



# U.S. Department of Health & Human Services

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**Food and Drug Administration**

## SAVE REQUEST

**USER:** (kml)  
**FOLDER:** K071092 - 96 pages  
**COMPANY:** HOWMEDICA OSTEONICS CORP. (HOWMOSTEA)  
**PRODUCT:** SCREW, FIXATION, BONE (HWC)  
**SUMMARY:** Product: ASNIS MICRO CANNULATED SCREW

**DATE REQUESTED:** Apr 27, 2016

**DATE PRINTED:** Apr 27, 2016

**Note:** Printed



K071092 1/1

**Summary of Safety and Effectiveness**  
**Asnis™ III Cannulated Screw System Line Extension**

MAY 11 2007

Proprietary Name: Asnis™ Micro Cannulated Screw  
Common Name: Bone Screw  
Classification Name and Reference: Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040  
Proposed Regulatory Class: **Class II**  
Device Product Code: 87 HWC: Screw, Fixation, Bone  
For Information contact: Vivian Kelly, Sr. Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, NJ 07430  
Phone: (201) 831-5581  
Fax: (201) 831-6038  
Date Summary Prepared: April 17, 2007

**Description:**

This Special 510(k) submission is a line extension to address modifications to the Asnis™ III Cannulated Screw System. This line extension is to add additional sizes of screws to the system.

**Intended Use**

The modifications do not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject device are provided below.

**Indications**

The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

**Substantial Equivalence:**

These additional components are substantially equivalent to their predicate systems in respect to design, intended use, performance and operational principle as internal fixation components. Predicate systems include the Asnis™ III Cannulated Screw System (K000080 and K024060) and other commercially available cannulated screws on the market such Vilex 2mm Screws (K973309, K991151 & K991197) and Synthes Cannulated Screws (K962823.) Mechanical testing was conducted to compare the strength of the subject device to predicate screws. The results demonstrate that the subject components are substantially equivalent in strength to the predicate components.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 11 2007

Howmedica Osteonics Corporation  
% Ms. Vivian Kelly, RAC  
Senior Regulatory Affairs Specialist  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K071092

Trade/Device Name: Asnis™ III Cannulated Screw System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth of threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: April 17, 2007  
Received: April 18, 2007

Dear Ms. Kelly:

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. Vivian Kelly, RAC

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 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 "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use K071092

510(k) Number (if known):

Device Name: Asnis™ III Cannulated Screw System

Indications for Use:

The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Prescription Use   X    
(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 OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)  
*Barbara Amel*  
**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K071092



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 11 2007

Howmedica Osteonics Corporation  
% Ms. Vivian Kelly, RAC  
Senior Regulatory Affairs Specialist  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K071092

Trade/Device Name: Asnis™ III Cannulated Screw System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth of threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: April 17, 2007  
Received: April 18, 2007

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Page 2 - Ms. Vivian Kelly, RAC

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Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use K071092

510(k) Number (if known):

Device Name: Asnis™ III Cannulated Screw System

Indications for Use:

The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Prescription Use  X   
(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 OF  
NEEDED)

Page 1 of 1

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Barbara Freeman*  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

33

510(k) Number K071092

3

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

April 19, 2007

HOWMEDICA OSTEONICS CORP.  
325 CORPORATE DRIVE  
MAHWAH, NJ 07430  
ATTN: VIVIAN KELLY

510(k) Number: K071092  
Received: 18-APR-2007  
Product: ASNIS MICRO  
CANNULATED SCREW

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (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 510(k) submission.

Please note the following documents as they relate to 510(k) review:  
1) 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 (MDUFMA). Please review this document at [www.fda.gov/cdrh/mdufma/guidance/1219.html](http://www.fda.gov/cdrh/mdufma/guidance/1219.html).  
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at [www.fda.gov/cdrh/ode/guidance/1567.html](http://www.fda.gov/cdrh/ode/guidance/1567.html). Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).  
3) 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](http://www.fda.gov/cdrh/ode/a02-01.html).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at [www.fda.gov/cdrh/elecsup.html](http://www.fda.gov/cdrh/elecsup.html).

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice [www.fda.gov/cdrh/devadvice/](http://www.fda.gov/cdrh/devadvice/). If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman  
Supervisory 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) Write the Payment Identification number on your check.	
<p>A 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:</p> <ol style="list-style-type: none"> <li>1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.</li> <li>2. Include 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.</li> <li>3. 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.)</li> <li>4. 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.)</li> <li>5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <a href="http://www.fda.gov/cdrh/mdufma/faqs.html#3a">http://www.fda.gov/cdrh/mdufma/faqs.html#3a</a>. You are responsible for paying all fees associated with wire transfer.</li> <li>6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.</li> </ol>			
<p>1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)</p> <p>HOWMEDICA OSTEONICS CORP 325 CORPORATE DR MAHWAH NJ 07430 US</p> <p>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 222183590</p>		<p>2. CONTACT NAME Vivian Kelly</p> <p>2.1 E-MAIL ADDRESS vivian.kelly@stryker.com</p> <p>2.2 TELEPHONE NUMBER (include Area code) 201-831-5581</p> <p>2.3 FACSIMILE (FAX) NUMBER (include Area code) 201-831-6038</p>	
<p>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: <a href="http://www.fda.gov/dc/mdufma">http://www.fda.gov/dc/mdufma</a>)</p> <p>Select an application type:</p> <p><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</p> <p><input type="checkbox"/> Biologics License Application (BLA)</p> <p><input type="checkbox"/> Premarket Approval Application (PMA)</p> <p><input type="checkbox"/> Modular PMA</p> <p><input type="checkbox"/> Product Development Protocol (PDP)</p> <p><input type="checkbox"/> Premarket Report (PMR)</p> <p>3.1 Select one of the types below</p> <p><input checked="" type="checkbox"/> Original Application</p> <p>Supplement Types:</p> <p><input type="checkbox"/> Efficacy (BLA)</p> <p><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</p> <p><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</p> <p><input type="checkbox"/> 180-day (PMA, PMR, PDP)</p>			
<p>4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)</p> <p><input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA</p> <p><input checked="" type="checkbox"/> NO, I am not a small business</p> <p>4.1 If Yes, please enter your Small Business Decision Number:</p>			
<p>5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.</p> <p><input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms</p> <p><input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population</p> <p><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</p> <p><input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially</p>			
<p>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).)</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO</p>			
<p>7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)</p> <p>b(4)</p>			

(Close Window)

(Print Cover sheet)

K8  
OR  
II 16



April 17, 2007

Via Federal Express

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

**Re: Special Premarket Notification: Asnis™ III Cannulated Screw System Line Extension**

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and Title 21 CFR §807, Subpart E, this 510(k) Premarket Notification is being submitted in duplicate for a line extension to Asnis™ III Cannulated Screw System to add smaller screw sizes. The Truthful and Accurate Statement immediately follow this letter. The Indications for Use Statement is included in Appendix E.

This submission contains methods, data, and analysis of these data, which Howmedica Osteonics Corp. considers "Trade Secret" and commercially privileged and confidential to Howmedica Osteonics Corp. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act.

Although we claim that the subject device is substantially equivalent to the predicate device within the meaning of Section 513(i)(1)(A) of the Federal Food, Drug and Cosmetic Act, nothing in this submission in any way reflects upon the completely unrelated federal patent law "doctrine of equivalents" or makes any claims in regards to trademark names.

If there are any questions, or if further information is needed, please contact the undersigned of the Howmedica Osteonics' Regulatory Affairs Department at (201) 831-5581 or via e-mail at [vivian.kelly@stryker.com](mailto:vivian.kelly@stryker.com).

Sincerely,  
Howmedica Osteonics Corp.



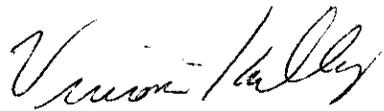
Vivian Kelly, RAC  
Senior Regulatory Affairs Specialist

K8

1407

**Premarket Notification**  
**Truthful and Accurate Statement**  
[as required by 21 CFR §807.87k)]

I certify that, in my capacity as a Senior Regulatory Affairs Specialist of Howmedica Osteonics Corp., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been willfully omitted.



Vivian Kelly, RAC  
Senior Regulatory Affairs Specialist

Date: 4/17/07

**SPECIAL 510(k) PREMARKET NOTIFICATION**

**ASNIS™ III CANNULATED SCREW SYSTEM  
LINE EXTENSION**

Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, New Jersey 07430

April 17, 2007

**Asnis™ III Cannulated Screw System Line Extension  
Special 510(k)**

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**Summary of Safety and Effectiveness**  
**Asnis™ III Cannulated Screw System Line Extension**

Proprietary Name: Asnis™ Micro Cannulated Screw  
Common Name: Bone Screw  
Classification Name and Reference: Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040  
Proposed Regulatory Class: Class II  
Device Product Code: 87 HWC: Screw, Fixation, Bone  
For Information contact: Vivian Kelly, Sr. Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
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Date Summary Prepared: April 17, 2007

**Description:**

This Special 510(k) submission is a line extension to address modifications to the Asnis™ III Cannulated Screw System. This line extension is to add additional sizes of screws to the system.

**Intended Use**

The modifications do not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject device are provided below.

**Indications**

The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

**Substantial Equivalence:**

These additional components are substantially equivalent to their predicate systems in respect to design, intended use, performance and operational principle as internal fixation components. Predicate systems include the Asnis™ III Cannulated Screw System (K000080 and K024060) and other commercially available cannulated screws on the market such Vilex 2mm Screws (K973309, K991151 & K991197) and Synthes Cannulated Screws (K962823.) Mechanical testing was conducted to compare the strength of the subject device to predicate screws. The results demonstrate that the subject components are substantially equivalent in strength to the predicate components.

**SECTION I**  
**ADMINISTRATIVE INFORMATION**

**Administrative Information:**

Name and Address of Sponsor,  
and Distributor:

Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, NJ 07430  
Reg. No: 2249697

Manufacturing Site(s):

Stryker Leibinger GmbH & Co, KG  
Bötzingen Straße 41  
D-79111 Freiburg, Germany  
Reg. No: 8010177

510(k) Contact Person

Vivian Kelly  
Senior Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, NJ 07430  
(201) 831-5581 (Phone)  
(201) 831-6038 (Fax)  
[Vivian.kelly@Stryker.com](mailto:Vivian.kelly@Stryker.com) (e-mail)

**Device Identification:**

Proprietary Name:

Asnis™ Micro Cannulated Screw

Common Name:

Bone Screw

Classification Name and Reference:

Smooth or Threaded Metallic Bone  
Fixation Fastener, 21 CFR §888.3040

Proposed Regulatory Class:

Class II

Device Product Code:

87 HWC: Screw, Fixation, Bone

**SECTION II**  
**DEVICE DESCRIPTION INFORMATION**

## **Introduction**

This Special 510(k) submission is a line extension to address modifications to the Asnis™ III Cannulated Screw System to add additional sizes of screws to the system.

## **Device History & Description**

Asnis™ III Cannulated Screw System was cleared in 510(k) submissions: K000080 and K024060. The system consists of self-cutting/self-tapping, cannulated screws in stainless steel and titanium and washers. The Ø4.0mm, Ø5.0mm, Ø 6.5mm and Ø8.0mm were cleared in K000080 in both fully or partially threaded styles in various lengths while K024060 added additional lengths and included dimensional changes to the Ø 6.5mm screw. The washers used with the system were cleared in K000080, K001614 and K012162.

## **Intended Use**

The modifications do not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The smaller screws will be used in the same kind of surgeries as the larger screws in procedures such as fracture fixations, osteotomies, arthrodeses, fusions, bone reconstruction and ligament fixation. The indications for use for the subject device are provided below.

## **Indications**

The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

## **Description of Device Modification**

This line extension is to add smaller sizes of screws for use in smaller bones such as phalanges, metacarpals, scaphoid, carpals, metatarsals, tarsals, the patella, the distal radius, the ankle (e.g. malleolus) and foot including the fore, mid- and hind foot. The screws will be used for the same types of surgeries as with the larger screws cleared in K000080 and K024060.

The additional screws will be available in diameters of 2.0mm and 3.0mm in varying lengths. They will also have a low profile head to reduce the potential of soft tissue irritation due to the areas (e.g. hand and foot) where they will be used. The cannulated screws will have the same thread and cutting flute design as the predicate screws and will be self-drilling/self-tapping. The screws will be available sterile and non-sterile.

### Accessories

Washers will be available for use with the Ø2.0mm and Ø3.0mm screws. They will be available as sterile and non-sterile. Also, k-wires will also be available to be used as guide wires to assist with placement during the procedure for the Ø2.0mm and Ø3.0mm screws.

Representative engineering drawings and catalog number information for the subject components are included in Appendix A.

### **Materials**

Both the subject and predicate screws and washers are fabricated from titanium alloy

b(4) [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

### **Labeling**

The draft package labels and the draft package insert are included in Appendix B.

### **Design Control**

Analyses of the design modifications to the system were performed to evaluate if there are any potential risks associated with the modifications. Mechanical testing was used to assess whether the subject devices fall within pre-established acceptance criteria. A

risk analysis was conducted according to EN ISO 14971. A chart with the potential risks and summary test reports are provided in Appendix C. A summary of the testing is provided below.

### Testing Summary

Mechanical testing was conducted to compare the strength of the subject device to predicate screws in b(4) [REDACTED].

[REDACTED]  
[REDACTED] [REDACTED]  
[REDACTED]  
[REDACTED].

[REDACTED]  
[REDACTED]  
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[REDACTED].

[REDACTED] b(4) [REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED] [REDACTED] [REDACTED]  
[REDACTED] [REDACTED] [REDACTED] [REDACTED]  
[REDACTED] [REDACTED] [REDACTED] [REDACTED]  
[REDACTED] [REDACTED] [REDACTED] [REDACTED]  
[REDACTED] [REDACTED] [REDACTED] [REDACTED]  
[REDACTED] [REDACTED] [REDACTED] [REDACTED]  
[REDACTED] [REDACTED] [REDACTED] [REDACTED]

**Summary**

The results demonstrate that the subject components are substantially equivalent in strength to the predicate components. See Test Reports BML 07/065 and BML 07/065 in Appendix C for a more descriptive explanation of the testing.

**Declaration of Conformity**

A Declaration of Conformity stating each of the following may be found in Appendix D.

- 1) A statement 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 that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR §820.30 and the records are available for review.

**Clinical Data**

Clinical data is not required in support of this 510(k). The design, materials and intended use of the subject components are substantially equivalent to those of predicate components presented under the Substantial Equivalence Information subsection. The testing conducted in support of this 510(k) and summarized in Appendix C is also sufficient to support the substantial equivalence of these devices to other commercially available cannulated screws and washers.

### **Sterility Information**

The subject components will be provided both sterile and non-sterile in the same manner as the predicate devices. Please refer to K000080 and K024060 for specific sterility information. The draft labeling in Appendix B-2 includes the sterility information.

### **Packaging Information**

The subject components will be packaged in the same manner as the predicate devices. All packaging will be of sufficient design and material quality to provide adequate protection from physical damage during transportation and storage.

### Sterile Products

The devices may be packaged individually or as a set with other components. The type of packaging used is essentially the same as the packaging used for other Howmedica Osteonics devices. All packaging material is commercially available from outside qualified vendors and meets industry standards. Depending on product type the following packaging systems are used: a double blister with Tyvek® lids or pouches constructed of coated Tyvek® and a laminate of polyester/polyolefin. Devices may also be double vacuum packed in inner and outer pouches. These sealed blisters or pouches are placed in individual cartons, and the entire package is then shrink-wrapped to ensure sterility.

### Non-Sterile Products

Typical packaging to be used for such applications is medical grade peel packs, blister packs, pouches, boxes with foam compartments, clear plastic tubes with end caps and fiberboard shippers and cartons.

**SECTION III**  
**SUBSTANTIAL EQUIVALENCE INFORMATION**

### **Substantial Equivalence Information**

The smaller screws and washers are substantially equivalent to their predicate systems from the Asnis™ III Cannulated Screw System (K000080 and K024060) and other commercially available cannulated screws on the market such Vilex 2mm Screws (K973309, K991151 & K991197) and Synthes Cannulated Screws (K962823) in respect to design, intended use, performance and operational principle as internal fixation components.

#### *Design*

The subject components' designs are based on the predicate system's design with changes as described in Description of Device Modification Section and employ the same basic design concepts as the predicate screws and washer in the Asnis™ III Cannulated Screw System.

Mechanical bench testing was conducted to compare the strength of the subject screws to their predicates. The results demonstrated that the subject devices are, at a minimum, equivalent in strength to the predicates b(4)

#### *Intended Use*

The subject devices have the same indications as their predicates in the Asnis™ III Cannulated Screw System for stabilizing various types of fractures of the small and long bones or the pelvis as discussed in the Intended Use or Indications of Use Sections. The Indications for Use Statements for the subject and predicate devices are included in Appendix E.

#### *Material*

The same materials are used to manufacture the screws and washers as those used to manufacture the Asnis™ III Cannulated Screw System.

### Operational Principles

The basic operational principle for the predicate devices, as well as the subject device is to provide stabilization of bone fractures or fragments. The method of site preparation and insertion are similar for all devices. Relative indications and contraindications for use are also similar.

Therefore, the subject device is substantially equivalent to the predicate devices. The risk chart and testing provided in Appendix C have sufficiently demonstrated the equivalence of the subject components to the predicate devices. A table outlining the basis of equivalency follows below.

Table of Equivalency				
Device	Asnis™ Micro Screws	Asnis™ III Cannulated Screw System	Vilex Cannulated Bone Screws	Synthes Cannulated Screws
	Subject Device	Predicate Device	Predicate Device	Predicate
<b>Manufacturer</b>				
	Stryker Leibinger GmbH	Stryker Trauma AG	Vilex Inc.	Synthes (USA)
<b>510(k) Number</b>				
	N/A	K000080 & K024060	K973309, K991151 & K991197	K962823
<b>Intended Use</b>				
Fracture fixation	X	X	X	X
<b>Material</b>				
Stainless Steel		X	X	X
Titanium Alloy	X	X	X	X
<b>Design</b>				
Cannulated	X	X	X	X
2mm Diameter	X		X	
3mm Diameter	X		X	X
Washers	X	X		X
<b>Operational Principles</b>				
Surgical Technique / Site Preparation	X	X	X	X
Indication / Contraindication	X	X	X	X

X denotes equivalency

## **APPENDICES**

<b>APPENDIX A</b>	<b>COMPONENT INFORMATION</b>
<b>APPENDIX B</b>	<b>PACKAGING INFORMATION</b>
<b>APPENDIX C</b>	<b>RISK ANALYSIS</b>
<b>APPENDIX D</b>	<b>STATEMENTS</b>
<b>APPENDIX E</b>	<b>INDICATION FOR USE STATEMENTS</b>

**APPENDIX A**  
**COMPONENT INFORMATION**

- A-1** Catalog Numbers
- A-2** Engineering Drawings

## APPENDIX A-1

### Catalog Numbers

\*Sterile component reference numbers will be denoted with an "S" on the end

Description	Reference Number*
2.0 mm Asnis Micro, Cannulated Screw, 8/5 mm	40-20108
2.0 mm Asnis Micro, Cannulated Screw, 10/5 mm	40-20110
2.0 mm Asnis Micro, Cannulated Screw, 11/6 mm	40-20111
2.0 mm Asnis Micro, Cannulated Screw, 12/6 mm	40-20112
2.0 mm Asnis Micro, Cannulated Screw, 13/7 mm	40-20113
2.0 mm Asnis Micro, Cannulated Screw, 14/7 mm	40-20114
2.0 mm Asnis Micro, Cannulated Screw, 15/7 mm	40-20115
2.0 mm Asnis Micro, Cannulated Screw, 16/8 mm	40-20116
2.0 mm Asnis Micro, Cannulated Screw, 17/6 mm	40-20117
2.0 mm Asnis Micro, Cannulated Screw, 18/6 mm	40-20118
2.0 mm Asnis Micro, Cannulated Screw, 19/6 mm	40-20119
2.0 mm Asnis Micro, Cannulated Screw, 20/6 mm	40-20120
2.0 mm Asnis Micro, Cannulated Screw, 22/6 mm	40-20122
2.0 mm Asnis Micro, Cannulated Screw, 24/7 mm	40-20124
2.0 mm Asnis Micro, Cannulated Screw, 26/7 mm	40-20126
2.0 mm Asnis Micro, Cannulated Screw, 28/7 mm	40-20128
2.0 mm Asnis Micro, Cannulated Screw, 30/7 mm	40-20130
2.0 mm Asnis Micro, Cannulated Screw, 17/9 mm	40-20217
2.0 mm Asnis Micro, Cannulated Screw, 18/9 mm	40-20218
2.0 mm Asnis Micro, Cannulated Screw, 19/10 mm	40-20219
2.0 mm Asnis Micro, Cannulated Screw, 20/10 mm	40-20220
2.0 mm Asnis Micro, Cannulated Screw, 22/11 mm	40-20222
2.0 mm Asnis Micro, Cannulated Screw, 24/11 mm	40-20224
2.0 mm Asnis Micro, Cannulated Screw, 26/13 mm	40-20226
2.0 mm Asnis Micro, Cannulated Screw, 28/13 mm	40-20228
2.0 mm Asnis Micro, Cannulated Screw, 30/15 mm	40-20230
2.0 mm Asnis Micro, Cannulated Screw, 32/7 mm	40-20132
2.0 mm Asnis Micro, Cannulated Screw, 32/15 mm	40-20232
2.0 mm Asnis Micro, Cannulated Screw, 34/8 mm	40-20134
2.0 mm Asnis Micro, Cannulated Screw, 34/17 mm	40-20234
2.0 mm Asnis Micro, Cannulated Screw, 36/8 mm	40-20136
2.0 mm Asnis Micro, Cannulated Screw, 36/17 mm	40-20236
2.0 mm Asnis Micro, Cannulated Screw, 38/9 mm	40-20138
2.0 mm Asnis Micro, Cannulated Screw, 38/19 mm	40-20238
2.0 mm Asnis Micro, Cannulated Screw, 40/9 mm	40-20140
2.0 mm Asnis Micro, Cannulated Screw, 40/19 mm	40-20240

3.0 mm, Asnis Micro, Cannulated Screw, 8/4.5mm	40-30108
3.0 mm, Asnis Micro, Cannulated Screw, 9/5.5 mm	40-30109
3.0 mm Asnis Micro, Cannulated Screw, 10/5.5 mm	40-30110
3.0 mm Asnis Micro, Cannulated Screw, 11/5.5 mm	40-30111
3.0 mm Asnis Micro, Cannulated Screw, 12/5.5 mm	40-30112
3.0 mm Asnis Micro, Cannulated Screw, 13/5.5 mm	40-30113
3.0 mm Asnis Micro, Cannulated Screw, 14/5.5 mm	40-30114
3.0 mm Asnis Micro, Cannulated Screw, 15/5.5 mm	40-30115
3.0 mm Asnis Micro, Cannulated Screw, 16/5.5 mm	40-30116
3.0 mm Asnis Micro, Cannulated Screw, 17/5.5 mm	40-30117
3.0 mm Asnis Micro, Cannulated Screw, 18/6.5 mm	40-30118
3.0 mm Asnis Micro, Cannulated Screw, 19/6.5 mm	40-30119
3.0 mm Asnis Micro, Cannulated Screw, 20/6.5 mm	40-30120
3.0 mm Asnis Micro, Cannulated Screw, 21/6.5 mm	40-30121
3.0 mm Asnis Micro, Cannulated Screw, 22/6.5 mm	40-30122
3.0 mm Asnis Micro, Cannulated Screw, 23/6.5 mm	40-30123
3.0 mm Asnis Micro, Cannulated Screw, 24/7.5 mm	40-30124
3.0 mm Asnis Micro, Cannulated Screw, 25/7.5 mm	40-30125
3.0 mm Asnis Micro, Cannulated Screw, 26/7.5 mm	40-30126
3.0 mm Asnis Micro, Cannulated Screw, 27/7.5 mm	40-30127
3.0 mm Asnis Micro, Cannulated Screw, 28/7.5 mm	40-30128
3.0 mm Asnis Micro, Cannulated Screw, 29/7.5 mm	40-30129
3.0 mm Asnis Micro, Cannulated Screw, 30/7.5 mm	40-30130
3.0 mm Asnis Micro, Cannulated Screw, 32/7.5 mm	40-30132
3.0 mm Asnis Micro, Cannulated Screw, 34/8.5 mm	40-30134
3.0 mm Asnis Micro, Cannulated Screw, 36/8.5 mm	40-30136
3.0 mm Asnis Micro, Cannulated Screw, 38/9.5 mm	40-30138
3.0 mm Asnis Micro, Cannulated Screw, 40/9.5 mm	40-30140
3.0 mm Asnis Micro, Cannulated Screw, 14/7.5 mm	40-30214
3.0 mm Asnis Micro, Cannulated Screw, 15/8.5 mm	40-30215
3.0 mm Asnis Micro, Cannulated Screw, 16/8.5 mm	40-30216
3.0 mm Asnis Micro, Cannulated Screw, 17/9.5 mm	40-30217
3.0 mm Asnis Micro, Cannulated Screw, 18/9.5 mm	40-30218
3.0 mm Asnis Micro, Cannulated Screw, 19/10.5 mm	40-30219
3.0 mm Asnis Micro, Cannulated Screw, 20/10.5 mm	40-30220
3.0 mm Asnis Micro, Cannulated Screw, 21/10.5 mm	40-30221
3.0 mm Asnis Micro, Cannulated Screw, 22/11.5 mm	40-30222
3.0 mm Asnis Micro, Cannulated Screw, 23/11.5 mm	40-30223
3.0 mm Asnis Micro, Cannulated Screw, 24/11.5 mm	40-30224
3.0 mm Asnis Micro, Cannulated Screw, 25/11.5 mm	40-30225
3.0 mm Asnis Micro, Cannulated Screw, 26/13.5 mm	40-30226
3.0 mm Asnis Micro, Cannulated Screw, 27/13.5 mm	40-30227
3.0 mm Asnis Micro, Cannulated Screw, 28/13.5 mm	40-30228
3.0 mm Asnis Micro, Cannulated Screw, 29/13.5 mm	40-30229
3.0 mm Asnis Micro, Cannulated Screw, 30/15.5 mm	40-30230
3.0 mm Asnis Micro, Cannulated Screw, 32/15.5 mm	40-30232
3.0 mm Asnis Micro, Cannulated Screw, 34/17.5 mm	40-30234

3.0 mm Asnis Micro, Cannulated Screw, 36/17.5 mm	40-30236
3.0 mm Asnis Micro, Cannulated Screw, 38/19.5 mm	40-30238
3.0 mm Asnis Micro, Cannulated Screw, 40/19.5 mm	40-30240
3.0 mm Asnis Micro, Cannulated Screw, 42/9.5 mm	40-30142
3.0 mm Asnis Micro, Cannulated Screw, 42/19.5 mm	40-30242
3.0 mm Asnis Micro, Cannulated Screw, 44/9.5 mm	40-30144
3.0 mm Asnis Micro, Cannulated Screw, 44/19.5 mm	40-30244
3.0 mm Asnis Micro, Cannulated Screw, 46/9.5 mm	40-30146
3.0 mm Asnis Micro, Cannulated Screw, 46/19.5 mm	40-30246
3.0 mm Asnis Micro, Cannulated Screw, 48/10.5 mm	40-30148
3.0 mm Asnis Micro, Cannulated Screw, 48/19.5 mm	40-30248
3.0 mm Asnis Micro, Cannulated Screw, 50/10.5 mm	40-30150
3.0 mm Asnis Micro, Cannulated Screw, 50/21.5 mm	40-30250

### Accessories

Description	Reference Number*
Washer 2.0mm	40-20900
Washer 3.0mm	40-30900
K-Wire 0.8 mm x 100 mm	45-20015
K-Wire 1.2 mm x 100 mm	45-30015

\*Sterile component reference numbers will be denoted with an "S" on the end

**APPENDIX A-2**  
**Engineering Drawings**

**Description**

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**Drawing No.**

b(4)  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**CONFIDENTIAL -**























**APPENDIX B**  
**PACKAGING INFORMATION**

- B-1**      Draft Labels
- B-2**      Draft Package Insert

## **APPENDIX B-1**

### **Draft Labels**

# DRAFT

# Copy

REF 40-30222

LOT

TITANIUM

3.0X22/10MM

ASNIS MICRO

Medical  
Implant

- 1 CANNULATED SCREW
- 1 KANÜLIERTE SCHRAUBE
- 1 VIS DE CANULE
- 1 VITE DI CANNULATA
- 1 TORNILLO DE LA CANULADO
- 1 SKRUV, KANYLERAD
- 1 SCHROEF, GECANNULEERD



Made in Germany  
NON STERILE

Stryker Leibinger GmbH & Co. KG

\* REF 40-30222

CANNULATED SCREW

LOT  
Quality Control

Manufactured and distributed by:  
Stryker Leibinger GmbH & Co. KG  
Bötzingenstr. 37-41  
D-79111 Freiburg/Germany

Distributed in the USA by:  
Stryker  
Kalamazoo, MI, 49002, USA



CE 1275  
stryker

0001 Caution: Federal law restricts this device to sale by or on order of a physician or hospital

REF 40-20108

LOT

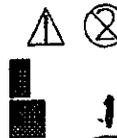
TITANIUM

2.0X8/4MM

ASNIS MICRO

Medical  
Implant

- 1 CANNULATED SCREW
- 1 KANÜLIERTE SCHRAUBE
- 1 VIS DE CANULE
- 1 VITE DI CANNULATA
- 1 TORNILLO DE LA CANULADO
- 1 SKRUV, KANYLERAD
- 1 SCHROEF, GECANNULEERD



Made in Germany  
NON STERILE

Stryker Leibinger GmbH & Co. KG

\* REF 40-20108

CANNULATED SCREW

LOT  
Quality Control

Manufactured and distributed by:  
Stryker Leibinger GmbH & Co. KG  
Bötzingenstr. 37-41  
D-79111 Freiburg/Germany

Distributed in the USA by:  
Stryker  
Kalamazoo, MI, 49002, USA



CE 1275  
stryker

0001 Caution: Federal law restricts this device to sale by or on order of a physician or hospital

**APPENDIX B-2**

**Draft Package Insert**

GB, USA: English ..... 3

6	ALL OF THESE INSTRUCTIONS FOR USE MUST BE READ CAREFULLY PRIOR TO CLINICAL USE	USA
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### Brief Description

Stryker Osteosynthesis implants are single use devices intended for the temporary fixation, correction or stabilization of bones. Stryker Osteosynthesis implants include varying designs of internal fixation devices and auxiliaries manufactured from materials recognized and accepted for implantation into the body. These materials conform to ASTM and/or ISO standards. For detailed information concerning the identification of the product (such as system association, catalogue no., material, expiration date of sterile products) please refer to the marking on the product and/or the labeling of the package.

### Important information for doctors and OR staff

**This package insert does not include all of the information necessary for selection and use of a device. Please see full labelling for all necessary information!**

The use of these devices provides the surgeon with a means of bone fixation for the management of fracture and reconstructive surgery. These devices are intended only to assist healing and are not intended to replace normal bone structures. No fracture fixation device that is subject to material fatigue can be expected to withstand activity levels in the same way as would a normal healthy bone. The fracture fixation system, therefore, will not be as strong, reliable or durable as a normal human bone.

Ensure that you are familiar with the intended uses, indications/contraindications, compatibility and correct handling of the implant, which are described in the operative technique manual for the product system.

Please remember that product systems may be subject to alterations that affect the compatibility of the implant with other implants or with instruments. For your information, avail yourself of the training courses and publications offered.

### Indications

The implant is intended for the temporary stabilization of bone segments or fragments until bone consolidation has been achieved.

### Intended Use

The indications for use of these internal fixation devices include:

- bone fracture fixation,
- osteotomy,
- arthrodesis,
- correction of deformity
- revision procedures where other treatments or devices have been unsuccessful,
- bone reconstruction procedures

For detailed information concerning the indications of the implant please refer to the specific operative technique manual of the product system being used.

### Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.

Material sensitivity, documented or suspected.

Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.

Patients having inadequate tissue coverage over the operative site.

Implant utilization that would interfere with anatomical structures or physiological performance.  
Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.  
Other medical or surgical conditions which would preclude the potential benefit of surgery.

## **WARNINGS AND PRECAUTIONS**

### **WARNING**

**Implant Selection and Sizing:** The correct selection of the fracture fixation appliance is extremely important. Failure to use the appropriate appliance for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

**Fixation Screws:** Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Stryker Osteosynthesis Implants are not compatible with magnetic resonance imaging (MRI) techniques, unless specified otherwise in the Product Labelling or respective Product Technical Guides.

### **CAUTION**

**Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.**

#### **Pre-operative**

The implant is for single use only.

Implants that came in contact with body fluids should never be reused.

Ensure that all components needed for the operation are available in the operation theatre.

Inspection is recommended prior to surgery to determine if instruments or implants have been damaged during storage or prior procedures.

#### **Intra-operative**

Avoid surface damage of implants.

Discard all damaged or mishandled implants.

Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load. If contouring is necessary, allowed by design or prescribed by Stryker Osteosynthesis, the physician should avoid sharp bends, reverse bends or bending the device at a screw hole. Such action must be performed with Stryker Osteosynthesis instruments and in accordance with the specified procedures (see operative technique manual). Implants can be available in different versions, varying for example in length, diameter, angle, right-hand and left-hand versions, material and number of drilled holes. Select the required version carefully.

During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, required for precise positioning and fixing is secure.

Implants which consist of several components must only be used in the prescribed combination (see operative technique manual).

After the procedure check the proper positioning of all implants using the image intensifier.

Do not use components of the Stryker Osteosynthesis product systems in conjunction with components from any other manufacturer's system unless otherwise specified (see operative technique manual).

#### **Post-operative**

**Post-operative patient activity:** These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.

The implant is a short-term implant. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g. X-ray checks) are advisable.

The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.

Implant removal should be followed by adequate post-operative management to avoid fracture or refracture of the bone.

#### Informing the patient

The implantation affects the patient's ability to carry loads and her/his mobility and general living circumstances. For this reason, surgeons must instruct patient individually on correct behavior after the implantation.

Surgeons must warn the patient that device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite expected service life and may need to be removed at some time in the future.

Explain the need to report unusual changes in the implantation area as well as falls or accidents even if the device or the site of operation did not appear to be harmed at the time.

Explain also the need to appear for the postoperative examinations (e.g. X-ray checks) and for the possible explantation of the implant.

#### **Adverse Effects**

In many instances, adverse results may be clinically related rather than device related. The following are the most frequent adverse effects involving the use of internal fracture fixation devices:

Delayed union or non-union of the fracture site.

These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load sharing devices which are intended to hold fractured bone surfaces in apposition to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.

Conditions attributable to non-union, osteoporosis, osteomalacia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.

Improper alignment can cause a mal-union of the bone and/or bending, cracking or even breakage of the device.

Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.

Early or late infection, both deep or superficial.

Deep venous thrombosis.

Avascular necrosis.

Shortening of the effected bone/fracture site.

Subclinical nerve damage may possibly occur as a result of the surgical trauma.

Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.

#### **Sterilization/Resterilization**

##### **DEVICES CONTAINING POLYETHYLENE CANNOT BE RESTERILIZED BY THE USER.**

Products delivered sterile have either been exposed to a minimum of 25 kGy of gamma radiation from a cobalt 60 source or have been sterilized by vacuum steam sterilization (please see product label for sterilization method applied). Products not labelled as sterile are non-sterile. The packaging of all sterile products should be inspected for flaws in the sterile barrier or expiration of shelf life before opening. In the presence of such a flaw or expiration of shelf life, the product must be assumed non-sterile. Care must be taken to prevent contamination of the component.

In the event of contamination (unless contaminated with body fluids), or expiration of shelf life or in the case of products supplied non-sterile, the product must be subjected to an appropriate cleaning process and sterilized by means of a validated sterilization procedure before use, unless specified otherwise in the product labeling or respective product technical guides.

The following process parameters are validated by Stryker Osteosynthesis and recommended for sterilization and/or resterilization:

Method: Moist heat sterilization according to ANSI/AAMI/ISO 11134

Cycle: Saturated steam with forced air removal

Exposure Phase and Drying Time: 4 to 18 minutes and drying between 8 and 35 minutes

Temperature: 132 - 137°C (270 - 277°F)



**APPENDIX C**  
**RISK ANALYSIS**

b(4) [REDACTED]

b(4) [REDACTED]





**APPENDIX C-2**

**Test Reports**

**- CONFIDENTIAL -**

## Test Report

b(4) Test Report











## Test Report

b(4) Test Report











**APPENDIX D**  
**STATEMENTS**

- D-1** Declaration of Conformity
- D-2** Statement of Scientific Technology and Indications

**APPENDIX D-1**  
**Declaration of Conformity**

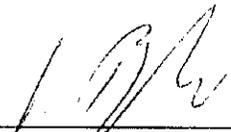
70

**Asnis™ III Cannulated Screw System**

**Declaration of Conformity**

All verification and validation activities were performed by the appropriately designated individual(s), and the results demonstrated that the predetermined acceptance criteria were met.

Stryker Trauma's manufacturing facilities are in conformance with the design control procedure requirements as specified in 21 CFR §820.30 and the records are available for review.

  
\_\_\_\_\_  
Vinz Burgherr  
Manager, R & D

2007-10-4  
Date

## **APPENDIX D-2**

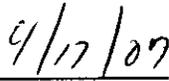
### **Statement of Scientific Technology and Indications**

## Statement of Scientific Technology and Indications

The indications for use of the subject components of the Asnis™ III Cannulated Screw System, as described in the labeling, have not changed from the indications for use of the currently available Asnis™ III Cannulated Screw System components.

In addition, the fundamental scientific technology of the subject components, as described in the labeling, has not changed from that of the predicate systems.

  
\_\_\_\_\_  
Vivian Kelly, RAC  
Senior Regulatory Affairs Specialist

  
\_\_\_\_\_  
Date

**APPENDIX E**  
**INDICATION FOR STATEMENTS**

- E-1**      Indications for Use Statement
- E-2**      Predicate Devices: Indications for Use

**APPENDIX E-1**

**Indication for Use Statement**

**Indications for Use** K071092

510(k) Number (if known):

Device Name: Asnis™ III Cannulated Screw System

Indications for Use:

The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Prescription Use   X    
(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 OF  
NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

## APPENDIX E-2

### Predicate Devices: Indication for Use Statements

Asnis III Cannulated Screw System  
K000080 and K024060

510(k) Number (if known): K 000080

Device Name: ASNIS III Cannulated Screw System

Indications For Use:

The Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

MRO for cmw  
(Division Sign-Off)  
Division of General Invasive Devices  
510(k) Number K 000080

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): K024060

Device Name: Asnis III Cannulated Screw System

Indications for Use

The Asnis III Cannulated Screw System intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

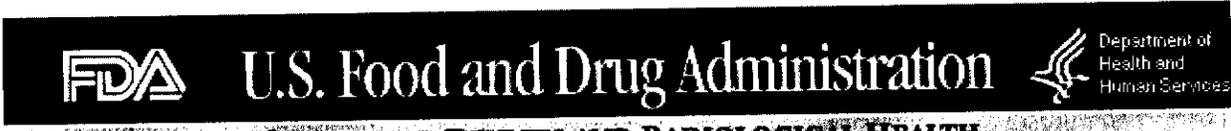
Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K024060

Vilex Cannulated Bone Screws  
(K973309, K991151 & K991197)



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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<u>Screw, Fixation, Bone</u>
<b>510(K) Number</b>	K973309
<b>Regulation Number</b>	<u>888.3040</u>
<b>Device Name</b>	VILEX CANNULATED BONE SCREW, DUVAL CANNULATED BON
<b>Applicant</b>	VILEX, INC. 811 Rt. 51, Industrial Complex Bldg. 10 Large, PA 15025
<b>Contact</b>	Abraham Lavi
<b>Classification Product Code</b>	<u>HWC</u>
<b>Date Received</b>	09/03/1997
<b>Decision Date</b>	01/16/1998
<b>Decision</b>	Substantially Equivalent For Some Indications (SN)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	Orthopedic
<b>Statement/Summary/Purged Status</b>	Statement Only
<b>Statement Type</b>	<u>Statement</u> Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 3/07/2007



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### 510(k) Premarket Notification Database

<b>Device Classification Name</b>	<a href="#">Screw, Fixation, Bone</a>
<b>510(K) Number</b>	K991151
<b>Regulation Number</b>	<a href="#">888.3040</a>
<b>Device Name</b>	VILEX CANNULATED BONE SCREW, DUVAL CANNULATED BON
<b>Applicant</b>	VILEX, INC. 1801 Rt. 51, Building 10 Jefferson Hills, PA 15025 0724
<b>Contact</b>	Abraham Lavi
<b>Classification Product Code</b>	<a href="#">HWC</a>
<b>Date Received</b>	04/06/1999
<b>Decision Date</b>	04/26/1999
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	Orthopedic
<b>Statement/Summary/Purged Status</b>	Statement Only
<b>Statement Type</b>	<a href="#">Statement</a> Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 3/07/2007

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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<a href="#">Screw, Fixation, Bone</a>
<b>510(K) Number</b>	K991197
<b>Regulation Number</b>	888.3040
<b>Device Name</b>	VILEX/DUVAL/ORTHEX CANNULATED BONE SCREW, MODELS
<b>Applicant</b>	VILEX, INC. 1801 Rt. 51, Building 10 Jefferson Hills, PA 15025 0724
<b>Contact</b>	Abraham Lavi
<b>Classification Product Code</b>	<a href="#">HWC</a>
<b>Date Received</b>	04/07/1999
<b>Decision Date</b>	04/26/1999
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	Orthopedic
<b>Statement/Summary/Purged Status</b>	Statement Only
<b>Statement Type</b>	<a href="#">Statement</a> Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

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90

Synthes Cannulated Screws  
(K962823)



K96 2823

OCT 1 1996

**Attachment VI: Summary of Safety and Effectiveness Information**

Synthes (USA)  
1690 Russell Road  
P.O. Box 1766  
Paoli, PA 19301

(610) 647 - 9700  
Contact: Angela J. Silvestri  
July 1996

Synthes Sterile 3.0 mm Cannulated Screw and Threaded Washer is compared to Synthes 2.7 mm Cannulated Screw and Threaded Washer.

Synthes 3.0 mm Cannulated Screw, used with the Threaded Washer, is generally intended for intra-articular fixation of small bones, such as the hand, wrist and forefoot. Specifically, it is intended for fractures of carpals and metacarpals, carpal and metacarpal arthrodesis; small fragments of the hand and wrist, and certain metatarsal - phalangeal applications (in foot). The 3.0 mm Cannulated Screw, by itself is intended for fixation of small bones, such as the hand, wrist and forefoot. The 3.0 mm Cannulated Screw and Threaded Washer are manufactured from 316L stainless steel or Ti-6Al-7Nb.

Synthes 2.7 mm Cannulated Screw, used with the Threaded Washer, is generally intended for intra-articular fixation of small bones, such as the hand, wrist and forefoot. Specifically, it is intended for fractures of carpals and metacarpals, carpal and metacarpal arthrodesis; small fragments of the hand and wrist, and certain metatarsal - phalangeal applications (in foot). The 2.7 mm Cannulated Screw, by itself is intended for fixation of small bones, such as the hand, wrist and forefoot. The 2.7 mm Cannulated Screw and Threaded Washer are manufactured from 316L stainless steel.

Synthes 3.0 mm Cannulated Screw and Threaded Washer are provided to the user sterile. Gamma Radiation will be used to sterilize the device.

In our opinion, Synthes 3.0 mm Cannulated Screw and Threaded Washer are at least equivalent to Synthes 2.7 mm Cannulated Screw and Threaded Washer, based on mechanical testing of both devices.

From: Reviewer(s) - Name(s) Tara Shephard

Subject: 510(k) Number K071092

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?  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

- 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):

888-3040 CLASS II HWC

Review: Jonita J 05DB 5/9/07  
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 5/11/07  
(Division Director) (Date)

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		N/A
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?	X	
7. Is the device subject to review by CDRH?		
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?		
11. If, yes, consult the ODE Integrity Officer.		X
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION**

K071092

Reviewer: Tara Shepherd, Biomedical Engineer (HFZ-410)

Division/Branch: DGRND/OJDB

Device Name: Asnis™ Micro Cannulated Screw

Product To Which Compared (510(k) Number If Known): Asnis™ III Cannulated Screw System (K000080 and K024060)

		YES NO		
1.	Is Product A Device	X		If <b>NO</b> = Stop
2.	Is Device Subject To 510(k)?	X		If <b>NO</b> = Stop
3.	Same Indication Statement?	X		If <b>YES</b> = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If <b>YES</b> = Stop <b>NE</b>
5.	Same Technological Characteristics?	X		If <b>YES</b> = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If <b>YES</b> = Go To 8
7.	Descriptive Characteristics Precise Enough?		X	If <b>NO</b> = Go To 10 If <b>YES</b> = Stop <b>SE</b>
8.	New Types Of Safety Or Effectiveness Questions?			If <b>YES</b> = Stop <b>NE</b>
9.	Accepted Scientific Methods Exist?			If <b>NO</b> = Stop <b>NE</b>
10.	Performance Data Available?	X		If <b>NO</b> = Request Data
11.	Data Demonstrate Equivalence?	X		Final Decision: <b>SE</b>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

**EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED**

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:  
*Performance data is necessary to determine equivalence to predicate.*
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 performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:  
*Performance data demonstrates that the device has the same or greater mechanical strength characteristics as the predicate device.*

ATTACH ADDITIONAL SUPPORTING INFORMATION

**SPECIAL 510(k): Device Modification  
ODE Review Memorandum (Decision Making Document is Attached)**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K071092

**Date:** May 7, 2007

---

**From:** Tara Shepherd, Biomedical Engineer (HFZ-410)

**Division:** DGRND/ORDB

**Device Name:** Asnis Micro Cannulated Screw

*ELF 5/8/07*

**Classification:** Smooth or Threaded Metallic Bone Fixation Fastener  
21 CFR 888.3040, Class II, 87 HWC

**Company:** Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, New Jersey 07430

**Contact:** Vivian Kelly, Senior Regulatory Affairs Specialist  
(Phone: 201-831-5581, Fax: 201-831-6038, Email: [Vivian.kelly@Stryker.com](mailto:Vivian.kelly@Stryker.com))

---

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)  
  
Asnis™ III Cannulated Screw System (K000080 and K024060)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

**Indications for Use:**

The Asnis™ III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

*The indication for use statement has not changed.*

**Labeling:**

*Labeling has not changed.*

**Package Insert:**

An alternative method for sterilization/resterilization has been added:

Alternative Method: Double Wrapped Method (AAMI CSR Technique)

Cycle: Pre-vac autoclave

Exposure Phase and Drying Time: 15 minutes of exposure and 5 minutes drying

Temperature: 132°C (270°F)

*Double wrapped method is the same as the wrapped gravity method approved in (K000080).  
Package insert changes do not affect the intended use and are adequate.*

- 3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

(b) (4)

A large rectangular area of text is completely redacted with black ink. The redaction is labeled with "(b) (4)" in red text at the top left corner.

(b) (4)

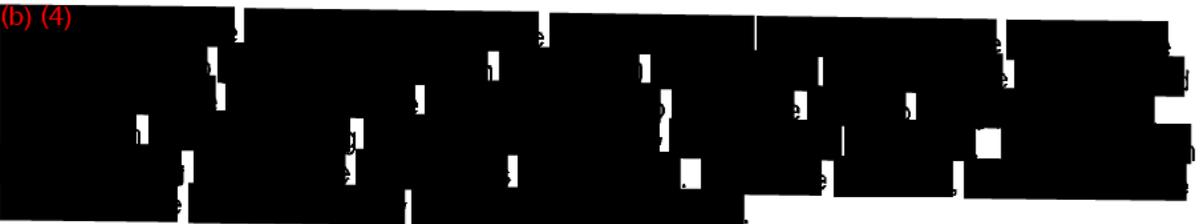
A large rectangular area of text is completely redacted with black ink. The redaction is labeled with "(b) (4)" in red text at the top left corner.

- 4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, etc.

(b) (4)

A rectangular area of text is completely redacted with black ink. The redaction is labeled with "(b) (4)" in red text at the top left corner.

(b) (4)

A large rectangular area of text is completely redacted with black ink. The redaction is labeled with "(b) (4)" in red text at the top left corner.

- 5. A **Design Control Activities Summary** which includes:
  - 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

ISO 14971:2000, Medical devices - Application of risk management to medical devices

- 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





*Conews  
BBB*

b(4) Verification Report  
[Redacted]

c) b(4) Verification Report  
[Redacted]

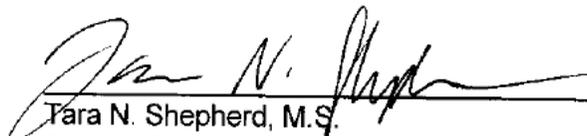
*The sponsor's Declaration of Conformity with Design Controls was provided in Appendix D.*

**6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

*The sponsor provided a truthful and accurate statement, a 510(k) Summary and Indications for Use.*

**Recommendation:**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

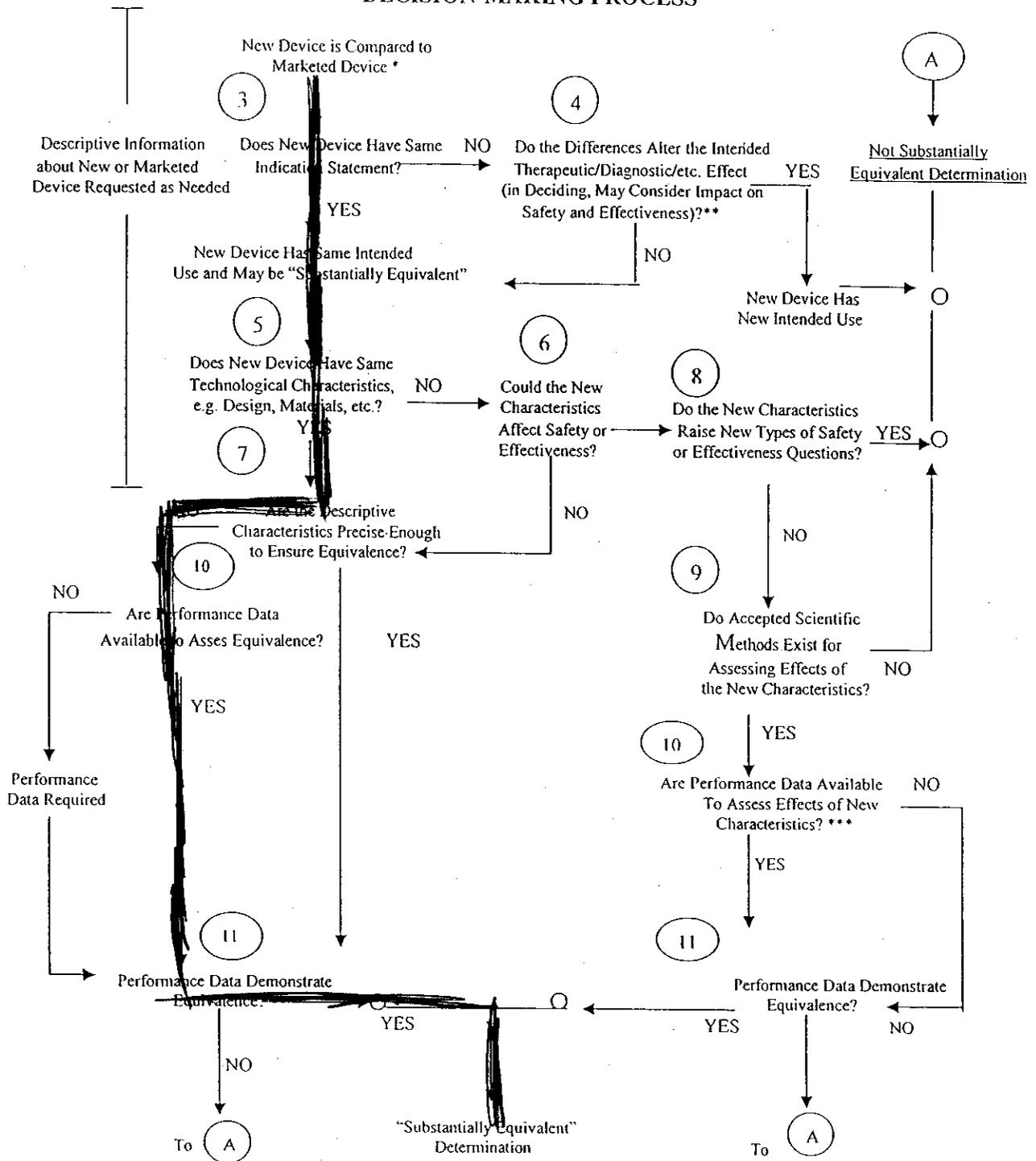
  
Tara N. Shepherd, M.S.  
Orthopedic Joint Devices Branch  
Division of General, Restorative and Neurological Devices

5/10/07  
(Date)

**CONTACT HISTORY:**

Called sponsor on 5/7/2007 to clarify the addition of the alternative sterilization method, double wrapped method, listed in the package insert. Double wrapped method is the same as the wrapped gravity method cleared in K000090.

## 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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.