style="list-style-type: none"> Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. | | |
| 1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code) INION OY LÄÄKÄRINKATU 2 TAMPERE, 33520 FINLAND | 2. CONTACT NAME HANNA MARTTILA 2.1 E-MAIL ADDRESS hanna.marttila@inion.com 2.2 TELEPHONE NUMBER (Include Area Code) +358 3 230 6600 2.3 FACSIMILE (FAX) NUMBER (Include Area Code) +358 3 230 6691 | 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) |
| 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: | | 3.1 Select one of the types below: |
| <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews Biologics License Application (BLA) | | <input checked="" type="checkbox"/> Original Application |
| <input type="checkbox"/> Premarket Approval Application (PMA) | | Supplement Types: |
| <input type="checkbox"/> Modular PMA | | <input type="checkbox"/> Efficacy (BLA) |
| <input type="checkbox"/> Product Development Protocol (PDP) | | <input type="checkbox"/> Panel Track (PMA, PMR, PDP) |
| <input type="checkbox"/> Premarket Report (PMR) | | <input type="checkbox"/> Real-Time (PMA, PMR, PDP) |
| | | <input type="checkbox"/> 180-day (PMA, PMR, PDP) |
| 4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.) | | |
| <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA | | <input checked="" type="checkbox"/> NO, I am not a small business |
| If Yes, please enter your Small Business Decision Number: | | |
| 5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. | | |
| <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population | |
| <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially | |
| 6. 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).) | | |
| <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO | | |
| 7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) | | |
| (b)(4) Confidential | | |

FDA 3601 (08/2003)

OR 13
II
X-70

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

| | | |
|--------------------------------|--------------------------------------|---|
| Date of Submission 2/3/2005 | User Fee Payment ID Number (b)(4) | FDA Submission Document Number (if known) |
|--------------------------------|--------------------------------------|---|

SECTION A TYPE OF SUBMISSION

| | | | | |
|--|--|---|--|--|
| PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement | PMA & HDE Supplement <input type="checkbox"/> Regular (120 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other | PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP | 510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party | Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify): |
| IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement | Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment | Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission): |

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 Inion Oy | Establishment Registration Number (if known) 9710629 | | |
| Division Name (if applicable) --- | Phone Number (including area code) (358) 3 230 6600 | | |
| Street Address Lääkärintie 2 | FAX Number (including area code) (358) 3 230 6691 | | |
| City TAMPERE | State / Province | ZIP/Postal Code 33520 | Country FINLAND |
| Contact Name Hanna Marttila | | | |
| Contact Title Regulatory Affairs Director | | Contact E-mail Address hanna.marttila@inion.com | |

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

| | | | |
|-------------------------------|------------------|---|---------|
| Company / Institution Name | | | |
| Division Name (if applicable) | | Phone Number (including area code) () | |
| Street Address | | FAX Number (including area code) () | |
| City | State / Province | ZIP/Postal Code | Country |
| Contact Name | | | |
| Contact Title | | Contact E-mail Address | |

14

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

| | | |
|--|--|---|
| <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site | <input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager |
| <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Response to FDA correspondence: | | <input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address |

Other Reason (specify):

SECTION D2 REASON FOR APPLICATION - IDE

| | | |
|--|---|---|
| <input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access | <input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final | <input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing |
|--|---|---|

Other Reason (specify):

SECTION D3 REASON FOR SUBMISSION - 510(k)

| | | |
|-------------------------------------|---|--|
| <input type="checkbox"/> New Device | <input type="checkbox"/> Additional or Expanded Indications | <input checked="" type="checkbox"/> Change in Technology |
|-------------------------------------|---|--|

Other Reason (specify):

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

| | | | | | |
|--|-----|---|--|--|--|
| Product codes of devices to which substantial equivalence is claimed | | | | Summary of, or statement concerning, safety and effectiveness information | |
| 1 | HTY | 2 | | 3 | |
| 5 | | 6 | | 7 | |
| | | | | <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 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 | K031712 | 1 | | 1 | |
| 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
pin, fixation, smooth

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|--|---|--------------|
| 1 | Inion OTPS™ Biodegradable Pin | 1 | |
| 2 | | 2 | |
| 3 | | 3 | |
| 4 | | 4 | |
| 5 | | 5 | |

FUA document numbers of all prior related submissions (regardless of outcome)

| | | | | | |
|---------|---|---|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 |
| K031712 | | | | | |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data Included in Submission

- Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

| | | |
|------------------------------------|--|---|
| Product Code HTY | C.F.R. Section (if applicable) 888.3040 | Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified |
| Classification Panel orthopedic | | |

Indications (from labeling)

The Inion OTPS™ Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

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

| | | | | | | | |
|--|--|--|--|--|--|---|--|
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | FDA Establishment Registration Number 9710629 | | <input checked="" type="checkbox"/> Manufacturer | | <input type="checkbox"/> Contract Sterilizer | |
| | | | | <input type="checkbox"/> Contract Manufacturer | | <input type="checkbox"/> Repackager / Relabeler | |
| Company / Institution Name Inion Oy | | | | Establishment Registration Number 9710629 | | | |
| Division Name (if applicable) --- | | | | Phone Number (including area code) (358) 3 230 6600 | | | |
| Street Address Lääkärintäti 2 | | | | FAX Number (including area code) (358) 3 230 6691 | | | |
| City Tampere | | State / Province | | ZIP/Postal Code 33520 | | Country FINLAND | |
| Contact Name Hanna Marttila | | Contact Title Regulatory Affairs Director | | Contact E-mail Address hanna.marttila@inion.com | | | |

(b)(4) Confidential and Proprietary Information

| | | | | | | | |
|---|--|---------------------------------------|--|--|--|---|--|
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | | FDA Establishment Registration Number | | <input type="checkbox"/> Manufacturer | | <input type="checkbox"/> Contract Sterilizer | |
| | | | | <input type="checkbox"/> Contract Manufacturer | | <input type="checkbox"/> 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/Postal Code | | Country | |
| Contact Name | | Contact Title | | Contact E-mail Address | | | |

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 | 10993-1 | ISO | Biological evaluation of medical devices- part 1:evaluation and testing | 2003 | 8/1/2003 |
| 2 | 10993-5 | ISO | Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity | 1999 | 8/23/1999 |
| 3 | 11607 | ISO | Packaging for terminally sterilized medical devices | 2003 | 2/15/2003 |
| 4 | 11137 | ISO | Sterilization of health care products. Requirements for validation and routine control. Radiation sterilization | 1995 | 3/1/1995 |
| | 15223 | ISO | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. | 2000 | 4/15/2000 |
| 6 | 14971 | ISO | Medical devices. Application of risk management to medical devices. | 2000 | 12/15/2000 |
| 7 | 14644 | ISO | Cleanrooms and associated controlled environments. Part 1 Classification of air cleanliness. Part 2 Specifications for testing and monitoring to prove continued compliance. | 1999 2000 | 3/3/1999 9/15/2000 |

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:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

**Special 510(k):
Device Modification
for
Inion OTPS™ Biodegradable Pin
January/6/2005**

Special 510(k)

5.1.2005

Final

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 1.4 Biomechanical testing..... 3
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F SAFETY AND EFFECTIVENESS..... 3

APPENDICES:

1. Special 510(k) Summary (letterhead paper)
2. Truthful and Accurate Statement (letterhead paper)
3. Declaration of Conformity (letterhead paper)
4. Labelling
 - Instructions for Use of the Inion OTPS™ Biodegradable Pin
 - Device Package Labelling
 - Drawing of the cardboard box with caution
5. Process steps of injection moulded pins and Design Control procedure at Inion Ltd.
6. Mechanical Test Report
7. *In vitro* Test Report
8. Dimensional Test Report
9. Biomechanical Test Report
10. Pyrogenicity Test Report
11. Risk Management Report

A: LIST OF ELEMENTS

| Special 510(k) Elements | Present | Comments |
|--|----------------|------------------------------------|
| Device trade or proprietary name | Yes | CDRH cover sheet 510(k) summary |
| Device common or usual name or classification | Yes | CDRH cover sheet 510(k) summary |
| Establishment registration number | Yes | CDRH cover sheet 510(k) summary |
| Class in which the device has been put under section 513 of the act and, if known the appropriate panel; or if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified. | Yes | CDRH cover sheet 510(k) summary |
| Action taken by the party required to register to comply with the requirements of the act under section 514 for special controls. | Yes | CDRH cover sheet |
| Proposed labels, labelling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. (Blue Book Memo #G91-1) | Yes | Appendix 4 |
| Special 510(k) summary | Yes | Appendix 1 |
| For class III only, a class III certification and a class III summary. | No | Not applicable, Class II |
| Photographs of the device. | No | Not applicable |
| Engineering drawings of the device. | No | Not applicable |
| Identification of the marketed device(s) to which equivalence is claimed including labelling and description of the device. Affiliated 510(k) numbers and product codes are voluntary in cover sheet. | Yes | CDRH cover sheet |
| Statement of similarities and/or differences with marketed device(s) | Yes | Page 7 |
| Data to show consequences and effects of a modified device | Yes | Pages 9-11 Appendices 6 to 11 |
| Submitter's name and address | Yes | CDRH cover sheet |
| Contact person, telephone number and fax number | Yes | CDRH cover sheet |
| Representative/Consultant if applicable | No | Not applicable |
| Table of Contents | Yes | Page 2 |

Special 510(k)

5.1.2005

Final

| Special 510(k) Elements | Present | Comments |
|--|----------------|-------------------|
| Name and address of manufacturing/packaging/sterilization facilities. Registration number of each facility when one exists. | Yes | CDRH cover sheet |
| Comparison table of the new device to the marketed device(s) | Yes | Page 12 (Table 2) |
| Action taken to comply with voluntary standards | Yes | CDRH cover sheet |
| Performance Data (bench, animal, clinical) | Yes | Appendices 6 to 9 |
| Sterilization information (Blue Book Memo #K90-1) | No | Not applicable |
| Software information (Blue Book Memo #K91-1) | No | Not applicable |
| Hardware information | No | Not applicable |
| Information requested in specific guidance documents (if applicable for this device) | Yes | See below * |
| Kit Certification Statement (for kit submission only) | No | Not applicable |
| Truthful and Accurate Statement | Yes | Appendix 2 |

* The New 510(k) Paradigm, alternate approaches to demonstrating substantial equivalence in premarket notifications

* Draft Guidance Document for Testing Biodegradable Polymer Implant Devices

B: STATEMENT OF INDICATIONS FOR USE

Applicant: Inion Ltd.

510(k) Number:

Device Name: Inion OTPS™ Biodegradable Pin

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Contraindications:

The Inion OTPS™ Biodegradable Pin should not be used in fractures and osteotomies of diaphyseal bone or in cases with insufficient quality or quantity of bone. Other contraindications are active or potential infections, patient conditions including limited blood supply, and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse).

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

C: LABELLING

Appendix 4 of this Special 510(k) premarket notification includes copies of proposed labelling for this device:

4.1 Instructions for Use of the Inion OTPS™ Biodegradable Pin

4.2 Device Package Labelling

4.3 Drawing of the cardboard box with caution

D: DEVICE DESCRIPTION

Previously 510(k) cleared Inion OTPS™ Biodegradable Pin (K031712) is manufactured by extrusion followed by grinding and cutting. With this special 510(k) we inform for additional manufacturing method by injection moulding followed by cutting. Injection moulded Inion OTPS™ Biodegradable Pins are identical in all the other aspects with the predicate pins except this manufacturing method. Material recipe with copolymer composition is identical. Only difference is that the molecular weight is slightly higher with the extrusion recipe than with the injection moulding recipe.

1. Intended use

No changes for current indications for use, which are as follows:

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Contraindications:

The Inion OTPS™ Biodegradable Pin should not be used in fractures and osteotomies of diaphyseal bone or in cases with insufficient quality or quantity of bone. Other contraindications are active or potential infections, patient conditions including limited blood supply, and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse).

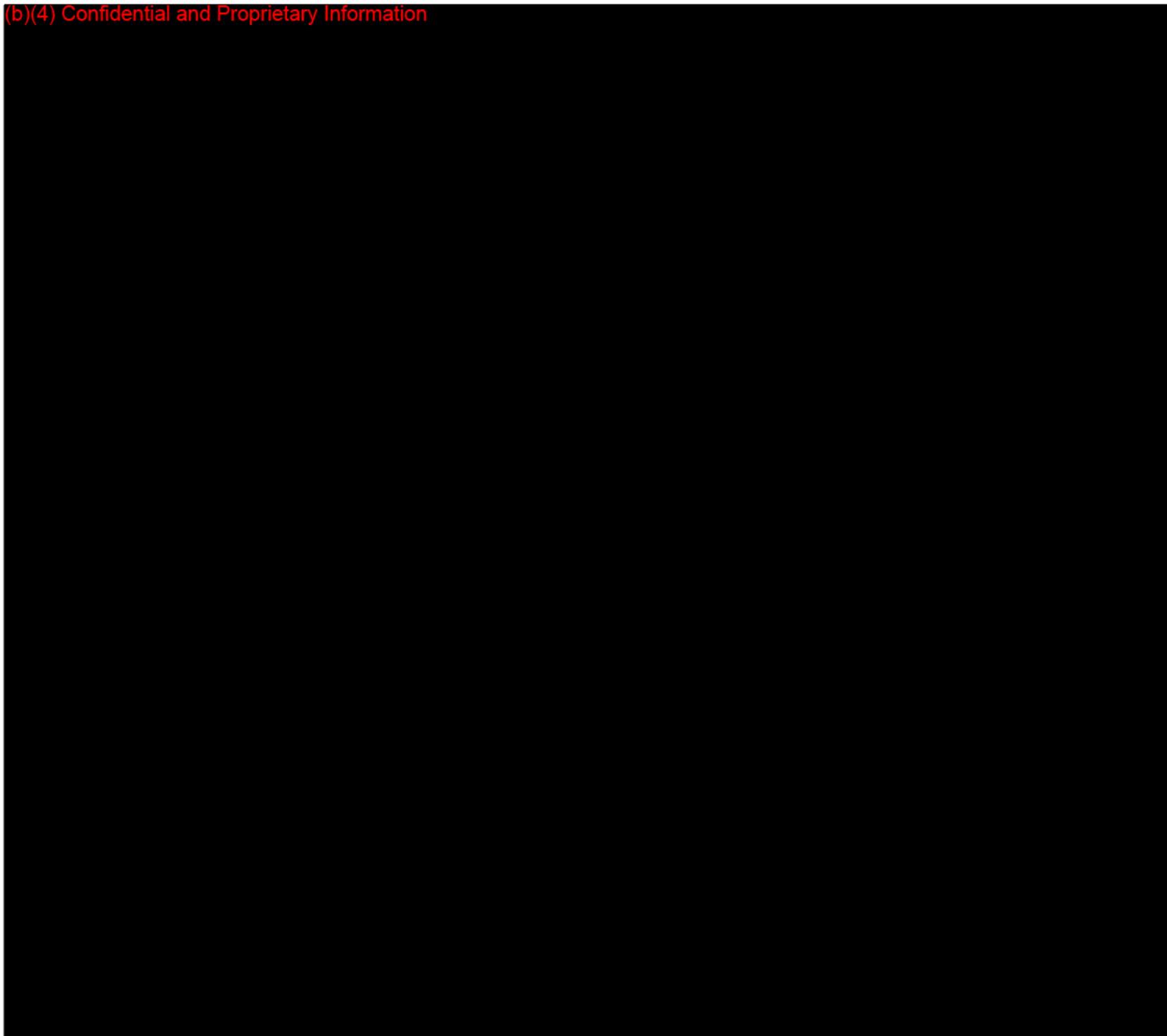
2. Specification

The new, injection moulded Inion OTPS™ Biodegradable Pin is substantially equivalent to the previous Inion OTPS™ Biodegradable Pin, which has received 510(k) clearance (K031712). The Inion OTPS™ Biodegradable Pin is intended to be used for identical indications as the predicate device. Also all the other specifications remain as they are (K031712) except manufacturing method and slight change in molecular weight of the raw material.

New Inion OTPS™ Biodegradable Pin is manufactured by injection moulding followed by cutting. Process steps are presented in Appendix 5. Injection moulded pins are designed to be use with the same customized instrumentation set as the predicate device. They will be offered with the same packaging and sterility options as predicate device. They have also identical principles of operation and technological characteristics.

3. Raw material

(b)(4) Confidential and Proprietary Information



E: DESIGN CONTROL ACTIVITIES

Design change for Inion OTPS™ Biodegradable Pin has been made in conformance with the design control procedure requirements as specified in 21 CFR 820.30. In practise this design change has been documented as a new project. Design control procedure was followed and applicable deliverables completed. In practise development project was divided into three phases with applicable reviews. Appendix 5 of this Special 510(k) premarket notification presents a table summary of design control activities at Inion Ltd.

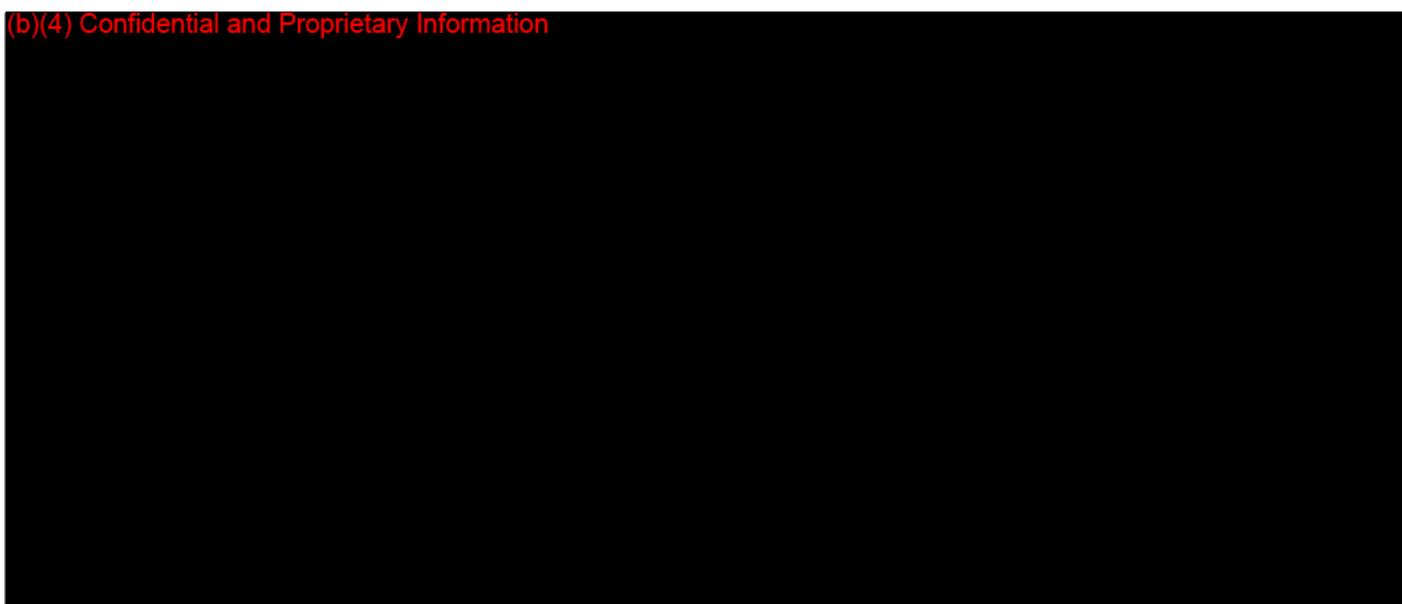
According to the design inputs of new production method for OTPS™ Pins, the design verification tests were to be done by comparing the injection moulded OTPS™ Pins to the extruded OTPS™ Pins. The injection moulded pin was required to be substantially equivalent with (or better than) the existing extruded OTPS™ Pin.

Injection moulded pin has been verified with *in-vitro* and mechanical testing, measuring dimension and with biomechanical testing. Shelf life testing is ongoing. Due to change in manufacturing method also initial LAL testing (pyrogenicity) has been conducted. Sterilization procedure has been validated in accordance with ISO 11137 standard. Test results will be discussed shortly below. Detailed test reports can be found from Appendices 6 to 11. Comparison table for the injection moulded vs. extruded pin has been presented page 12, Table 2.

1. Verification testing

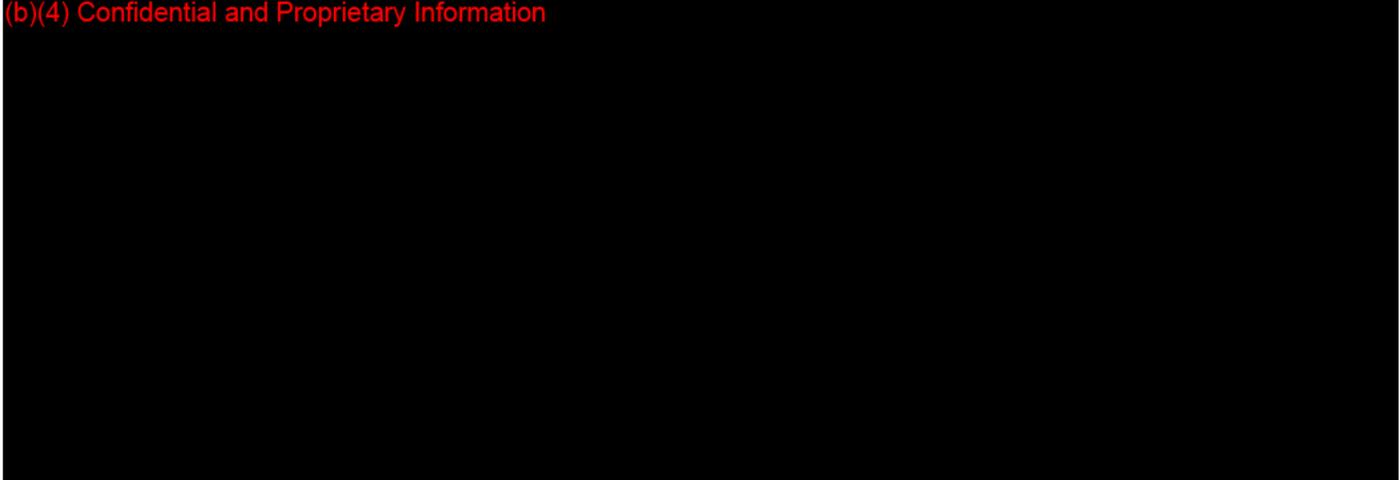
1.1 Mechanical testing

(b)(4) Confidential and Proprietary Information



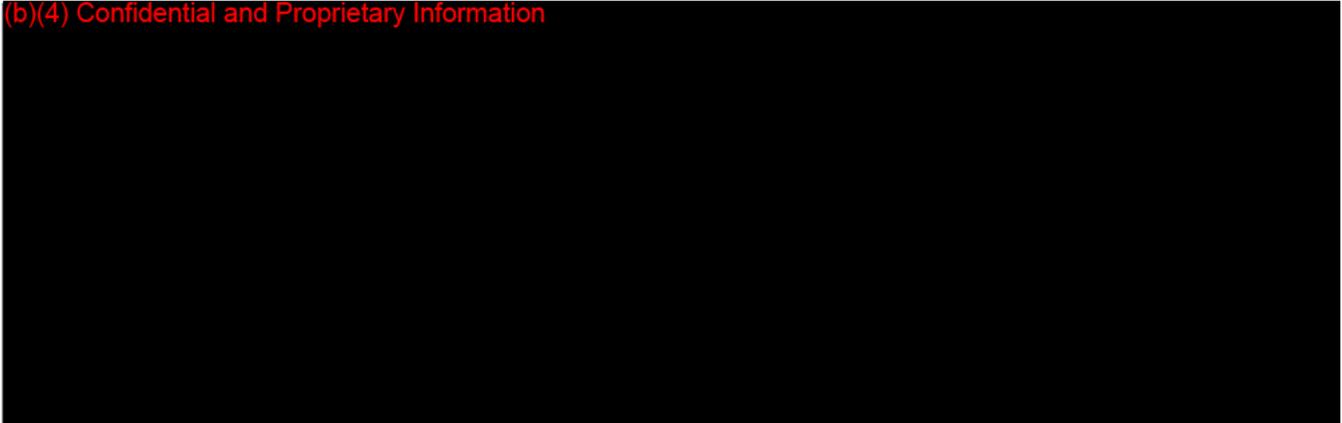
1.2 In vitro testing

(b)(4) Confidential and Proprietary Information



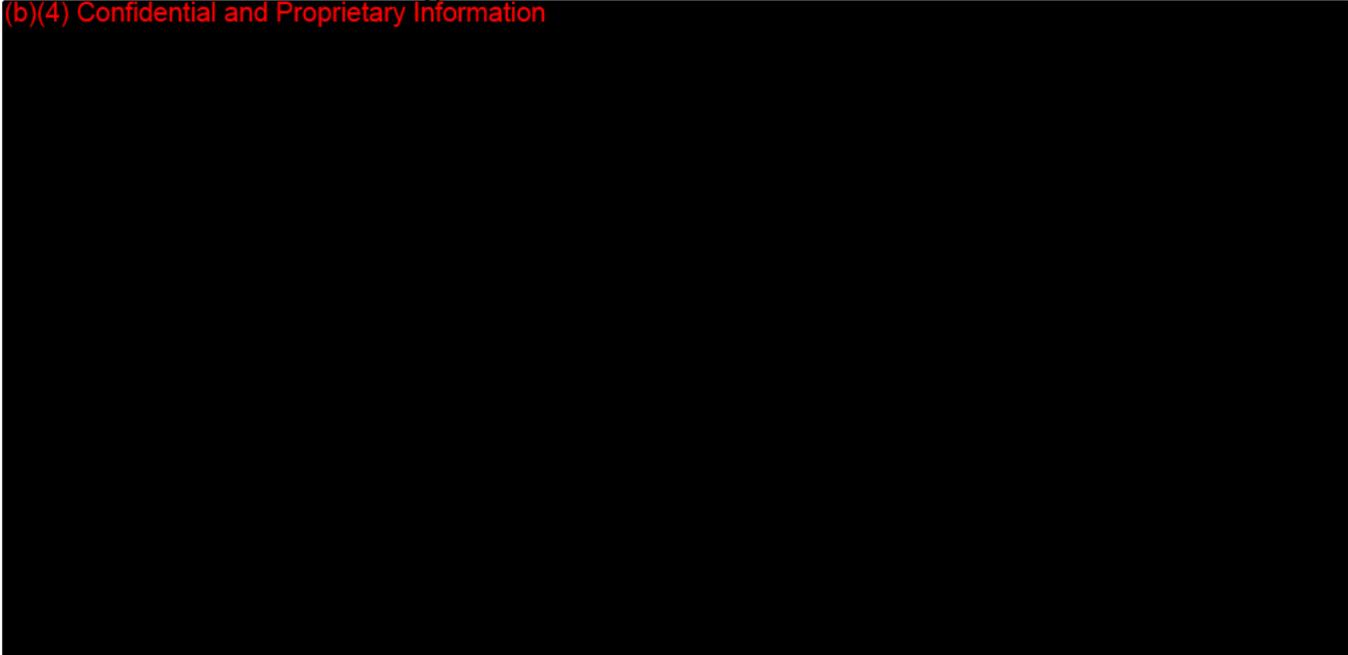
1.3 Dimensional testing

(b)(4) Confidential and Proprietary Information



1.4 Biomechanical testing

(b)(4) Confidential and Proprietary Information

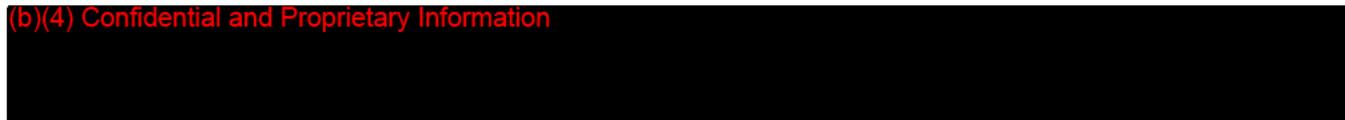


Special 510(k)

5.1.2005

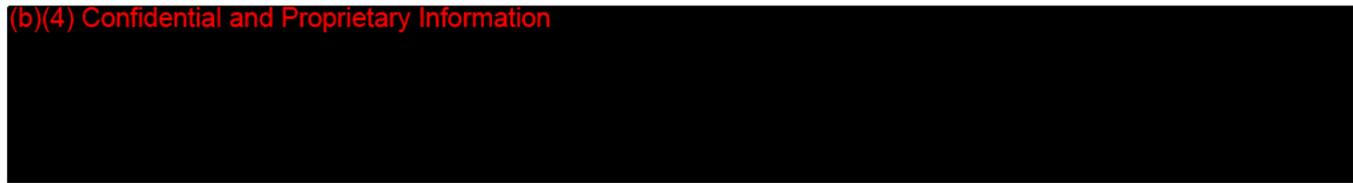
Final

(b)(4) Confidential and Proprietary Information



2. Pyrogenicity

(b)(4) Confidential and Proprietary Information



3. Risk Management

(b)(4) Confidential and Proprietary Information

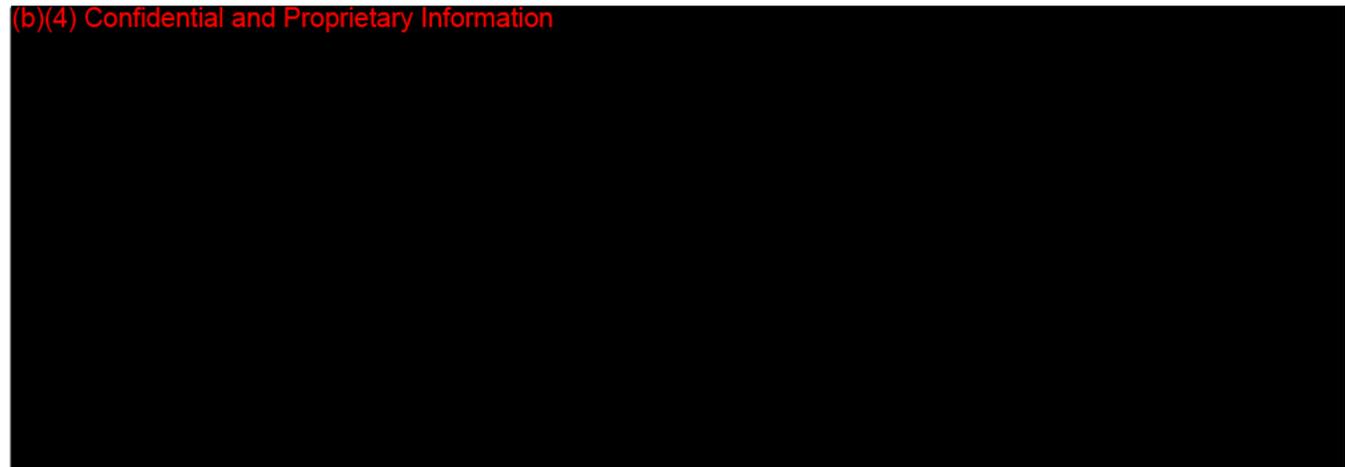


Table 2: Comparison table

| Product | Inion OTPS™ Biodegradable Pin (K031712) | Inion OTPS™ Biodegradable Pin |
|--|--|--|
| Indications for Use | The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriateadditional immobilization (e.g. rigid fixation implants, cast, brace). | The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriateadditional immobilization (e.g. rigid fixation implants, cast, brace). |
| Dimensions: Diameter Length | 1.5 mm and 2.0 mm 20 mm to 50 mm | 1.5 mm and 2.0 mm 20 mm to 50 mm |
| Material | (b)(4) Confidential and Proprietary Information | |
| Manufacturing method | | |
| Sterilization | | |
| Mechanical Testing: Three point bending | | |
| <p>1.5 mm</p> <p>2.0 mm</p> | | |
| Shear strength | (b)(4) Confidential and Proprietary Information | |
| <p>1.5 mm</p> <p>2.0 mm</p> | | |

F SAFETY AND EFFECTIVENESS

Injection moulded Inion OTPS™ Biodegradable Pins are essentially identical with the previously 510(k) cleared extruded/machined Pins. Raw material composition with the both devices is identical except slightly lower molecular weight with the injection moulding recipe when compared to the extrusion/machining recipe. Degradation by-products are biocompatible, with no short - or long-term safety concerns. There are no new risks associated with use of the injection moulded Inion OTPS™ Biodegradable Pins as compared to the predicate device.

Injection moulded Inion OTPS™ Biodegradable Pins are substantially equivalent to predicate device used in maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts as shown by the verification testing and do not raise any new questions on safety and effectiveness.



SPECIAL 510(k) SUMMARY

for the INION OTPS™ Biodegradable Pin / device modification

MANUFACTURER

Inion Ltd.
Lääkärintä 2
FIN-33520 Tampere

Contact Person

Hanna Marttila
Regulatory Affairs Director
Lääkärintä 2
FIN-33520 Tampere
Phone: +358 3 2306 600
Fax: +358 3 2306 691
Hanna.Marttila@Inion.fi

DEVICE NAME

Trade name: Inion OTPS™ Biodegradable Pin
Common/Usual Name: Pin, Fixation

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification Panel: Orthopedic
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY

PREDICATE DEVICE

Inion OTPS™ Biodegradable Pin (K031712)

CONFORMANCE WITH PERFORMANCE STANDARDS

No applicable mandatory performance standards exist for this device.

THE REASON FOR Special 510(k)

Currently the Inion OTPS™ Biodegradable Pins are manufactured by extrusion followed by grinding and cutting. This special 510(k) is submitted to additional manufacturing method by injection moulding followed by cutting.



DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion OTPS™ Biodegradable Pin is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

Previously 510(k) cleared Inion OTPS™ Biodegradable Pin (K031712) is manufactured by extrusion followed by grinding and cutting. With this special 510(k) we inform for additional manufacturing method by injection moulding followed by cutting. Injection moulded Inion OTPS™ Biodegradable Pins are identical in all the other aspects with the predicate pins except this manufacturing method. Material recipe with copolymer composition is identical. Only difference is that the molecular weight is slightly higher with the extrusion recipe than with the injection moulding recipe.

EQUIVALENCE TO MARKETED PRODUCTS

Injection moulded Inion OTPS™ Biodegradable Pins are essentially identical with the previously 510(k) cleared extruded/machined Pins. Raw material composition with the both devices is identical except slightly lower molecular weight with the injection moulding recipe when compared to the extrusion/machining recipe. Degradation by-products are biocompatible, with no short - or long-term safety concerns. There are no new risks associated with use of the injection moulded Inion OTPS™ Biodegradable Pins as compared to the predicate device.

Injection moulded Inion OTPS™ Biodegradable Pins are substantially equivalent to predicate device used in maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts as shown by the verification testing and do not raise any new questions on safety and effectiveness.



TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as the CEO of Inion Ltd., 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.

Place and Date:

Tampere, 3rd of February 2005

Signature:


Auvo Kaikkonen, CEO

K_____



DECLARATION OF CONFORMITY

Manufacturer: Inion Oy
Lääkärintäti 2
FIN-33520 Tampere

Product: Inion OTPS™ Biodegradable Pin

Classification: Class II

We herewith declare that,

Inion OTPS™ Biodegradable Pin

Is in conformance with the following Consensus Standards

ISO 10993 Part 1- Biological evaluation of medical devices
ISO 10993 Part 5 - Test for in vitro cytotoxicity
ISO 11607 Packaging for terminally sterilized medical devices
ISO 11137 Requirements for validation and routine control
ISO 15223: Symbols to be used with medical device labels, labelling and information to be supplied
ISO 14971: Application of risk management to medical devices
ISO 14644-1 Cleanroom and associated controlled environments. Part 1
ISO 14644-2 Cleanroom and associated controlled environments. Part 2

Tampere, January 28, 2005


Marjukka Eklund
Director, QC/QA

12000150 (3/080105)

ENGLISH

INION OTPS™ BIODEGRADABLE PIN INSTRUCTIONS FOR USE

DESCRIPTION

The **INION OTPS™ BIODEGRADABLE PIN** is intended to maintain accurate alignment of fragments of fractured bone in the presence of appropriate immobilization.

The **INION OTPS™ BIODEGRADABLE PIN** is made of degradable co-polymers composed of L-lactic, D-lactic and trimethylene carbonate. These polymers have a long history of safe medical use and they degrade in vivo by hydrolysis into alpha-hydroxy acids that are metabolised by the body. The coloured pins are dyed green for better visualization during the surgical procedure by a minimal amount of Drug and Cosmetic (D&C) Green No. 6, which is used in several biodegradable sutures. The pin gradually loses its strength during 18-36 weeks. Bioresorption takes place within two to four years.

The **INION OTPS™ BIODEGRADABLE PIN** is offered in different sizes and it is designed to be used with customized instrumentation, e.g. the **INION OTPS™ TROCAR TIP DRILL**, **PIN APPLICATORS** and **ARTHROSCOPIC** instruments.

The **INION OTPS™ BIODEGRADABLE PIN** is sterile, non-collagenous, and non-pyrogenic.

INDICATIONS

The **INION OTPS™ BIODEGRADABLE PIN** is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

CONTRAINDICATIONS

The **INION OTPS™ BIODEGRADABLE PIN** should not be used in fractures and osteotomies of diaphyseal bone or in cases with insufficient quality or quantity of bone. Other contraindications are active or potential infections, patient conditions including limited blood supply, and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse). There are currently no known additional contraindications to the use of the **INION OTPS™ BIODEGRADABLE PIN**.

INFORMATION FOR USE

Surgical considerations and reminders

- Prophylactic perioperative antibiotic treatment is recommended.
- Use proper local, regional or general anaesthesia.
- Maintain sterile field throughout the procedure.
- Proper exposure using standard surgical procedure.
- Thoroughly prepare the surgical site preserving the neurovascular structures by careful dissection.
- Good alignment/reduction of the fracture/osteotomy followed by fixation with clamp(s).
- Radiographs can be taken before wound closure to check the alignment/reduction after fixation.
- Meticulous hemostasis and complete primary skin closure over the implant are essential.

Implantation of the pin

- Choose appropriate **INION OTPS™ BIODEGRADABLE PIN** for the indication.
- Using the appropriate (corresponding to the pin diameter) **INION OTPS™ TROCAR TIP DRILL**, drill a hole through the fracture/osteotomy plane.
- Introduce the pin into the hole by hand or by using the appropriate (corresponding to the pin diameter) **INION OTPS™ PIN APPLICATOR**. The pin should sink a bit into the drilled hole if not, slightly widen the opening of the hole with the drill.
- Push the pin applicator onto the pin and press the applicator shaft to contact with the pin. The **INION OTPS™ PIN APPLICATOR** must be used to ensure proper insertion of the pin into the drill hole. During insertion of the pin, hold the applicator and the pin parallel to the long axis of the drill hole to prevent bending of the pin.
- Tap the applicator shaft into the cylinder with a small mallet so that the entire pin is forced fully into the drill hole. This prevents the head of the pin protruding which could cause soft tissue irritation.
- When necessary, a hot wire or scissors can be used to cut the pin before insertion or after insertion if the pin is too long.
- Two or more drill holes with fixing pins can be applied if necessary (depending on the nature and size of the fracture).
- When performing arthroscopic pin fixation, use the **INION OTPS™ ARTHROSCOPIC** instruments.

Post operative reminders

- As with any surgical procedure, careful postoperative management is important for optimal healing.
- Provide the patient with detailed instructions for postoperative care.
- Use appropriate additional immobilization (e.g. a suitable cast, brace and/or crutches) during bone healing.
- Antibiotic therapy at the discretion of the clinician.

Evaluation of results

Radiographs can be taken to evaluate bone healing.

WARNINGS

- The **INION OTPS™ BIODEGRADABLE PIN** implants provide fixation and are not intended to replace healthy bone or withstand the stress of full load bearing.
- Incorrect selection, placement, positioning, and fixation of the implant can cause subsequent undesirable results. The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.

PRECAUTIONS

- Instruments are available to aid accurate implantation of the **INION OTPS™ BIODEGRADABLE PIN**. Surgical instruments are subject to wear with normal usage and may break. Surgical instruments are only to be used for their intended purpose. All instruments are to be regularly inspected for wear and damage. Use only the **INION OTPS™ PIN** instruments.
- When two or more pins are used, insert the pins at divergent angles to one another rather than parallel, for best results.
- DO NOT use for unintended applications! Proper function (i.e., effectivity and safety) of these implants can not be guaranteed in case of off-label use.
- The patient should be warned that premature bending, loosening, breakage or migration of the pin may result from early weight bearing, stress and activity.

SPECIAL PATIENT POPULATIONS

The effect of the **INION OTPS™ BIODEGRADABLE PIN** upon the healing of growth plate has not been tested clinically.

ADVERSE EFFECTS

Complications are similar to those with any method of internal fixation:

- Premature bending, loosening, breakage or migration of the devices may result from early stress, activity or load bearing.
- Infection can lead to failure of the procedure.
- Neurovascular injuries can occur due to surgical trauma.
- Implantation of foreign materials can result in an inflammatory response or allergic reaction. Transient local fluid accumulation may occur in sterile circumstances.

STERILITY

The **INION OTPS™ BIODEGRADABLE PIN** implants have been sterilized with ionizing irradiation. Use immediately after opening the sterile seal. Use only devices that are contained in unopened and undamaged packages. For single use only. DO NOT re-sterilize. DO NOT use implant beyond the expiration date on the label.

STORAGE

Store at room temperature (15 to 30°C or 59 to 86°F) at a normal relative humidity. Product should not exceed a maximum temperature of 49°C or 120°F. Product exceeding this temperature must be discarded.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a licensed physician.

MANUFACTURER

INION Ltd.
Lääkärintäti 2
33520 Tampere
Finland
Tel. +358 3 230 6600
Fax +358 3 230 6601
info@inion.com
www.inion.com

Inner Label (89 x 55 mm)

REF PIN-1520 **LOT** 0303013  2003-03  2006-03-01

1.5 x 20 mm pin **1.5 mm OTPS**

| | |
|-----------------------|----------------------|
| 1,5 x 20 mm Nagel | 1,5 x 20 mm năi |
| Broche de 1,5 x 20 mm | Περόνη 1,5 x 20 χιλ. |
| Perno 1,5 x 20 mm | Pen 1,5 x 20 mm |
| Pino 1,5 x 20 mm | 1,5 x 20 mm tapp |
| Pin de 1,5 x 20 mm | 1,5 x 20 mm sauva |
| Gwóźdz 1,5 x 20 mm | Hřeb 1,5 x 20 mm |

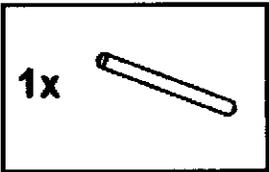
HBC1

HBC2

+M224PIN15209P
+5580130603010303013P4

Patent No. US 6,447,548   15 30 °C / 59 86 °F  0434 **STERILE R** 

Manufacturer: Inion Ltd., Lääkärintie 2, 33520 Tampere, FINLAND



Outer Label (90 x 173 mm)

49 °C
Warning: Product must be discarded, if temperature exceeds 49°C (120°F) according to temperature indicator (black dot).

120 °F



15 °C - 30 °C (59 °F - 86 °F)
Recommended product storage between

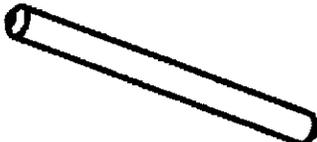
1.5 x 20 mm pin
1.5 x 20 mm Nagel
Broche de 1.5 x 20 mm
Perno 1.5 x 20 mm
Pino 1.5 x 20 mm
Pin de 1.5 x 20 mm
Goudele 1.5 x 20 mm
1.5 x 20 mm nål
Nepovnj 1.5 x 20 pin
Pinn 1.5 x 20 mm
1.5 x 20 mm tapp
1.5 x 20 mm earpin
Hib 1.5 x 20 mm

REF PIN-1520 1.5 x 20 mm pin
LOT 0303013
HIBC2

REFPIN-1520 LOT 0303013

1.5 x 20 mm pin
1.5 mm OTPS

1x



HIBC1
 2003-03
HIBC2
+M224PIN15209P
 2006-03-01
+3380130603010303013P4

   0434 **STERILE R**  15 °C / 59 °F / 30 °C / 86 °F

Patent No. US 6,607,548
Manufacturer: Inlon Ltd, Lääkärintäti 2, 33520 Tampere, FINLAND

Patient Card Label (59 x 82 mm)

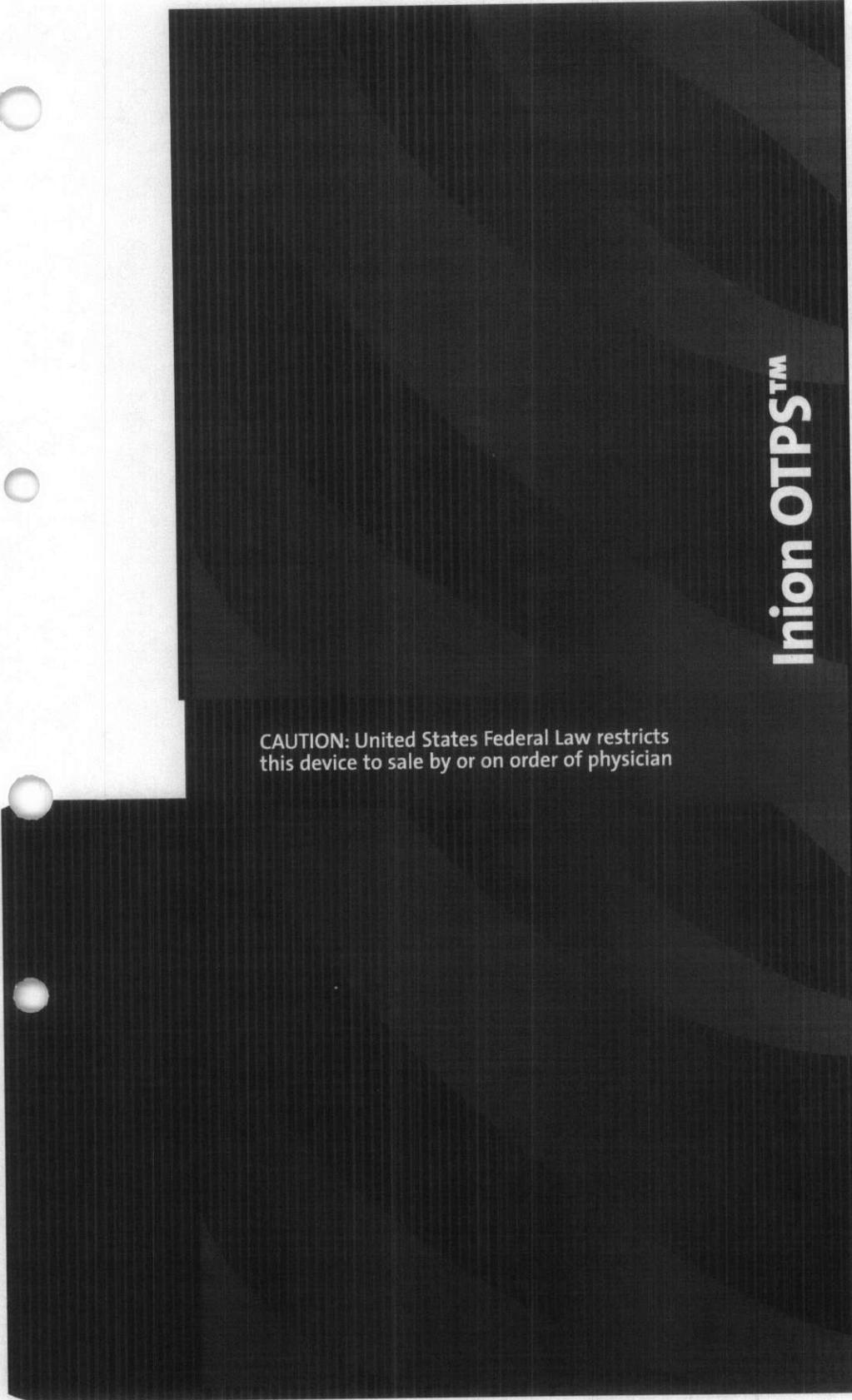
| Inion OTPS™ | |
|-----------------------|----------------|
| Patient chart | Karta pacjenta |
| Patientenkarte | Patientkort |
| Carte du patient | Κάρτα ασθενούς |
| Cartella del paziente | Patiëntkaart |
| Ficha do paciente | Potilaskortti |
| Tarjeta de paciente | Karta pacjenta |

| | | |
|--|--------------------|---|
| REFPIN-1520 | LOT 0303013 |  2006-03-01 |
| 1.5 x 20 mm pin | | 1.5 mm OTPS |
| Manufacturer: Inion Ltd., Lääkärintatu 2, 33520 Tampere, Finland | | |

| | | |
|--|--------------------|---|
| REFPIN-1520 | LOT 0303013 |  2006-03-01 |
| 1.5 x 20 mm pin | | 1.5 mm OTPS |
| Manufacturer: Inion Ltd., Lääkärintatu 2, 33520 Tampere, Finland | | |

| | | |
|--|--------------------|---|
| REFPIN-1520 | LOT 0303013 |  2006-03-01 |
| 1.5 x 20 mm pin | | 1.5 mm OTPS |
| Manufacturer: Inion Ltd., Lääkärintatu 2, 33520 Tampere, Finland | | |

| | | |
|--|--------------------|---|
| REFPIN-1520 | LOT 0303013 |  2006-03-01 |
| 1.5 x 20 mm pin | | 1.5 mm OTPS |
| Manufacturer: Inion Ltd., Lääkärintatu 2, 33520 Tampere, Finland | | |



CAUTION: United States Federal Law restricts this device to sale by or on order of physician

Inion OTPS™

NOINI



INION

**Biodegradable
Fixation
System**

INION

INION Ltd.
Lääkärintätkä 2
FIN-33520 Tampere, FINLAND
tel +358-3-2306600 • fax +358-3-2306601
email: info@inion.com • internet: www.inion.com



Overall Process Flow

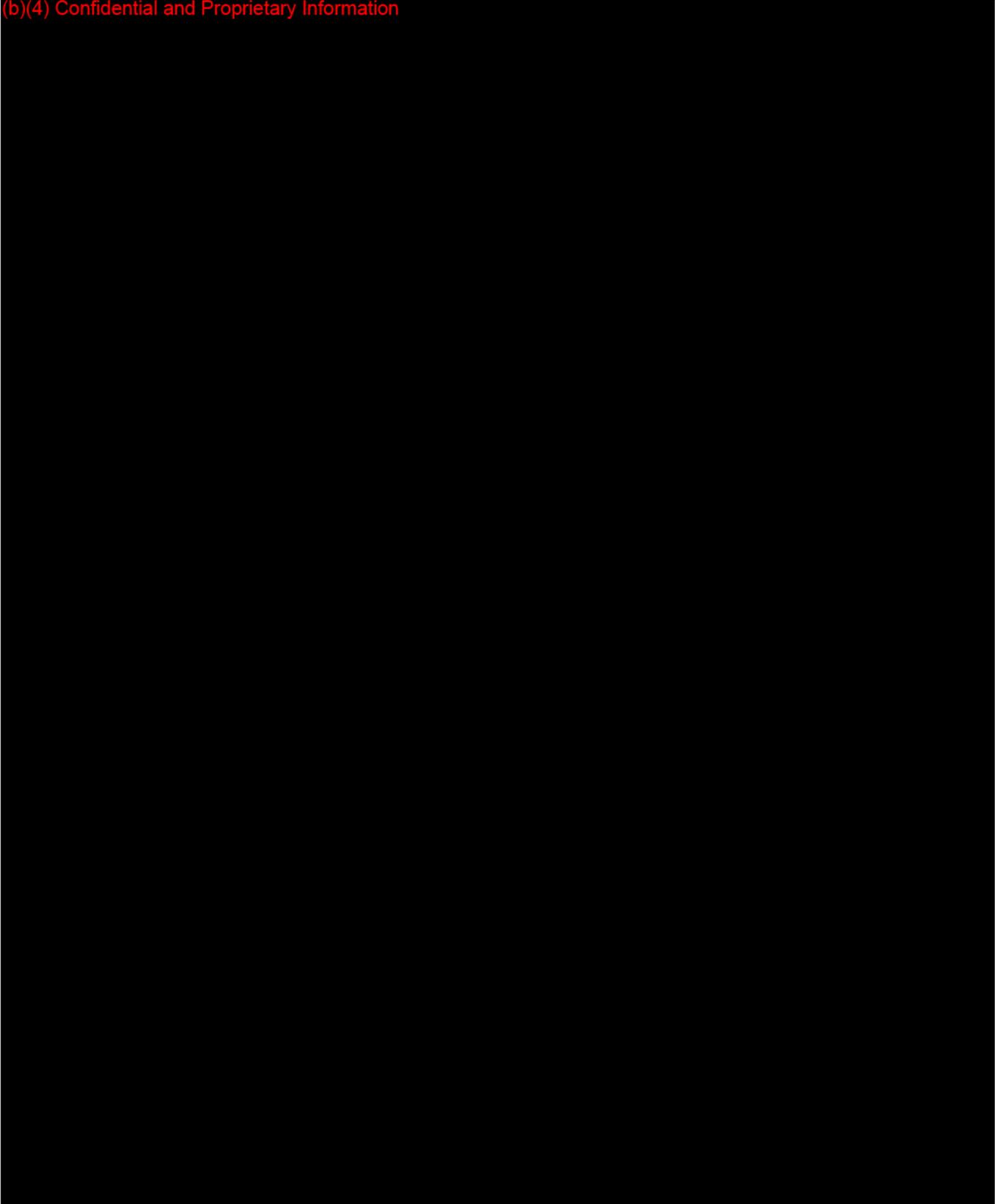
New production method for OTPS Pins

Inion Ltd / Totti Lindgren, Production Development Manager

28/12/04, updated 21/01/2005

Process steps of injection moulded pins

(b)(4) Confidential and Proprietary Information



(b)(4) Confidential and Proprietary Information

TABLE 1. DEVELOPMENT PHASES AND DELIVERABLES IN EACH PHASE



Inion Oy

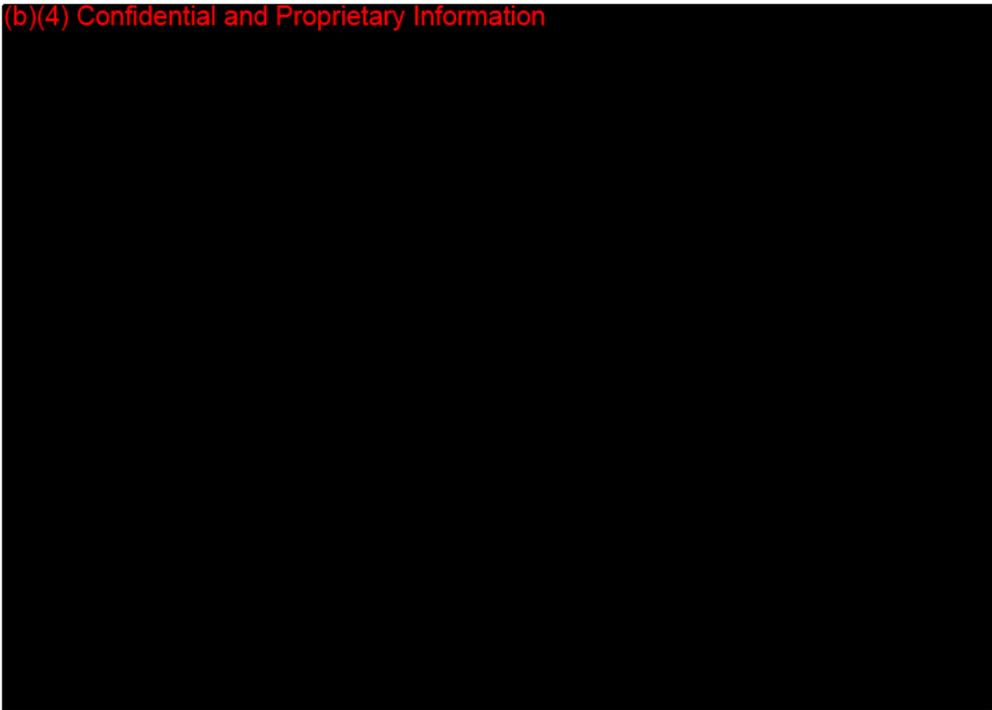
Created 10 January 2005

Updated 1 February 2005

Mechanical Test Report

Injection Moulded OTPS Pin

(b)(4) Confidential and Proprietary Information



Confidential

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Pi-Suy
Subject: 510(k) Number K050275
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.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

| | | |
|---|---|--|
| Is this device subject to Section 522 Postmarket Surveillance? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this a prescription device? | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was this 510(k) reviewed by a Third Party? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Special 510(k)? | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |

Truthful and Accurate Statement Requested Enclosed
 A 510(k) summary OR A 510(k) statement
 The required certification and summary for class III devices
 The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO 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):

HTY/II
 Review: _____
 (Branch Chief) (Branch Code) (Date) CRDB 3/7/05
 Final Review: Mark Miller
 (Division Director) (Date) 3/7/05

Revised: 4/2/03

Document: K050275

Device Name: Inion OTPS™ Biodegradable Pin

Classification: II, 87/HTY, 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Submitted By: Inion

Date Decision Due: 3/9/05

Reviewed By: Pei Sung, Ph.D.

Pei 3/7/05

Recommendation:

This subject Special 510(k) notification:

- Fulfills the requirements for a "Special" 510(k)
- Requires more data.
- Transfer to traditional 510(k).

Type letter and wording suggested:

- "SE" Letter Attached
- "SN" Letter Attached
- "AI" Letter Attached
- "AI" via Telephone and/or FAX

Summary:

The modified device(s) has/have the following similarities to its/their predicate cleared via K031712 :

- The same indications for use statement
- Incorporate the same design
- Are manufactured from the same materials

The only modification described in this Special 510(K) is to change the manufacture method from extrusion to injection.

This submission does contain information/data on modifications made to the submitter's own device and 510(k).

The sponsor has provided the necessary to fulfill the requirements for a Special 510(k). As part of a "Special" 510(k), the sponsor is not required to provide much of the information in the traditional 510(k). Therefore, the "SE" decision is primarily based on an administrative review rather than a scientific review, as was the Special regulations were intended.

This Special 510(k) Include:

1. Coversheet identifying the application as “Special 510(k): Device Modification”;
2. Name and 510(k) of device for which it is a modification;
3. Description of the device modification(s);
4. Statement that intended use of modified device as described in its labeling have not changed;
5. Information that fundamental scientific technology of the modified device has not changed;
6. Design control activities summary:
 - a) 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;
 - b) 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;
 - c) Declaration of conformity with design; and
7. General information required for all 510(k) submissions.

A device comparison table of the characteristics of the subject device, including design, materials, and intended use, to the predicate is enclosed in Table 2 of Section 12. The summary mechanical measurement of the modified and the predicate is summarized below:

| | | | |
|--|------|---------------------------|-------------------|
| | Size | Subject, Injection molded | K031712, Extruded |
|--|------|---------------------------|-------------------|

(b)(4) Confidential and Proprietary Information



Conclusion:

The sponsor has provided the necessary to fulfill the requirements for a Special 510(k). The sponsor has adequately addressed all deficiencies

Decision Making Documentation

Product to which compared: see review

YES NO

| | | | | |
|-----|---|---|--|--------------------------------------|
| 1. | Is Product A Device | x | | If NO = Stop |
| 2. | Is 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 |
| 7. | Descriptive Characteristics Precise Enough? | x | | If NO = Go To 10 If YES = Stop SE |
| 8. | New Types Of Safety Or Effectiveness Questions? | | | If YES = Stop NE |
| 9. | Accepted Scientific Methods Exist? | | | If NO = Stop NE |
| 10. | Performance Data Available? | | | If NO = Request Data |
| 11. | Data Demonstrate Equivalence? | | | Final Decision: |

Note: "Yes" responses to questions 4,6,8,11, and every "No" response requires an explanation.

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performances data are needed:
11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:

Internal Administrative Form

| | YES | NO |
|---|-----|----|
| 1. Did the firm request expedited review? | | x |
| 2. Did we grant expedited review? | | x |
| 3. Have you verified that the Document is labeled Class III for GMP purposes? | x | |
| 4. If not, has POS been notified? | | |
| 5. Is the product a device? | x | |
| 6. Is the device exempt from 510(k) by regulation or policy? | | x |
| 7. Is the device subject to review by CDRH? | x | |
| 8. Are you aware that this device has been the subject of a previous NSE decision? | | x |
| 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)? | | |
| 10. Are you aware of the submitter being the subject of an integrity investigation? | | x |
| 11. If yes, consult the ODE Integrity Officer. | | |
| 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991. | | |

Screening Checklist

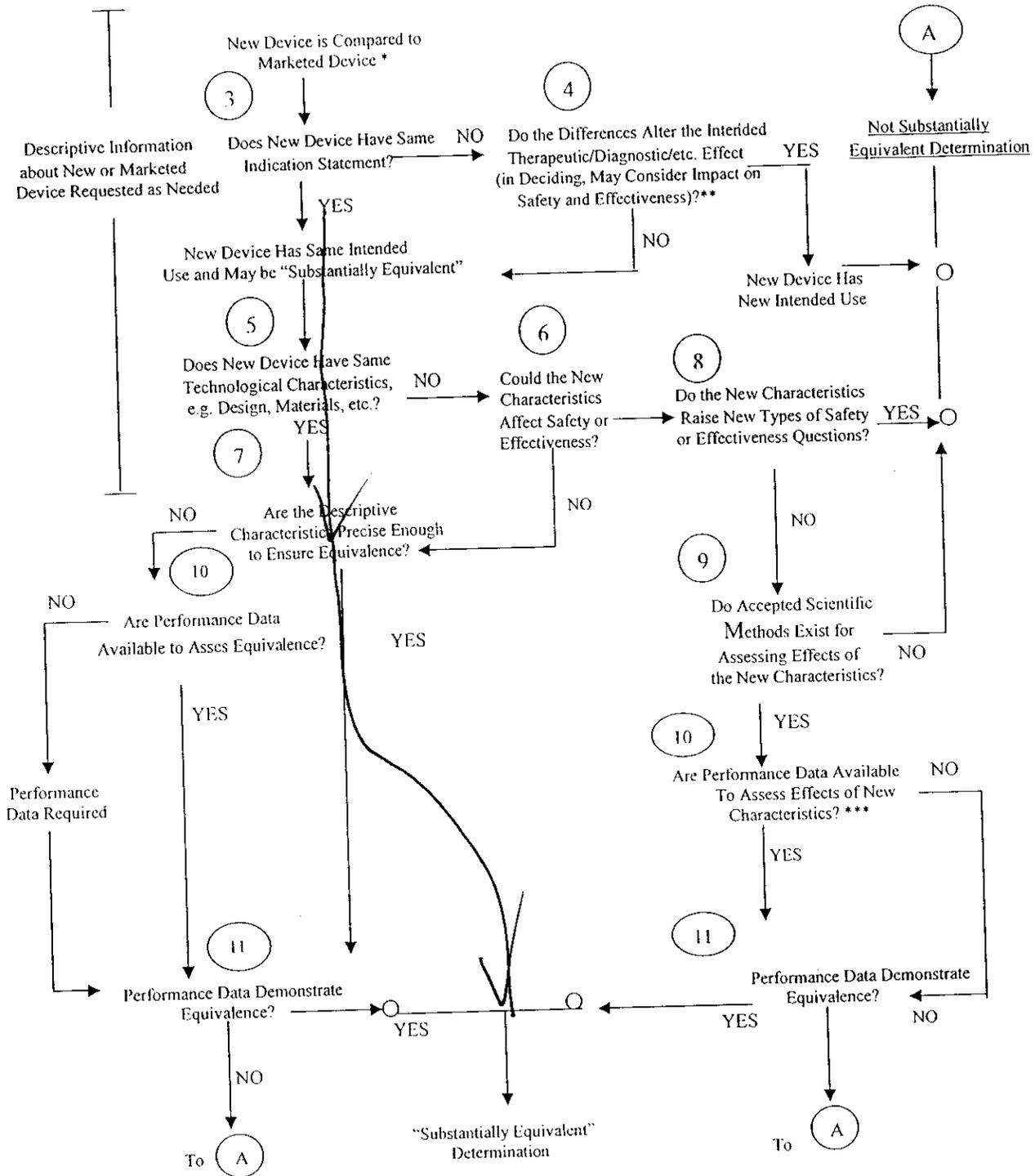
| 2. GENERAL INFORMATION: REQUIRED IN SPECIAL 510(K) SUBMISSIONS | | | | | | | |
|--|--|----|------------------------------|----|-------------|----|--|
| Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) | NA | | YES | | NO | | |
| | SPECIALS | | ABBREVIATED | | TRADITIONAL | | |
| | YES | NO | YES | NO | YES | NO | |
| a) trade name, classification name, establishment registration number, device class | x | | | | | | |
| 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 | | | | | | |
| e) address of manufacturer | x | | | | | | |
| f) Truthful and Accurate Statement | x | | | | | | |
| g) Indications for Use enclosure | x | | | | | | |
| h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES) | x | | | | | | |
| i) Class III Certification & Summary (FOR ALL CLASS III DEVICES) | | | | | | | |
| j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals | x | | | | | | |
| k) Proposed Labeling | x | | | | | | |
| l) Comparison Information (similarities and differences) to named legally marketed equivalent device | x | | | | | | |
| m) If kit, kit certification | | | | | | | |
| 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 | x | | | | | | |
| b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED* | x | | * If no - STOP not a special | | | | |
| c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED* | x | | * If no - STOP not a special | | | | |
| d) Design Control Activities Summary | x | | | | | | |
| 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 | x | | | | | | |
| 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 | x | | | | | | |
| iii) A declaration of conformity with design controls. | x | | | | | | |

Passed Screening: Yes

Reviewed by: Pei Sung

Concurred by: _____

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.