



**USER:** PROPHET WRIGHT, ANGELA R (arp)

**FOLDER:** K033769 - 160 pages (FOI:04002212)

**COMPANY:** HOWMEDICA OSTEONICS CORP  
(HOWMOSTEB)

**PRODUCT:** PROSTHESIS, KNEE, FEMOROTIBIAL,  
NON-CONSTRAINED, CEMENTED,  
METAL/POLYMER (HSX)

**SUMMARY:** Product: EIUS UNICOMPARTMENTAL KNEE  
SYSTEM

**DATE REQUESTED:** Wed Apr 25 24:00:00 2007

**DATE PRINTED:** Thu Jun 21 08:59:00 2007

**Note:** Releasable Version

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K033769

Line Extension to the EIUS® Unicompartamental Knee System

Special 510(k) Premarket Notification

FEB 13 2004

**Special 510(k) Summary of Safety and Effectiveness:  
Line Extension to the EIUS® Unicompartamental Knee System**

Proprietary Name:	EIUS® Unicompartamental Knee System
Common Name:	Unicompartamental Knee System
Proposed Regulatory Class:	Class II Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer, 21 CFR 888.3520
Device Product Code:	87 HSX
For Information contact:	Denise Duchene Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Dr. Mahwah, NJ 07430 Telephone: (201) 831-5612 Fax: (201) 831-6038 Email: dduchene@howost.com
Date Summary Prepared:	November 12, 2003

**Predicate Device Identification**

The EIUS® Unicompartamental Knee System consists of various sizes of femoral components and tibial components and the Scorpio Total Knee System consists of various femoral, tibial and patellar components. The EIUS Unicompartamental Knee System additional tibial components are equivalent to the currently marketed EIUS tibial components with the exception of the thickness, cement recess and material. The material is equivalent to the currently marketed Scorpio Knee System tibial inserts; whereas the cement recess without a keel is equivalent to the UNIX Unicompartamental Knee and the Biomet Repicci Unicompartamental All Polyethylene Tibia component (also available without a keel). The EIUS Unicompartamental Knee System was determined substantially equivalent under K992287, the UNIX Unicompartamental Knee was determined substantially equivalent under K923011, the Biomet component was cleared under K980665, and the Scorpio Total Knee Tibial Insert components were determined substantially equivalent under K962152.

**Description of Device Modification**

This submission is intended to address a line extension to the EIUS® Unicompartamental Knee System. The line extension includes additional tibial components, 8mm, 9mm, 10mm, and 12mm components without a keel and 6mm components with and without a keel. Also, some changes were made to the cement recess of the tibial component to ensure adequate thickness under the femoral condyle. Finally, the material will change from the current polyethylene material to the polyethylene material used in the Scorpio Knee System. The new components will be used for resurfacing of either the medial or lateral proximal tibia.

page 1 of 2

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Line Extension to the EIUS<sup>®</sup> Unicompartmental Knee System

2033769

Special 510(k) Premarket Notification

**Intended Use:**

The EIUS<sup>®</sup> Unicompartmental Knee System is intended for use in unicompartmental knee arthroplasty. It is intended to be used for patients with moderately disabling joint disease of the knee resulting from painful osteoarthritis or traumatic arthritis; revision of previous unsuccessful unicompartmental knee replacement or other procedure, or as an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

**Statement of Technological Comparison:**

The subject components share the same intended use and basic design concept as that of the predicate devices. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 13 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Denise Duchene  
Senior Regulatory Affairs Specialist  
Howmedica Osteonics Corporation  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K033769

Trade/Device Name: EIUS<sup>®</sup> Unicompartmental Knee System – Tibial Components

Regulation Number: 21 CFR 888.3520

Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented  
prosthesis

Regulatory Class: II

Product Code: HSX

Dated: January 16, 2004

Received: January 20, 2004

Dear Ms. Duchene:

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](#).

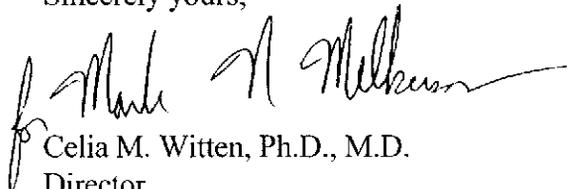
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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. Denise Duchene

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K033769

Device Name: EIUS® Unicompartmental Knee System – Tibial Components

### Indications For Use:

The EIUS® Knee System components are for use in Unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis

These components are single use only and are intended for implantation with bone cement.

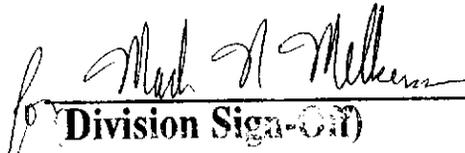
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 \_\_\_\_\_  
**Division Sign-Off**  
**Division of General, Restorative,**  
**and Neurological Devices**

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**510(k) Number**   K033769



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 13 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Denise Duchene  
Senior Regulatory Affairs Specialist  
Howmedica Osteonics Corporation  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K033769

Trade/Device Name: EIUS<sup>®</sup> Unicompartmental Knee System – Tibial Components  
Regulation Number: 21 CFR 888.3520

Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented  
prosthesis

Regulatory Class: II

Product Code: HSX

Dated: January 16, 2004

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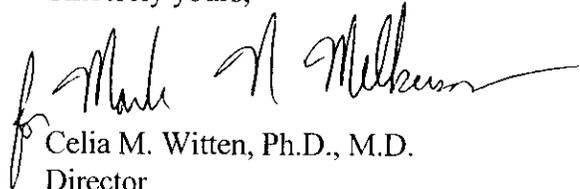
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Page 2 - Ms. Denise Duchene

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Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2

## Indications for Use

510(k) Number (if known): K033769

Device Name: EIUS® Unicompartamental Knee System – Tibial Components

### Indications For Use:

The EIUS® Knee System components are for use in Unicompartamental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
- Revision of previous unsuccessful unicompartamental knee replacement or other procedure
- As an alternative to tibial osteotomy in patients with unicompartamental osteoarthritis

These components are single use only and are intended for implantation with bone cement.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 Division Sign-Off  
 Division of General, Restorative,  
 and Neurological Devices

Page 1 of  1

510(k) Number  K033769

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 23 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Denise Duchene  
Senior Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K033769  
Trade Name: EIUS<sup>®</sup> Unicompartmental Knee System – Tibial Components  
Dated: December 1, 2003  
Received: December 3, 2003

Dear Ms. Duchene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following item:

1. (b) (4)

a. A legally marketed predicate unicompartmental tibial component (b) (4) for your components; or

b. A revised Design Verification Summary which assesses the following risks associated (b) (4) These risks could be assessed by performing the following Design Verification Activities and providing appropriate acceptance criteria in the Design Verification Summary:

i. (b) (4)

Please compare the results of the subject devices to results for a legally marketed predicate (b) (4) unicompartmental tibial component; and

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Page 2 - Ms. Denise Duchene

(b) (4)



If the performance data you supply does not adequately demonstrate the substantial equivalence of the components in question, you may be required to supply clinical data. Please be advised that prior to initiating a clinical study in the United States, an investigational device exemption (IDE) must be submitted for review and approval by FDA.

When using a standard to demonstrate equivalence, providing a declaration of conformity or a statement that the device will comply prior to marketing, may be provided in lieu of data. Please refer to our document, titled Use of Standards in Substantial Equivalence Determinations located at <http://www.fda.gov/cdrh/ode/guidance/1131.pdf> for additional guidance.

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

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and

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Page 3 - Ms. Denise Duchene

processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Jonathan Peck at (301) 594-2036. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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Ms. Denise Duchene  
Senior Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K033769  
Trade Name: EIUS® Unicompartmental Knee System – Tibial Components  
Dated: December 1, 2003  
Received: December 3, 2003

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b. A revised Design Verification Summary which assesses the following risks associated with an (b) (4) (b) (4) these risks could be assessed by performing the following Design Verification Activities and providing appropriate acceptance criteria in the Design Verification Summary:

(b) (4)

Please compare the results of the subject devices to results for a legally marketed predicate (b) (4) unicondylar tibial component; and

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Page 2 - Ms. Denise Duchene

(b) (4)



If the performance data you supply does not adequately demonstrate the substantial equivalence of the components in question, you may be required to supply clinical data. Please be advised that prior to initiating a clinical study in the United States, an investigational device exemption (IDE) must be submitted for review and approval by FDA.

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You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 3 - Ms. Denise Duchene

processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

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Sincerely yours,

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

FILE  
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
410	Zimmerman	11/30/09						
410	Peck	12/23/09						

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cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ-410 Division  
D.O.  
f/t:JPeck:elh:12/22/03  
elh:12/23/03

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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

December 03, 2003

HOWMEDICA OSTEONICS CORP  
325 CORPORATE DR.  
MAHWAH, NJ 07430  
ATTN: DENISE DUCHENE

510(k) Number: K033769  
Received: 03-DEC-2003  
Product: EIUS  
UNICOMPARTMENTAL  
KNEE SYSTEM

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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

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](http://www.fda.gov/cdrh/ode/a02-01.html).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. 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

10 0 33769

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.

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:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. 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.
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.)
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.)
5. 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.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the OBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

HOWMEDICA OSTEONICS CORP  
 325 CORPORATE DR  
 MAHWAH, NJ 07430

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)  
 222183590

2. CONTACT NAME  
 DENISE DUCHENE

2.1 E-MAIL ADDRESS  
 dduchene@howost.com

2.2 TELEPHONE NUMBER (Include Area Code)  
 201-831-5612

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)  
 201-831-6038

10/11/09 11:29 AM  
 FDA/CDRH/PMO

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:

- Premarket notification (510(k)); except for third party reviews
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below:

- Original Application

Supplement Types:

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

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

- YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- NO, I am not a small business

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

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

- This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- The sole purpose of the application is to support conditions of use for a pediatric population
- The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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).)

- YES
- NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b) (4)

SK 9  
 Se  
 OK II



K 033769

stryker®  
**Howmedica**  
**OSTEONICS**

300 Commerce Court  
Mahwah, NJ 07430

Via Federal Express

December 1, 2003

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

DEC 3 11:20 AM '03

**Re: Special 510(k) Notification: Line Extension to the EIUS® Unicompartmental Knee System**

Ladies and Gentlemen:

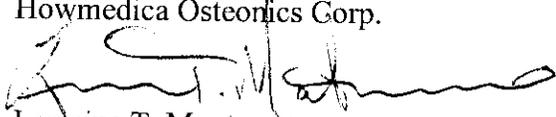
Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, notification is made of the intention of Howmedica Osteonics Corp. to introduce into interstate commerce a line extension to the EIUS Unicompartmental Knee System. The FDA Orthopedic Panel considers these devices as Class II, knee joint femorotibial, metal/polymer, cemented prostheses.

This submission contains methods, data, and analysis of these data that 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 the Freedom of Information (FOI) Act.

The Indications for Use Form, Truthful and Accuracy Statement and Medical Device User Fee Cover Sheet immediately follow this letter.

Your early attention to this submission is appreciated. Please refer any questions regarding this submission to Denise Duchene at (201) 831-5612.

Sincerely,  
Howmedica Osteonics Corp.

  
Lorraine T. Montemurro  
Regulatory Affairs Manager

OK II

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## Indications for Use

510(k) Number (if known): K033769

Device Name: EIUS® Unicompartmental Knee System – Tibial Components

### Indications For Use:

The EIUS® Knee System components are for use in Unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis

These components are single use only and are intended for implantation with bone cement.

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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of   1  

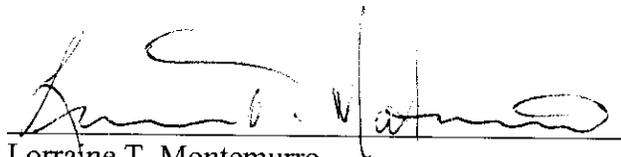
59



300 Commerce Court  
Mahwah, NJ 07430

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

I certify that, in my capacity as Regulatory Affairs Manager for Howmedica Osteonics Corp., I believe to the best of my knowledge that all information and data submitted in this premarket notification [510(k)] are truthful and that no material facts have been willfully omitted.

  
\_\_\_\_\_  
Lorraine T. Montemurro  
Regulatory Affairs Manager

12/01/03  
Date

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**SPECIAL 510(K) PREMARKET NOTIFICATION  
LINE EXTENSION TO THE EIUS<sup>®</sup> UNICOMPARTMENTAL KNEE SYSTEM  
DECEMBER 1, 2003**

**stryker**  
**Howmedica**  
**OSTEONICS**  
325 CORPORATE DR.  
MAHWAH, NJ 07430

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**Special 510(k) Summary of Safety and Effectiveness:  
Line Extension to the EIUS® Unicompartmental Knee System**

Proprietary Name:	EIUS® Unicompartmental Knee System
Common Name:	Unicompartmental Knee System
Proposed Regulatory Class:	Class II Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer, 21 CFR 888.3520
Device Product Code:	87 HSX
For Information contact:	Denise Duchene Sr. Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Dr. Mahwah, NJ 07430 Telephone: (201) 831-5612 Fax: (201) 831-6038 Email: dduchene@howost.com
Date Summary Prepared:	November 12, 2003

**Predicate Device Identification**

The EIUS® Unicompartmental Knee System consists of various sizes of femoral components and tibial components and the Scorpio Total Knee System consists of various femoral, tibial and patellar components. The EIUS Unicompartmental Knee System additional tibial components are equivalent to the currently marketed EIUS tibial components with the exception of the thickness, cement recess and material. The material is equivalent to the currently marketed Scorpio Knee System tibial inserts; whereas the cement recess without a keel is equivalent to the UNIX Unicompartmental Knee and the Biomet Repicci Unicompartmental All Polyethylene Tibia component (also available without a keel). The EIUS Unicompartmental Knee System was determined substantially equivalent under K992287, the UNIX Unicompartmental Knee was determined substantially equivalent under K923011, the Biomet component was cleared under K980665, and the Scorpio Total Knee Tibial Insert components were determined substantially equivalent under K962152.

**Description of Device Modification**

This submission is intended to address a line extension to the EIUS® Unicompartmental Knee System. The line extension includes additional tibial components, 8mm, 9mm, 10mm, and 12mm components without a keel and 6mm components with and without a keel. Also, some changes were made to the cement recess of the tibial component to ensure adequate thickness under the femoral condyle. Finally, the material will change from the current polyethylene material to the polyethylene material used in the Scorpio Knee System. The new components will be used for resurfacing of either the medial or lateral proximal tibia.

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Line Extension to the EIUS<sup>®</sup> Unicompartmental Knee System

Special 510(k) Premarket Notification

**Intended Use:**

The EIUS<sup>®</sup> Unicompartmental Knee System is intended for use in unicompartmental knee arthroplasty. It is intended to be used for patients with moderately disabling joint disease of the knee resulting from painful osteoarthritis or traumatic arthritis; revision of previous unsuccessful unicompartmental knee replacement or other procedure, or as an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

**Statement of Technological Comparison:**

The subject components share the same intended use and basic design concept as that of the predicate devices. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.

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Line Extension to the EIUS® Unicompartmental Knee System

Special 510(k) Premarket Notification

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

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Line Extension to the EIUS® Unicompartamental Knee System

Special 510(k) Premarket Notification

**Manufacturer Identification**

**Name and Address of the Sponsor of the 510(k) Submission:**

Howmedica Osteonics Corp.  
325 Corporate Dr.  
Mahwah, New Jersey 07430  
Establishment Registration Number: 2249697

**Name and Address of the Manufacturers of the Device:**

Howmedica Osteonics Corp.  
325 Corporate Dr.  
Mahwah, NJ 07430  
Establishment Registration Number: 2249697

**Name and Address of the Distributor of the Device:**

Howmedica Osteonics Corp.  
325 Corporate Dr.  
Mahwah, NJ 07430  
Establishment Registration Number: 2249697

**Contact Person:**

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Sr. Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
325 Corporate Dr.  
Mahwah, New Jersey 07430  
Telephone: (201) 831-5612  
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Email: dduchene@howost.com

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Line Extension to the EIUS® Unicompartmental Knee System

Special 510(k) Premarket Notification

**SECTION II**  
**DEVICE IDENTIFICATION**

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Line Extension to the EIUS® Unicompartmental Knee System

Special 510(k) Premarket Notification

**Device Identification**

**Proprietary Name:** EIUS® Unicompartmental Knee System  
**Common Name:** Unicompartmental Knee System  
**Classification Name and Reference:** Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer  
21 CFR 888.3520  
**Proposed Regulatory Class:** Class II  
**Device Panel/Product Code:** 87 HSX - Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer

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**SECTION III  
DEVICE DESCRIPTIVE INFORMATION**

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## Introduction

This Special 510(k) submission is intended to address a line extension to the predicate EIUS Unicompartmental Knee System. The line extension includes additional tibial components, 8mm, 9mm, 10mm and 12mm components without a keel and 6mm components with and without a keel. Note the 6mm components are actually 6mm under the condyle. There is no change in intended use or the indications for use for the subject device when compared to the previously cleared device.

## Device History and Description

The EIUS Unicompartmental Knee System consists of a distal femoral resurfacing component and proximal tibial resurfacing component intended to replace either the medial or lateral compartments of the knee joint during unicompartmental arthroplasty. The femoral and tibial components are available in various sizes and styles. The system was originally named the "First Step Uni Knee" and was determined substantially equivalent via 510(k) K992287. The EIUS Knee System is fabricated from (b) (4) cobalt chromium (femoral component) and ultra high molecular weight polyethylene (UHMWPE) (tibial component).

The current tibial component is available in 8mm, 9mm, 10mm and 12mm thicknesses for the left medial / right lateral and/or right medial / left lateral compartments. The components are designed with an articulating (b) (4). The underside of the tibial components contains a cement recess and a keel. A minor modification was made to the cement recess (b) (4).

This modified cement recess is included in the engineering drawing in Appendix A.

The additional components will be available in 6mm thickness for the left medial / right lateral and/or the right medial / left lateral. These components are designed with (b) (4). The underside of the tibial components contains a modified cement recess to ensure a minimum of 6mm under the condyle and a keel. The remaining additional components will be available in 6mm, 8mm, 9mm, 10mm, 12mm thicknesses without a keel for the left medial / right lateral and/or right medial / left lateral compartments. The 6mm component will have the same cement recess as the other additional 6mm component with a keel; whereas, the thicker components will have the same cement recess as the current product.

A complete listing of all the additional EIUS tibial components is included in Appendix A.

## Intended Use

The EIUS Unicompartmental Knee System components are intended for use in unicompartmental knee arthroplasty. The components of the EIUS Unicompartmental Knee System are single use devices, which are sold sterile and are for cemented use only.

The specific indications / contraindications for the EIUS Knee System are stated below:

### Indications:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis;
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure;
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

**Contraindications:**

- Any active or suspected latent infection in or about the knee joint.
- Any mental neuromuscular disorder, which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Ligamentous instability such that the postoperative stability afforded by the unicompartmental knee prosthesis would be compromised.
- Damage to the contralateral compartment of the ipsilateral knee.
- Deterioration or destruction of the patello-femoral joint.
- Inflammatory arthritic conditions, particularly rheumatoid arthritis.
- Severe deformity and/or recurrent subluxation of the knee joint.
- Obesity. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of fixation of the device or failure of the device itself.

**Description of Device Modification**

The EIUS Unicompartmental Knee System is being modified to provide additional tibial components. The additional components will be available in a “6mm” thickness (b) (4) with and without a keel and the currently available thicknesses without a keel. In addition, a modification was made to the cement recess on the tibial components to ensure that the “6mm” component was a minimum of 6mm under the condyle. Finally, the tibial component material is changing from (b) (4) (b) (4) s used in other knee products (i.e.: the Scorpio® Total Knee System Tibial Insert component).

A component list and engineering drawings for the subject EIUS Unicompartmental Knee System tibial components can be found in Appendix A.

**Materials**

Listed below are the materials used to fabricate the subject components: ASTM F648 – Ultra High Molecular Weight Polyethylene (b) (4). This is the same material used to manufacture the current tibial inserts determined substantially equivalent under K962152. The material properties are provided in the table on the following page:

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Stage 1 Data for (b) (4) Polyethylene

Property	Non-irradiated (0 Mrad)	Irradiated (2.8 Mrad)
	Mean (Std. Dev.)	Mean (Std. Dev.)
UTS (MPa)	(b) (4)	
Yield Strength (MPa)		
Modulus of Elasticity (MPa)		
% Elongation		
Molecular Weight (g/cc)		
Density		
% Crystallinity		
Melting Temp. (Deg. C)		

**Labeling**

The draft labels and the draft package insert for the subject EIUS Unicompartmental Knee System components are presented in Appendix B.

**Design Control**

Analyses were performed to evaluate the potential risks associated with the changes made to the EIUS Unicompartmental Knee System. Mechanical testing was used to assess whether the subject device falls within preestablished acceptance criteria. The overall risk analysis method used was FMEA. A chart with the potential risks and an Engineering Analysis are provided in Appendix C. The testing is summarized below:

(b) (4)

(b) (4)



**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.

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**Sterility Information**

The components of EIUS Unicompartmental Knee System are single use devices and are provided sterile. The implants are sterilized to a Sterility Assurance Level (SAL) of  $10^{-6}$  using:

- Method: Gamma Irradiation
- Source: Cobalt 60
- Dose: (b) (4)
- Validation: (b) (4)

**Packaging Information**

The EIUS Tibial components are packaged in a double blister (b) (4)

(b) (4)

(b) (4)

placed in the cardboard container, sealed via the primary package labels, and enveloped in shrink-wrap.

**Substantial Equivalence Information**

The features of the subject EIUS Unicompartmental Knee System components are substantially equivalent to corresponding features of the predicate EIUS Unicompartmental Knee System (K992287), the UNIX Unicompartmental Knee System – keeless design (K923011), the Scorpio Total Knee System (material) (K962152), and the Biomet Repicci Unicondylar Knee System – keeless and thickness (K980665). The intended use, packaging, and sterilization of the subject and unmodified system components are identical. Mechanical properties are equivalent to the predicate EIUS unicompartmental Knee System, the UNIX unicompartmental knee system, the Scorpio Total Knee System (material properties only), or the Biomet Repicci Unicompartmental Knee System.

The Biomet Repecci unicondylar knee replacement cement fixation consists of (b) (4) vaffle pattern along with (b) (4) for cement fixation (See Figure A). The overall thickness of the component at the thinnest section under the femoral condyle is identical to the thinnest EIUS component proposed (b) (4)

The Repicci cement pockets are approximately (b) (4) diameter at the bone/prosthesis interface (surface (b) (4) 2mm deep and have a 60° undercut. The EIUS cement pockets have a (b) (4) which is approximately (b) (4) wide for the smallest size (b) (4). Due to the significantly larger surface area of the EIUS cement pockets versus the Repicci (b) (4). Also, the smallest EIUS components are (b) (4) while the Repicci components are 32mm, resulting in additional surface area for the cement fixation. Furthermore, the larger surface area of the EIUS component with the (b) (4) into the component compared to the (b) (4) in the Repicci Unicompartmental tibial component, (b) (4)

The surface area calculations shown above (b) (4) as well as the waffle pattern for Repicci. If these features are added, (b) (4) for the EIUS and (b) (4) for Repicci is attained (b) (4) making the (b) (4) for EIUS versus (b) (4) for Repicci.

Appendix C-1 shows the (b) (4) which has the largest cement surface area (b) (4) surface area of (b) (4) in<sup>2</sup>, followed by the 6mm cement mantle design also with (b) (4) although (b) (4) of this is for (b) (4). It is apparent that as the (b) (4) (b) (4) Also, testing showed that (b) (4) cement pockets, (b) (4). This is probably due to deformation and cantilever bending produced from the point, posterior loading of the test tibial components, and zero compressive force representing the joint load. Therefore, from the rationale above due to the (b) (4) (b) (4) the cement fixation of the proposed EIUS designs will perform significantly better than the Repicci in (b) (4).

Note: Surface area cement calculations were obtained from (b) (4)

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**APPENDICES**

**APPENDIX A**

**COMPONENT INFORMATION**

**APPENDIX B**

**PACKAGING INFORMATION**

**APPENDIX C**

**RISK ANALYSIS**

**APPENDIX D**

**STATEMENTS**

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**APPENDIX A: COMPONENT INFORMATION**

- A-1 List of Subject Components
- A-2 Engineering Drawings for the Subject EIUS Knee System Components
- A-3 Engineering Drawings for the Predicate Device Unicompartmental Knee System Components

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Appendix A-1: List of Subject Components

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<b>Catalog Number</b>	<b>Component Name</b>
<b>Tibial Components with Keel</b>	
6636-2-306	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 6mm
6636-2-406	Tibial Component Small, LM /RL, 6mm
6636-2-506	Tibial Component Medium, LM /RL, 6mm
6636-2-606	Tibial Component Large, LM /RL, 6mm
6636-2-706	Tibial Component X-Large, LM /RL, 6mm
6636-2-316	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 6mm
6636-2-416	Tibial Component Small, RM /LL, 6mm
6636-2-516	Tibial Component Medium, RM /LL, 6mm
6636-2-616	Tibial Component Large, RM /LL, 6mm
6636-2-716	Tibial Component X-Large, RM /LL, 6mm
<b>Tibial Components without Keel</b>	
6636-0-306	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 6mm
6636-0-406	Tibial Component Small, LM /RL, 6mm
6636-0-506	Tibial Component Medium, LM /RL, 6mm
6636-0-606	Tibial Component Large, LM /RL, 6mm
6636-0-706	Tibial Component X-Large, LM /RL, 6mm
6636-0-316	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 6mm
6636-0-416	Tibial Component Small, RM /LL, 6mm
6636-0-516	Tibial Component Medium, RM /LL, 6mm
6636-0-616	Tibial Component Large, RM /LL, 6mm
6636-0-716	Tibial Component X-Large, RM /LL, 6mm
6636-0-308	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 8mm
6636-0-408	Tibial Component Small, LM /RL, 8mm
6636-0-508	Tibial Component Medium, LM /RL, 8mm
6636-0-608	Tibial Component Large, LM /RL, 8mm
6636-0-708	Tibial Component X-Large, LM /RL, 8mm
6636-0-318	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 8mm
6636-0-418	Tibial Component Small, RM /LL, 8mm
6636-0-518	Tibial Component Medium, RM /LL, 8mm
6636-0-618	Tibial Component Large, RM /LL, 8mm
6636-0-718	Tibial Component X-Large, RM /LL, 8mm
6636-0-309	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 9mm
6636-0-409	Tibial Component Small, LM /RL, 9mm
6636-0-509	Tibial Component Medium, LM /RL, 9mm

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6636-0-609	Tibial Component Large, LM /RL, 9mm
6636-0-709	Tibial Component X-Large, LM /RL, 9mm
6636-0-319	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 9mm
6636-0-419	Tibial Component Small, RM /LL, 9mm
6636-0-519	Tibial Component Medium, RM /LL, 9mm
6636-0-619	Tibial Component Large, RM /LL, 9mm
6636-0-719	Tibial Component X-Large, RM /LL, 9mm
6636-0-310	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 10mm
6636-0-410	Tibial Component Small, LM /RL, 10mm
6636-0-510	Tibial Component Medium, LM /RL, 10mm
6636-0-610	Tibial Component Large, LM /RL, 10mm
6636-0-710	Tibial Component X-Large, LM /RL, 10mm
6636-0-320	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 10mm
6636-0-420	Tibial Component Small, RM /LL, 10mm
6636-0-520	Tibial Component Medium, RM /LL, 10mm
6636-0-620	Tibial Component Large, RM /LL, 10mm
6636-0-720	Tibial Component X-Large, RM /LL, 10mm
6636-0-312	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 12mm
6636-0-412	Tibial Component Small, LM /RL, 12mm
6636-0-512	Tibial Component Medium, LM /RL, 12mm
6636-0-612	Tibial Component Large, LM /RL, 12mm
6636-0-712	Tibial Component X-Large, LM /RL, 12mm
6636-0-322	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 12mm
6636-0-422	Tibial Component Small, RM /LL, 12mm
6636-0-522	Tibial Component Medium, RM /LL, 12mm
6636-0-622	Tibial Component Large, RM /LL, 12mm
6636-0-722	Tibial Component X-Large, RM /LL, 12mm

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Line Extension to the EIUS® Unicompartmental Knee System

Special 510(k) Premarket Notification

Appendix A-2  
Engineering Drawings for the Subject EIUS Unicompartmental Knee System

-CONFIDENTIAL-

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**APPENDIX B: PACKAGING INFORMATION**

- B-1** Draft Labels for the Subject Components
- B-2** Draft Package Insert for the Subject Components
- B-3** Labels for the Predicate Components
- B-4** Package Insert for the Predicate Components

Appendix B-1  
Draft Labels for the Subject Components

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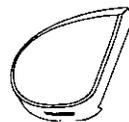
44

Catalog No. **6636-2-306**

# EIUS® UNI KNEE

## Tibial Component

- All Polyethylene
- Left Medial/Right Lateral
- X-Small
- 6mm Thickness



\*+H825663623060J\*



\*+\$\$8010908TESTJ6\*

HOWMEDICA OSTEONICS CORP.  
59 Route 17  
Allendale, NJ 07401  
A subsidiary of Stryker Corp.



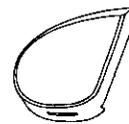
**WARNING-This Device Is Intended for Cemented Use Only in the U.S.A.**

REF **6636-2-306**

# EIUS® UNI KNEE

## Tibial Component

- All Polyethylene
- Left Medial/Right Lateral
- X-Small
- 6mm Thickness



### Composant tibial

· Tout · polyethylene · Très Petit · Interne gauche/lateral droit · Épaisseur 6mm

### Tibiakomponente

· Aus Polyethylen · Extra Klein · Links medial/Rechts lateral · Dicke 6mm

### Componente tibiale

· Tutto in polietilene · Extra Piccolo · Sinistro mediale/destro laterale · Spessore 6mm

### Componente tibial

· Polietileno · Extra Pequeño · Medial izquierdo/lateral derecho · 6mm Grosor,

### Tibiacomponent

· Geheel en al van polyethyleen · Extra Klein · Links mediaal/rechts lateraal · 6mm Dikte

### Tibial komponent

· 100% polyetylen · Extra Liten · Vänster medial/höger lateral · 6mm tjocklek



Authorized representative in Europe  
RA/QA Manager  
STRYKER France  
BP 50040-95946 Roissy CDG Cedex  
FRANCE  
Tel. (33) 1.48.17.50.00



STERILE R

CE0473



2008-09

UHMWPI

CAUTION: Federal Law(USA) restricts this device to sale by or on the order of a Physician

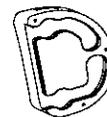
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Catalog No. **6636-0-306**

# EIUS® UNI KNEE

## Tibial Component

- All Polyethylene
- Left Medial/Right Lateral
- X-Small
- 6mm Thickness
- WITHOUT keel



\*+H825663603060H\*



\*+\$8010908TESTH4\*

HOWMEDICA OSTEONICS CORP.  
59 Route 17  
Allendale, NJ 07401  
A subsidiary of Stryker Corp.



I.D.#  
SN



SAMPLE

**WARNING-This Device is Intended for Cemented Use Only in the U.S.A.**

REF **6636-0-306**

# EIUS® UNI KNEE

## Tibial Component

- All Polyethylene
- Left Medial/Right Lateral
- X-Small
- 6mm Thickness
- WITHOUT keel



### Composant tibial

· Tout - polyethylene · Épaisseur 6mm · Interne gauche/latéral droit · sans quille · Très Petit

### Tibiakomponente

· Aus Polyethylen · Dicke 6mm · Links medial/Rechts lateral · ohne Kielstück · Extra Klein

### Componente tibiale

· Tutto in polietilene · Spessore 6mm · Sinistro mediale/destro laterale · senza carena · Extra Piccolo

### Componente tibial

· Polietileno · 6mm Grosor · Medial izquierdo/lateral derecho · sin quilla · Extra Pequeño

### Tibiacomponent

· Geheel en al van polyethyleen · 6mm Dikte · Links mediaal/rechts lateraal · niet gevleugeld · Extra Klein

### Tibial komponent

· 100% polyetylen · 6mm tjocklek · Vänster medial/höger lateral · utan köl · Extra Liten



Authorized representative in Europe  
RA/QA Manager  
STRYKER France  
BP 50040-95946 Roissy CDG Cedex  
FRANCE  
Tel. (33) 1.48.17.50.00



STERILE R

CE0473



2008-09

UHMWPI

CAUTION: Federal Law(USA) restricts this device to sale by or on the order of a Physician

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Line Extension to the EIUS<sup>®</sup> Unicompartmental Knee System

Special 510(k) Premarket Notification

Appendix B-2  
Draft Package Insert for the Subject Components

**stryker**  
**Howmedica**  
**OSTEONICS**

**Total Knee Joint Replacement  
Prostheses For Cement Applications**

Howmedica Osteonics Corp.  
359 Veterans Boulevard  
Rutherford, NJ USA 07070  
A Subsidiary of Stryker Corp.

Authorized Representative in Europe:  
RA/QA Manager Stryker France  
BP 50040-95946 Roissy CDG Cedex  
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A Subsidiary of Stryker Corp.

Howmedica Osteonics Corp.  
Stryker Ireland  
Carrigwohill Industrial Estate  
County Cork  
Ireland

CE 0473

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Printed in U.S.A.

0095-3-201J



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TOTAL KNEE JOINT REPLACEMENT  
 PROSTHESES FOR CEMENT APPLICATIONS  
 PROTHÈSES A CIMENTER POUR  
 ARTHROPLASTIES TOTALES DU GENOU  
 KNEEGELENKTOTAL ENDPROTHESEN  
 FÜR ZEMENTIERTE ANWENDUNGEN  
 PROTESI TOTALI RICOSTRUTTIVE DI  
 GINOCCHIO CON USO DI CEMENTO  
 SUSTITUCIÓN TOTAL DE LA ARTICULACIÓN DE LA RODILLA  
 PROTÊSIS PARA APLICACIONES CEMENTADAS  
 SUBSTITUIÇÃO TOTAL DE ARTICULAÇÃO DO JOELHO  
 PROTÊSE PARA APLICAÇÕES CIMENTADAS  
 TOTAL KNÄLEDSPLASTIK  
 PROTËS FOR CEMENTERAD APPLIKATION  
 KOKOPOLYVINYLPROTEESI  
 SEMENTILLISIA SOVELLUKSIJA VARTIEN  
 FILDSTÄNDIG KNÄLEDS SUBSTITUTIONS  
 PROTËSE TIL CEMENT APPLIKATIONER  
 VOLLEDIGE KNEGEWICHTVERVANGINGEN  
 PROTËSE VOOR CEMENTTOEPASSINGEN  
 OAIKH ANTIKATAITAIH TONATYOY  
 TPPOEZEI TIA EPAMOTFEI ME TIMMENTO  
 人工膝關節全置換術  
 テメント使用人工膝節

English  
 PACKAGE INSERT  
 ATTENTION OPERATING SURGEON

The advancement of total knee replacement has provided the surgeon with a means of restoring mobility, correcting deformity, and reducing pain with the use of implanted prosthetic devices. These devices, while proven successful, are made of metal and plastic materials. No prosthetic device can be expected to withstand activity levels and loads in the same way as would a normal healthy joint. The prosthetic system, therefore, will not be as strong, reliable, or durable as a natural human knee joint.

- In using total knee joint implants, the surgeon should be aware of the following:
- A. The correct selection and positioning of the implant is extremely important. Success in total joint replacement requires the selection of the proper size, shape, and designed implants. Total joint prostheses require careful sealing, rigid fixation and adequate bone support.
  - B. In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:
    - 1) The patient's weight. An overweight or obese patient can produce higher loads on the prosthesis which can lead to failure of the device. The effect of these loads will be accentuated when a small sized prosthesis must be used because of bone size in such patients.
    - 2) The patient's occupation or activity. If the patient is involved in an occupation or activity which includes significant impact loads (walking, running, lifting or twisting), the resultant forces can cause failure of the fixation, the device, or both. High levels of physical activities over the course of years can also accentuate the normal wear that occurs with prosthetic joints. The prosthesis will not restore function to the level expected with a normal healthy joint, and the patient should not have, and should be disabused of, unrealistic functional expectations. (See PRECAUTIONS section for more information.)
    - 3) A condition of senility, mental illness, or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
    - 4) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
    - 5) Orthopaedic history. The prognosis for success of the procedure is dependent upon the patient's orthopaedic history. Patients who have had multiple previous procedures and/or implants should be carefully counseled regarding the anticipated outcome of the procedure.
    - 6) Quality of bone. Survivorship of the total knee replacement may be affected by weakened bone stock, which may be the result of certain systemic or metabolic diseases such as those treated with steroids, immunosuppressants or chemotherapeutics.

49/09

**DESCRIPTION**

Howmedica manufactures a wide variety of ticompartiment reconstructive knee systems in various sizes and styles to accommodate various patient and surgeon requirements for primary and revision cemented applications. The selection of the prosthesis system is dependent upon the type of surgery required. Femoral, tibial and patellar components are available for knee reconstruction. The metallic components (the femoral component, tibial and patellar baseplates, tibial and patellar wedges and spacers) are manufactured from cast cobalt-chromium-nickel alloy (Vitallium® Alloy) conforming to ASTM standard F75. The screws and stem extensors are manufactured from wrought cobalt-chromium-nickel alloy (Vitallium® Alloy) conforming to ASTM standard F1537.

The polyethylene components are manufactured from ultra-high-molecular-weight polyethylene (UHMWPE) conforming to ASTM standard F664.

**Femoral Components**

Femoral components (except superstabilizer) are available with porous and non-porous coated options. The superstabilizer and superstabilizer configurations. Certain femoral components can be converted from one configuration to another, e.g., condylar to stabilizer, by the addition of a modular stabilizer box.

**Tibial Components**

The tibial components are available in a wide range of sizes and thicknesses. Tibial components include one piece all-polyethylene and modular styles consisting of a polyethylene insert and metallic baseplate. The baseplates are available with porous and non-porous coating options and adjunct fixation options. The inserts are available with varying degrees of constraint in the condylar styles, stabilizer and superstabilizer configurations.

**Patellar Components**

The patellar components are available in all-polyethylene or metal-backed with porous coating.

**Accessories**

Stem extenders are designed to attach to the stem of the femoral or tibial component to provide additional stability. Wedges are designed for cemented applications to provide additional spacing while the tibial bone defects. Spacers are designed to provide additional spacing where there is femoral bone defects and may be mechanically secured to the femoral component or cemented in place. Screws are available for adjunct assembly of tibial inserts to baseplates or tibial baseplate to tibial bone.

**Product Label**

The product label provides information regarding the specific material(s) from which the device is manufactured.

**INDICATIONS**

Indications for use of total knee replacement prostheses include:

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- 2) rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed;
- 5) post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- 6) reparable fracture of the knee.

**CONTRAINDICATIONS**

Absolute contraindications include:

- 1) overt infection;
- 2) distant foci of infections (which may cause hematogenous spread to the implant site);
- 3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- 4) skeletal immature patients;
- 5) cases where there is poor bone stock which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

- 1) uncooperative patient or patient with neurological disorders who is incapable of following instructions;
  - 2) osteoporosis;
  - 3) metabolic disorders which may impair bone formation;
  - 4) osteomalacia; and,
  - 5) previous arthrodeseis.
- A higher incidence of implant failure has also occurred in paraplegics, cerebral palsy and patients with Parkinson's disease.

**WARNINGS**

Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and reduced service life of the prosthetic implant. The surgeon should be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

**Cemented application.** Care should be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning (complete removal of bone chips,

bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.

**Prosthetic components.** Femoral, tibial and patellar components of different prosthetic systems, or from different manufacturers, should not be mixed, since tolerances or materials may be incompatible. Modular components must be assembled securely to prevent disassociation. Repeated assembly and disassembly of the modular components could compromise the critical locking action of the components and should be avoided. Surgical debris must be cleaned from components before assembly. Debris may interfere with the locking mechanism of modular components, which in turn may lead to early failure of the procedure.

**Patella Component.** Because the patella component has the smallest bearing and fixation surfaces, the patella or patella component is more vulnerable to subluxation and loosening/dislodation. Particular attention, during surgery, to patella tracking is necessary for success of the procedure.

**Fixation screws.** Fixation screws, when used, should be fully sealed to maximize stable fixation, and to avoid interference with the proper seating of components. Use only screws recommended for the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals. These bone screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. Metal components. Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or in animal organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such a phenomenon, in spite of the millions of implants in use. (See reference 1.)

**Alignment of components.** Care should be taken to restore the proper joint alignment and to balance ligamentous tension. Misalignment of the femur or joint can cause excessive wear, loosening of the prosthesis and pain leading to earlier-than-desired revision of one or more of the prosthetic components.

**Polyethylene wear.** As would be expected, wear of the polyethylene surfaces of tibial and patella components has been reported, following total knee replacement. Higher rates of wear may be initiated by particles of cement, metal or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear likely will shorten the useful life of the prosthesis, and lead to an earlier-than-desired revision to replace the worn prosthetic components.

**PRECAUTIONS**

**Information for patients.** The patient should be advised of the short and long term limitations of the procedure and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and handling affecting the joint replacement have been implicated in failure of the reconstruction. Fracture and/or wear of the prosthetic implants, loosening of the components, result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

The patient should be cautioned to limit activities, protect the replaced joint from unreasonable stresses and follow the instructions of the physician with respect to follow-up care and treatment.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device can and should be applied to normal healthy joint, that the implant can 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 replaced at some time in the future.

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have also been associated with transient bacteremia, to prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage, prior to surgery.

Re-use. An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

Handling. Handling of implants is important, particularly porous coated implants. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials. All implants where the coating has been damaged or contaminated should be discarded. The highly polished portion of the implant should not come in contact with hard surfaces.

**ADVERSE EFFECTS**

- 1) With all joint replacements, asymptomatic, localized progressive bone resorption (osteolysis) may occur around or remote from the prosthetic components as a consequence of foreign body reaction to particulate matter. Particulate matter is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of abrasion, fretting, abrasion and fatigue. Secondly, particulate matter can also be generated by third-body wear. Osteolysis can lead to future complications. (See IMPORTANT INFORMATION section for more information.)
- 2) Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in cellular reactions that may include lymphocytes, macrophages and fibroblasts.
- 3) Peripheral neuropathies have been reported following total joint surgery. Sub-clinical nerve damage has been reported, and may be a result of surgical trauma.
- 4) Dislocation and subluxation of implant components can result from improper

- positioning and/or migration of the components. Soft tissue laxity including muscle, fibrous tissue and ligaments can also contribute to these conditions.
- 5) Implants can loosen or migrate due to trauma or loss of fixation.
  - 6) Infection can lead to failure of the joint replacement.
  - 7) While rare, fatigue fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment or extreme duration of service.
  - 8) Soft tissue (ligamentous) imbalance can cause excessive wear and/or failure of the implant.
  - 9) Intraoperative fracture of the femur, tibia or patella can occur while preparing the bone sites and/or seating of the implants.
  - 10) Allergic reactions to the materials utilized in the implant, although uncommon, can occur.
- Intraoperative and early postoperative complications can include, but are not limited to:**
- 1) deep venous thrombosis;
  - 2) damage to blood vessels;
  - 3) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
  - 4) a sudden drop in intraoperative blood pressure associated with the use of bone cement;
  - 5) varus-valgus deformity with resultant limb/prosthesis malalignment;
  - 6) cardiovascular disorders including pulmonary embolism or myocardial infarction;
  - 7) hematoma;
  - 8) delayed wound healing;
  - 9) joint replacement which may necessitate removal of the prosthesis and subsequent arthrodesis. Appropriate antibiotic prophylaxis and strict adherence to aseptic procedures is mandatory; and,
  - 10) femoral, tibial or patella bone or component fracture.
- Late postoperative complications can include, but are not limited to:**
- 1) late (or early) loosening, change in position of the components, wear and bending or cracking of one or more prosthetic components. (Clinical experience suggests that particular attention to the terms contained in the Warnings and Precautions sections of this package insert may help minimize the risk of their occurring.);
  - 2) patellar fracture as a result of excess tension, or inadvertent intraoperative weakening;
  - 3) aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy;
  - 4) late ligamentous instability.

- 5) peripatellar calcification or ossification, with or without impingement to joint mobility;
- 6) inadequate range of motion due to improper selection or positioning of components, impingement or peripatellar calcification and dystrophy; and,
- 7) bone fractures, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the leg, all of which have been reported in association with total knee replacement.

**IMPORTANT PHYSICIAN INFORMATION**

**A. Bone Resorption and Osteolysis.** Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone, and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localized foreign-body reaction to particulate debris (e.g., cement, metal, UHMWPE, and ceramics), generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Regarding the etiology, it has been hypothesized that particulate debris generated by articulation of the implant interface, where they recruit macrophages and stimulate production and amount of particulate debris as well as the rate of debris release of cytokines, and cellular mediators (IL-1, IL-2, IL-5, PGE2, INF3). These mediators have been shown to mediate osteolytic bone resorption. Clinical and basic research is continuing in order to better understand the scientific basis for the causes of this phenomenon and explore potential ways to reduce its occurrence.

Since osteolysis is frequently asymptomatic, routine periodic radiographic examination is vital to help detect and minimize any serious future complications. However, radiographs may not completely define the extent of osteolysis. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

**B. Polyethylene Thickness.** Theoretical analyses have indicated that contact stresses in the tibial component vary with the thickness of the polyethylene component. In general, thicker inserts are thought to have lower contact stresses than thinner ones. These implications of the theoretical stress differences have not been clinically established. The physician should consider the trade-off between additional tibial bone resection and the use of a thicker insert. Patient related factors, such as weight, age and activity level should be part of the decision.

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- C. **Component Matching.** There are corresponding tibial widths designed to articulate and conform with the appropriately-sized femoral components. Failure to correctly match components could result in premature failure of the tibial component and contribute to joint laxity.
- D. **Product Label.** See product label for information regarding the specific product referenced in this package insert.

**HOW SUPPLIED**

These products are delivered sterile in containers which have been exposed to a minimum of 25 kGy of gamma radiation from a cobalt 60 source. The package of all sterile products should be examined prior to use for possible breaks in the sterile barrier.

**RESTERILIZATION**

Devices containing POLYETHYLENE, POROUS COATING, PLASMA SPRAY, HYDROXYAPATITE, CERAMICS or METHYLMETHACRYLATE CANNOT BE AUTO-CLAVED OR RESTERILIZED BY THE USER.

Components that have not been contaminated with fluids, in particular body fluids, can be resterilized using the following parameters in a gravity displacement steam autoclave:

	250° F (121° C) 20 PSI (1.4 Bars)	270° F (132° C) 30 PSI (2 Bars)
Wrapped individual Component (single or multi component) or Sterilization Case	40 minutes	20 minutes

The double wrapping method used is the AAMI CSR technique. These cycles were developed with only this item in the chamber and using the middle shelf. Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

**CAUTION**

Federal Law in the USA restricts this device to sale by or on the order of a physician.

**REFERENCES**

1. Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study in Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

Appendix B-3  
Labels for the Predicate Components

**stryker**  
**Howmedica**  
**OSTEONICS**

**CE 0050**

Howmedica International S.de R.L.  
 Raheen Business Park, Limerick, Ireland.

<b>REF 6636-2-518</b>		<b>STERILE R</b>	Tantalum and Dur. <sup>®</sup> Stabilized UHMWPE	<b>LOT D8212</b>	<b>SAMPLE</b>
EIUS Duration® enkeltsek. knæ tibiakomponent, medium, 8mm højre medial / venstre lateral			EIUS Duration® Uni. knie tibiadeel, middelgroot, 8mm rechts mediaal / links lateraal		
Joelho Uni. EIUS Duration® Componente tibial, Médio, 8mm Dir. Int. / Esq. Ext.					
EIUS Duration® Uni.-polvi Sääntuosa, keskikoko, 8mm Oikea mediaal. / Vasen lateraal					
Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.					
 <b>2003-08</b> Made in IRELAND			 <b>2008-08</b>	U.S. Pat. 5,414,049; 5,543,471 & 5,449,745	



\*+E025663625181E\*



\*+\$D8212SAMPLEEP\*

**stryker**  
**Howmedica**  
**OSTEONICS**  
**REF 6636-2-518**



EIUS Duration® Uni. Knee Tibial Component, Medium, 8mm Right Medial / Left Lateral	
EIUS Duration® Genou Unicomp. Composant Tibial, Moyen, 8mm Droit Int. / Gauche Externe	
EIUS Duration® Uni. Knie Tibiakomponente, Mittel, 8mm Rechts Medial / Links Lat	
<b>LOT D8212</b>	<b>SAMPLE</b>
 <b>2008-08</b>	

**stryker**  
**Howmedica**  
**OSTEONICS**

**CE 0050**

<b>REF 6636-2-518</b>		<b>STERILE R</b>	<b>LOT D8212</b>	<b>SAMPLE</b>
EIUS Duration® Uni. Knee Tibial Component, Medium, 8mm Right Medial / Left Lateral			Tantalum and Dur. <sup>®</sup> Stabilized UHMWPE	



\*+E025663625181E\*



\*+\$D8212SAMPLEEP\*

**DEVICE IS INTENDED  
 FOR CEMENT USE  
 ONLY IN THE U.S.A.**

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Appendix B-4  
Package Insert for the Predicate Components

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CE0050

**stryker**  
**Howmedica**  
**OSTEONICS**

TOTAL KNEE JOINT REPLACEMENT PROSTHESIS  
(FOR CEMENTED USE ONLY IN USA)

PROTHESES POUR ARTHOPLASTIES TOTALES DU GENOU  
KNIEGELENKTOTALENDOPROTHESEN

PROTESI TOTALI RICOSTRUTTIVE DI GINOCCHIO  
SUSTITUCIÓN TOTAL DE LA ARTICULACIÓN DE LA  
RODILLA PRÓTESIS

PROTES FÖR TOTAL KNÄPLASTIK  
膝関節全置換術用インプラント  
TOTALE KNIETPROTHESE

TÄYDELLINEN POLVEN TEKONIVELPROTEESI

PROTESER TIL TOTAL KNÆPLASTIK

PRÓTESE TOTAL DO JOELHO

ΠΡΟΘΕΣΗ ΟΛΙΚΗΣ ΑΝΤΙΚΑΤΑΣΤΑΣΗΣ ΤΗΣ ΑΡΘΡΩΣΗΣ ΤΟΥ ΓΟΝΑΤΟΥ

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**Howmedica**

**English**

**TOTAL KNEE JOINT REPLACEMENT PROSTHESIS**

**(For cemented use only in USA)**

**PACKAGE INSERT**

**ATTENTION OPERATING SURGEON**

The advancement of total knee replacement has provided the surgeon with a means of restoring mobility, correcting deformity, and reducing pain with the use of implanted prosthetic devices. These devices, while proven successful, are manufactured from metal and plastic materials. No prosthetic device can therefore be expected to withstand activity levels and loads in the same way as would a normal healthy joint. The prosthetic system, therefore, will not be as strong, reliable, or durable as a natural human knee joint.

**In using total knee joint implants, the surgeon should be aware of the following:**

- A. The correct selection and positioning of the implant is extremely important.** Success in total joint replacement requires the selection of the proper size, shape, and designed implants. Total joint prostheses require careful seating, rigid fixation and adequate bone support.
- B. In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:**
  - 1) The patient's weight.** An overweight or obese patient can produce higher loads on the prosthesis which can lead to failure of the device. The effect of these loads will be accentuated when a small sized prosthesis must be used because of bone size in such patients.
  - 2) The patient's occupation or activity.** If the patient is involved in an occupation or activity which includes significant impact loads (walking, running, lifting or twisting), the resultant forces can cause failure of the fixation, the device, or both. High levels of physical activities over the course of years can also

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- 3) **A condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- 4) **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- 5) **Orthopaedic history.** The prognosis for success of the procedure is dependent upon the patient's orthopaedic history. Patients who have had multiple previous procedures and/or implants should be carefully counseled regarding the anticipated outcome of the procedure.
- 6) **Quality of bone.** Survivorship of the total knee replacement may be affected by weakened bone stock, which may be the result of certain systemic or metabolic diseases such as those treated with steroids, immunosuppressants or chemotherapeutics.

**DESCRIPTION**

Howmedica manufactures a wide variety of tricompartment reconstructive knee systems in various sizes and styles to accommodate various patient and surgeon requirements for primary and revision cemented applications. The selection of the prosthesis system is dependent upon the type of surgery required. Femoral, tibial and patellar components are available for knee reconstruction. The metallic components (the femoral component, tibial and patellar baseplates, sintered beads, wedges and spacers) are manufactured from cast cobalt-chromium-molybdenum alloy (Vitalium® Alloy) conforming to ASTM standard F75. The stems and stem extenders are manufactured from wrought cobalt-chromium-molybdenum alloy (Vitalium® Alloy) conforming to ASTM standard F1537. The polyethylene components are manufactured from ultra-high-molecular-weight polyethylene (UHMWPE) conforming to ASTM standard F648.

**Femoral Components**

Femoral components (except superstabilizer) are available with porous and non-porous coated options: condylar, stabilizer and superstabilizer configurations. Certain femoral components can be converted from one configuration to another, e.g., condylar to stabilizer, by the addition of a modular stabilizer box.

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**Tibial Components**

The tibial components are available in a wide range of sizes and thicknesses. Tibial components include one piece all-polyethylene and modular styles consisting of a polyethylene insert and metallic baseplate. The baseplates are available with porous and non-porous coating options and adjunct friction options. The inserts are available with varying degrees of constraint in the condylar styles, stabilizer and superstabilizer configurations.

**Patellar Components**

The patellar components are available in all-polyethylene or metal-backed with porous coating.

**Accessories**

Stem extenders are designed to attach to the stem of the femoral or tibial component to provide additional stability. Wedges are designed for cemented applications to provide additional spacing where there are tibial bone defects. Spacers are designed to provide to the femoral component or cemented in place. Screws are available for adjunct assembly of tibial inserts to baseplates or tibial baseplate to tibial bone.

**Product label**

The product label provides information regarding the specific material(s) from which the device is manufactured.

**INDICATIONS**

**Indications for use of total knee replacement prostheses include:**

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis;
- 2) rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed;
- 5) post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- 6) irreparable fracture of the knee.

**CONTRAINDICATIONS**

**Absolute contraindications include:**

- 1) overt infection;

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60

- 2) distant foci of infections (which may cause hematogenous spread to the implant site);
- 3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- 4) skeletally immature patients;
- 5) cases where there is poor bone stock which would make the procedure unjustifiable.

**Conditions presenting an increased risk of failure include:**

- 1) uncooperative patient or patient with neurological disorders who is incapable of following instructions;
  - 2) osteoporosis;
  - 3) metabolic disorders which may impair bone formation;
  - 4) osteomalacia; and,
  - 5) previous arthrodesis.
- A higher incidence of implant failure has also occurred in paraplegics, cerebral palsy and patients with Parkinson's disease.

**WARNINGS**

Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and reduced service life of the prosthetic implant. The surgeon should be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

**Cemented application.** Care should be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning (complete removal of bone chips, bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.

**Prosthetic components.** Femoral, tibial and patellar components of different prosthetic systems, or from different manufacturers, should not be mixed, since tolerances or materials may be incompatible. Modular components must be assembled securely to prevent disassociation. Repeated assembly and disassembly of the modular components could compromise the critical locking action of the components and should be avoided. Surgical debris must be cleaned from components before assembly. Debris may interfere with the locking mechanism of modular components, which in turn may lead to early failure of the procedure.

**Patella Component.** Because the patella component has the smallest bearing and fixation surfaces, the patella or patella component is more vulnerable to subluxation and loosening/dislocation. Particular attention, during surgery, to patella tracking is necessary for success of the procedure.

**Fixation screws.** Fixation screws, when used, should be fully sealed to maximize stable fixation, and to avoid interference with the proper seating of components. Use only screws recommended for the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals. These bone screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

**Metal components.** Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such a phenomenon, in spite of the millions of implants in use. (See reference 1.)

**Alignment of components.** Care should be taken to restore the proper joint alignment and to balance ligamentous tension. Misalignment of the limb or joint can cause excessive wear, loosening of the prosthesis and pain leading to earlier-than-desired revision of one or more of the prosthetic components.

**Polyethylene wear.** As would be expected, wear of the polyethylene surfaces of tibial and patella components has been reported following total knee replacement. Higher rates of wear may be initiated by particles of cement, metal or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear likely will shorten the useful life of the prosthesis, and lead to an earlier-than-desired revision to replace the worn prosthetic components.

**PRECAUTIONS**

**Information for patients.** The patient should be advised of the short and long term implications of the procedure and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint (placement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

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- 2) distant foci of infections (which may cause hematogenous spread to the implant site);
- 3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- 4) skeletally immature patients;
- 5) cases where there is poor bone stock which would make the procedure unjustifiable.

**Conditions presenting an increased risk of failure include:**

- 1) uncooperative patient or patient with neurological disorders who is incapable of following instructions;
- 2) osteoporosis;
- 3) metabolic disorders which may impair bone formation;
- 4) osteomalacia; and,
- 5) previous arthrodesis.

A higher incidence of implant failure has also occurred in paraplegics, cerebral palsy and patients with Parkinson's disease.

**WARNINGS**

Improper selection, placement, positioning and fixation of the implant components may result in unusual stress conditions and reduced service life of the prosthetic implant. The surgeon should be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

**Cemented application.** Care should be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning (complete removal of bone chips, bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.

**Prosthetic components.** Femoral, tibial and patellar components of different prosthetic systems, or from different manufacturers, should not be mixed, since tolerances or materials may be incompatible. Modular components must be assembled securely to prevent disassociation. Repeated assembly and disassembly of the modular components could compromise the critical locking action of the components and should be avoided. Surgical debris must be cleaned from components before assembly. Debris may interfere with the locking mechanism of modular components, which in turn may lead to early failure of the procedure.

**Patella Component.** Because the patella component has the smallest bearing and fixation surfaces, the patella or patella component is more vulnerable to subluxation and loosening/dislocation. Particular attention, during surgery, to patella tracking is necessary for success of the procedure.

**Fixation screws.** Fixation screws, when used, should be fully seated to maximize stable fixation, and to avoid interference with the proper seating of components. Use only screws recommended for the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals. These bone screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

**Metal components.** Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such a phenomenon, in spite of the millions of implants in use. (See reference 1.)

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**PRECAUTIONS**

**Information for patients.** The patient should be advised of the short and long term limitations of the procedure and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

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The patient should be cautioned to limit activities, protect the replaced joint from unreasonable stresses and follow the instructions of the physician with respect to follow-up care and treatment.

The patient should be warned of surgical risks, and made aware of possible adverse effects: healthy joint, that the implant 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 replaced at some time in the future.

**Transient bacteremia** can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have also been associated with transient bacteremia. To prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

**Instruments.** Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components.

While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage, prior to surgery.

**Re-use.** An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity which would reduce its service life.

**Handling.** Handling of implants is important, particularly porous coated implants. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials. All implants where the coating has been damaged or contaminated should be discarded. The highly polished portion of the implant should not come in contact with hard surfaces.

**ADVERSE EFFECTS**

- 1) With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around or remote from the prosthetic components as a consequence of foreign body reaction to particulate matter. Particulate matter is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondly, particulate matter can also be generated by third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. (See **IMPORTANT PHYSICIAN INFORMATION** section for more information.)

- 2) Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in cellular reactions that may include lymphocytes, macrophages and fibroblasts.

- 3) Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may be a result of surgical trauma.

- 4) Dislocation and subluxation of implant components can result from improper positioning and/or migration of the components. Soft tissue laxity including muscle, fibrous tissue and ligaments can also contribute to these conditions.

- 5) Implants can loosen or migrate due to trauma or loss of fixation.

- 6) Infection can lead to failure of the joint replacement.

- 7) While rare, fatigue fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment or extreme duration of service.

- 8) Soft tissue (ligamentous) imbalance can cause excessive wear and/or failure of the implant.

- 9) Intraoperative fracture of the femur, tibia or patella can occur while preparing the bone sites and/or sealing of the implants.

- 10) Allergic reactions to the materials utilized in the implant, although uncommon, can occur.

**Intraoperative and early postoperative complications can include, but are not limited to:**

- 1) deep venous thrombosis;
- 2) damage to blood vessels;
- 3) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
- 4) a sudden drop in intraoperative blood pressure associated with the use of bone cement;
- 5) varus-valgus deformity with resultant limb/prosthesis malalignment;
- 6) cardiovascular disorders including pulmonary embolism or myocardial infarction; herniation;
- 7) herniation;
- 8) delayed wound healing;
- 9) deep wound infection (early or late), a potentially serious complication of all joint replacement which may necessitate removal of the prosthesis and subsequent arthrodesis. Appropriate antibiotic prophylaxis and strict adherence to aseptic procedures is mandatory, and;
- 10) femoral, tibial or patella bone or component fracture.

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**Late postoperative complications can include, but are not limited to:**

- 1) late (or early) loosening, change in position of the components, wear, and bending or cracking of one or more prosthetic components (Clinical experience suggests that particular attention to the items contained in the Warnings and Precautions sections of this package insert may help minimize the risk of their occurring);
- 2) patellar fracture as a result of excess tension, or inadvertent intraoperative weakening;
- 3) aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy;
- 4) late ligamentous instability;
- 5) periparticular calcification or ossification, with or without impediment to joint mobility;
- 6) inadequate range of motion due to improper selection or positioning of components, impingement or periparticular calcification and dystrophy; and,
- 7) bone fractures, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the leg, all of which have been reported in association with total knee replacement.

**IMPORTANT PHYSICIAN INFORMATION**

**A. Bone Resorption and Osteolysis.** Bone resorption can occur as a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis leads to implant loosening and failure. Localized progressive bone resorption due to reasons other than stress shielding or infection may occur around the prosthetic components as well as between the components and bone, and this has been termed osteolysis. It is generally agreed that osteolysis is a result of localized foreign-body reaction to particulate debris (e.g., cement, metal, UHMWPE, and ceramics), generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Regarding the etiology, it has been hypothesized that particulate debris generated by articulation of the

components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris as well as the rate of debris generation. The phagocytic action has been demonstrated in vitro to induce release of cytokines and cellular mediators (IL-1, IL-2, IL-6, PGE2, TNF $\alpha$ ). These mediators have been shown to modulate osteoclastic bone resorption. Clinical and basic research is continuing in order to better understand the scientific basis for the causes of this phenomenon and explore potential ways to reduce its occurrence.

Since osteolysis is frequently asymptomatic, routine periodic radiographic examination is vital to help detect and minimize any serious future complication. However, radiographs may not completely define the extent of osteolysis. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

**B. Polyethylene Thickness.** Theoretical analyses have indicated that contact stresses in the tibial component vary with the thickness of the polyethylene component. In general, thicker inserts are thought to have lower contact stresses than thinner ones. These stresses may affect the wear of the implant components; however, the clinical implications of the theoretical stress differences have not been conclusively established. The physician should consider the trade-off between additional tibial bone resection and the use of a thicker insert. Patient related factors, such as weight, age and activity level should be part of the decision.

**C. Component Matching.** There are corresponding tibial widths designed to articulate and conform with the appropriately-sized femoral components. Failure to correctly match components could result in premature failure of the tibial component and contribute to joint laxity.

**D. Ultra-High-Molecular-Weight Polyethylene (UHMWPE).** Pending the completion of additional research, Howmedica recommends that its UHMWPE orthopaedic implant components, which have been conventionally sterilized in air, and shelf stored in air more than five years after the date of manufacture, should not be implanted.

**E. Product Label.** See product label for information regarding the specific product referenced in this package insert.

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**HOW SUPPLIED**

These products are delivered sterile in containers which have been exposed to a minimum of 25 kGy of gamma radiation from a cobalt 60 source. The package of all sterile products should be examined prior to use for possible breaks in the sterile barrier.

**RESTERILIZATION**

Devices containing POLYETHYLENE, POROUS COATING, PLASMA SPRAY, HYDROXYAPATITE, CERAMICS or METHYLMETHACRYLATE CANNOT BE AUTOCLAVED OR RESTERILIZED BY THE USER.

Components that have not been contaminated with fluids, in particular body fluids, can be resterilized using the following parameters in a gravity displacement steam autoclave:

	250° F (121° C) 20 PSI (1.4 Bars)	270° F (132° C) 30 PSI (2 Bars)
Wrapped individual Component (single or multi component) or Sterilization Case	40 minutes	20 minutes

The double wrapping method used is the AAMI CSR technique. These cycles were developed with only this item in the chamber and using the middle shelf. Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

**CAUTION**

Federal Law in the USA restricts this device to sale by or on the order of a physician.

**REFERENCES**

- Olof Hyren, Joseph K. McLaughlin et al., "Cancer Risk After Hip Replacement With Metal Implants: A Population Based Cohort Study In Sweden," Journal Of The National Cancer Institute, Volume 87, Number 1, January 4, 1995.

**Français**

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**APPENDIX D: STATEMENTS**

**D-1**

Declaration of Conformity

**D-2**

Statement of Scientific Technology and Indications

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Line Extension to the EIUS® Unicompartmental Knee System

Special 510(k) Premarket Notification

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

LSO

Line Extension to the EIUS® Unicompartmental Knee System

Special 510(k) Premarket Notification

**stryker®**  
**Howmedica**  
**OSTEONICS**

300 Commerce Court  
Mahwah, NJ 07430

**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.

Howmedica Osteonics' 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.



J. D'Alessio  
Project Manager - Early Intervention

12/1/2003  
Date

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**APPENDIX D-2**  
**Statement of Scientific Technology and Indications**

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Line Extension to the EIUS® Unicompartmental Knee System

Special 510(k) Premarket Notification

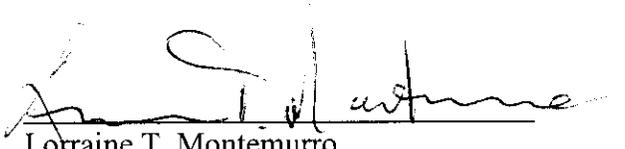
**stryker®**  
**Howmedica**  
**OSTEONICS**

300 Commerce Court  
Mahwah, NJ 07430

**Statement of Scientific Technology and Indications**

The indications for use of the EIUS Unicompartmental Knee System as described in the labeling have not changed from the indications for use of the currently available EIUS Unicompartmental Knee System

In addition, the fundamental scientific technology of the EIUS Unicompartmental Knee System as described in the labeling has not changed from that of the available EIUS Unicompartmental Knee System.



Lorraine T. Montemurro  
Regulatory Affairs Manager

12-01-03  
Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Jonathan Peck

Subject: 510(k) Number K033769/S1

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) No

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):

87 HSX Class II

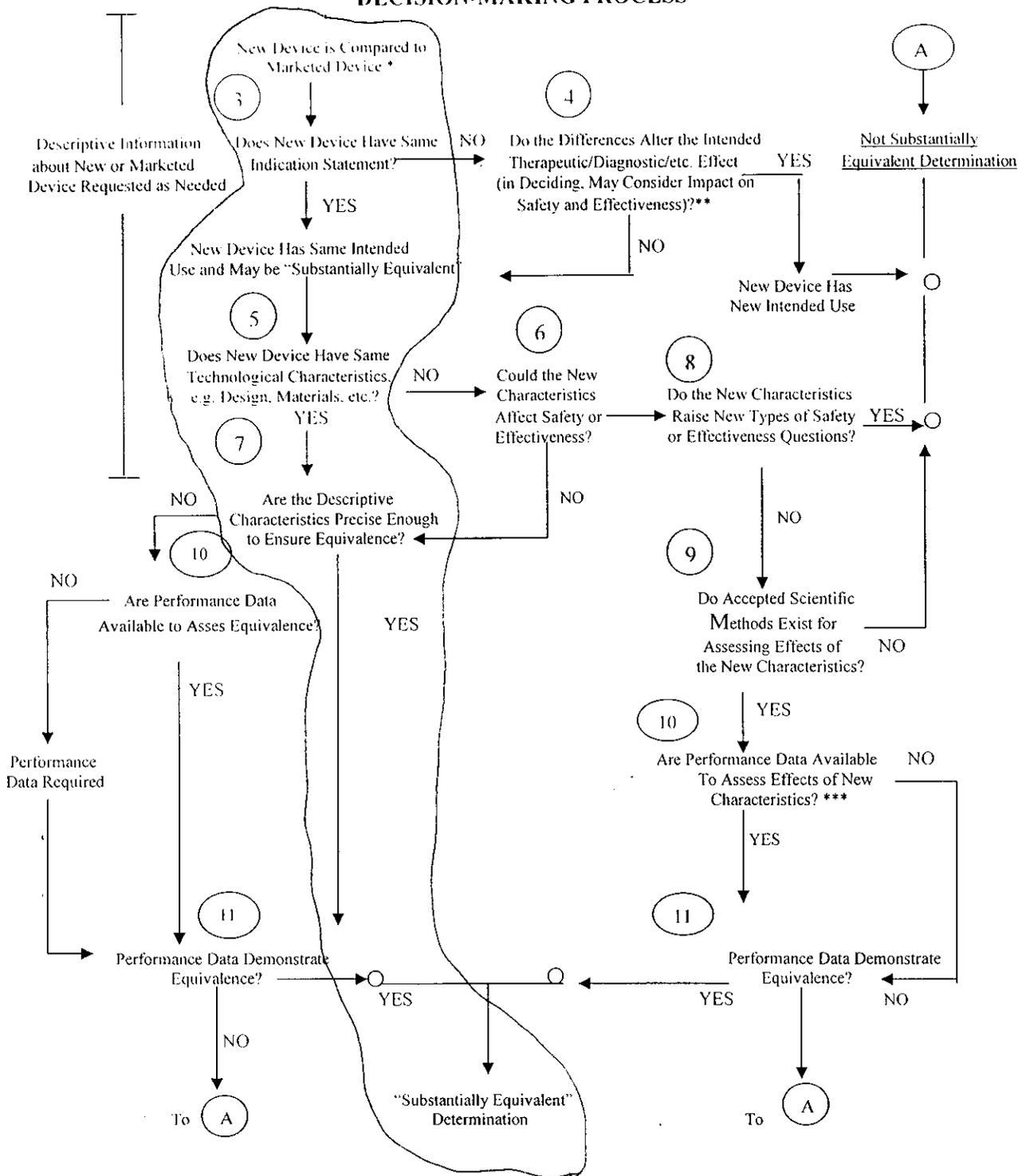
Review: B. Zimmerman ORDB 2/12/04  
(Branch Chief) (Branch Code) (Date)

Final Review: Made M 2/13/04  
(Division Director) (Date)

Revised: 4/2/03

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### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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**SPECIAL 510(k) MEMORANDUM**

**To:** K033769/S1  
**From:** Jonathan H. Peck, Biomechanical Engineer  
 ODE/DGRND/Orthopedic Devices Branch  
**Date:** December 9, 2003  
**Subject:** EIUS Unicompartmental Knee System  
 Product Code: 87HSX; 21 CFR 888.3520 - Prosthesis, Knee, Femorotibial,  
 Non-Constrained, Cemented, Metal Polymer  
**Firm:** Howmedica Osteonics Corp  
 325 Corporate Drive  
 Mahwah, NJ 07430  
**Contact:** Denise Duchene  
 Phone: (201) 831-5612  
 Fax: (201) 831-6038  
**Decision:** SE

**Supplement 1 (Information from previous submission is indented):**

The sponsor submitted a supplement on January 16, 2004 in an attempt to address the deficiency below. The concern is that (b) (4)

(b) (4)

(b) (4) This was confirmed with a set of measurements made by the sponsor on one of the subject tibial components and (b) (4)

(b) (4)

(b) (4)

	(b) (4)
<b>Minimum Poly Thickness (mm)</b>	(b) (4)
<b>Overall Area (mm<sup>2</sup>)</b>	
<b>Area of Cement Reservoirs (mm<sup>2</sup>)</b>	
<b>Area of Cement Reservoirs/Overall Area (%)</b>	
<b>Area with Minimum Thickness of at least 6.0mm under condyle (mm<sup>2</sup>)</b>	
<b>Area with Minimum Thickness of at least 6.0mm under condyle/Overall Area (%)</b>	

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(b) (4)

**Recommendation:**

Due to the comparison above between the subject device and the predicate (b) (4) (b) (4) I recommend that the subject devices should be found substantially equivalent (SE) to legally marketed predicate devices.

(b) (4)

**Contact Record:**

In a teleconference on January 9<sup>th</sup>, 2004 between Denise Duchene, and others from Howmedica and Barbara Zimmerman and myself, we discussed (b) (4)

(b) (4)

(b) (4) We asked for more detailed engineering drawings of the subject and predicate devices.

**Review of Initial Submission:**

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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

*The sponsor wishes to make a line extension to the EIUS Unicompartmental Knee System (K992287). The line extension includes additional tibial components.*

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.

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*The sponsor states that the subject device shares the same intended use as the predicates.*

*The EIUS Knee System components are for use in Unicompartmental knee arthroplasty as a result of:*

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis*
  - Revision of previous unsuccessful Unicompartmental knee replacement or other procedure*
  - As an alternative to tibial osteotomy in patients with Unicompartmental osteoarthritis*
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**. This submission proposes the following modifications to the predicate device(s):

*The line extension includes additional tibial components, 8mm, 9mm 10mm and 12mm components without a keel and 6mm components with and without a keel. Also, some changes were made to the cement recess of the tibial component to ensure adequate thickness under the femoral condyle. Finally, the material will change from the current polyethylene material to the polyethylene material used in the Scorpio Knee System (K962152).*

(b) (4)

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

*The new 8-12mm components are identical to the old components except that they lack a central keel and are manufacture from the polyethylene used for the Scorpio Total Knee System.*

*The proposed 6mm components have a minimum thickness below 6mm. See deficiencies below.*

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
  - 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.

(b) (4)

design and 8-12mm EIUS components without a keel. The sponsor claims that the force the component can withstand is adequate as it surpasses the maximum force seen. (b) (4)

(b) (4)

(b) (4)

- c) A declaration of conformity with design controls. The declaration of conformity should include:
  - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
  - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

**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 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.

2/11/01

(Reviewer's Signature)

(Date)

**Correspondence:**

I spoke with Denise Duchene on 12/16/03 and asked her to provide (b) (4)

(b) (4)

I spoke with Denise Duchene on 12/18/03 to discuss options for the file such as an AI hold or She told me on 12/19/03 that she would prefer the submission be placed on hold.

(b) (4)

(b) (4)

- a. A legally marketed predicate unicompartmental polyethylene tibial component with

(b) (4)

- b. A revised Design Verification Summary which assesses the following risks associated (b) (4)  
(b) (4) These risks could be assessed by performing the following Design Verification Activities and providing appropriate acceptance criteria in the Design Verification Summary:



If the performance data you supply does not adequately demonstrate the substantial equivalence of the components in question, you may be required to supply clinical data. Please be advised that prior to initiating a clinical study in the United States, an investigational device exemption (IDE) must be submitted for review and approval by FDA.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Jonathan Peck  
Subject: 510(k) Number K 033769

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<sub>6</sub>

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):

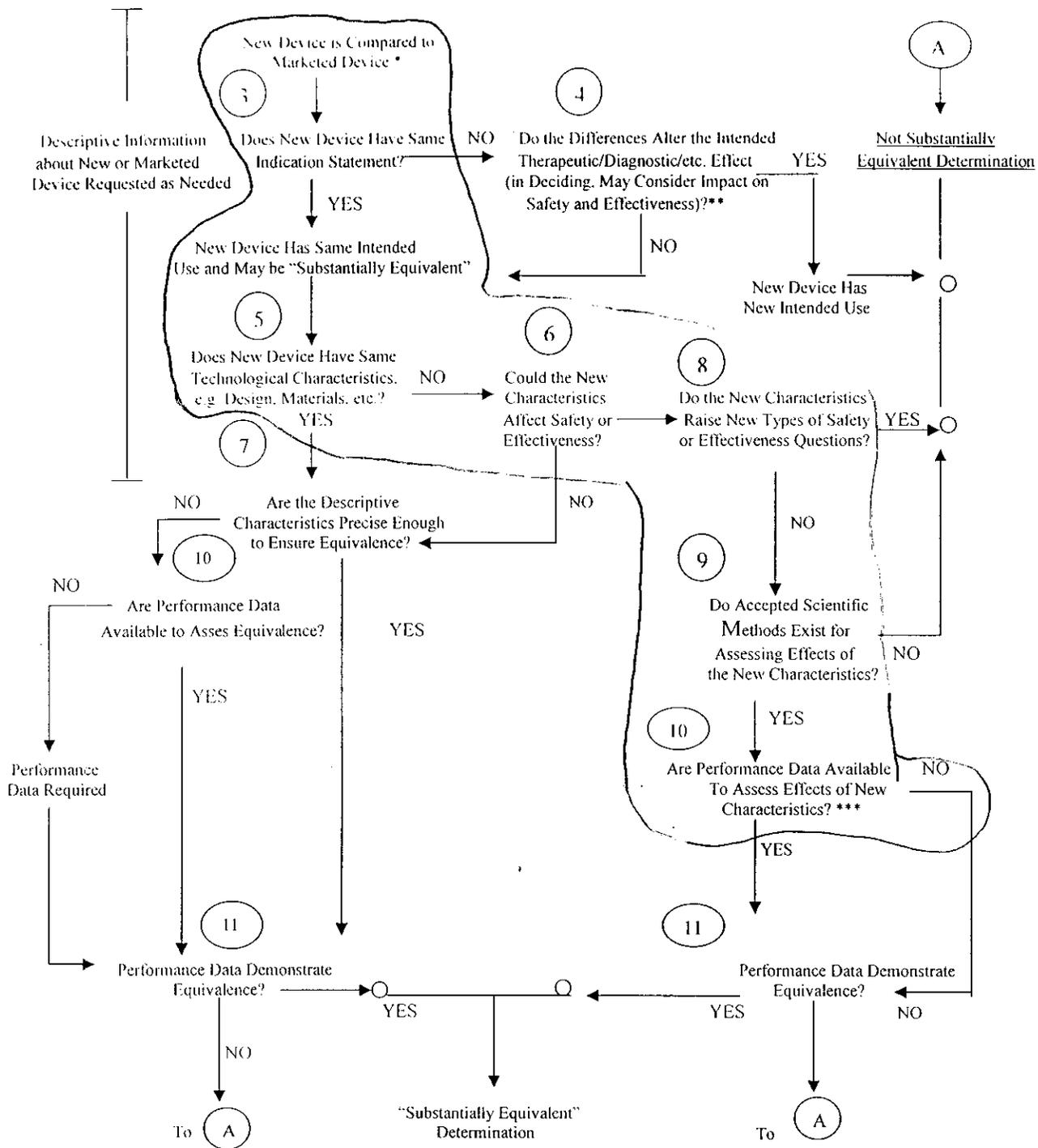
87 HSX, Class II

Review: [Signature] 02DB 12/23/03  
(Branch Code) (Branch Code) (Date)

Final Review: \_\_\_\_\_ (Date)  
(Division Director)

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### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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**SPECIAL 510(k) MEMORANDUM**

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**To:** K033769  
**From:** Jonathan H. Peck, Biomechanical Engineer  
ODE/DGRND/Orthopedic Devices Branch  
**Date:** December 9, 2003  
**Subject:** EIUS Unicompartmental Knee System  
Product Code: 87HSX; 21 CFR 888.3520 - Prosthesis, Knee, Femorotibial,  
Non-Constrained, Cemented, Metal Polymer  
**Firm:** Howmedica Osteonics Corp  
325 Corporate Drive  
Mahwah, NJ 07430  
**Contact:** Denise Duchene  
Phone: (201) 831-5612  
Fax: (201) 831-6038  
**Decision:** **Hold (AI)**

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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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

*The sponsor wishes to make a line extension to the EIUS Unicompartmental Knee System (K992287). The line extension includes additional tibial components.*

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.

*The sponsor states that the subject device shares the same intended use as the predicates.*

*The EIUS Knee System components are for use in Unicompartmental knee arthroplasty as a result of:*

- *Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis*
- *Revision of previous unsuccessful Unicompartmental knee replacement or other procedure*
- *As an alternative to tibial osteotomy in patients with Unicompartmental osteoarthritis*

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**. This submission proposes the following modifications to the predicate device(s):

*The line extension includes additional tibial components, 8mm, 9mm 10mm and 12mm components without a keel and 6mm components with and without a keel. Also, some changes were made to the cement recess of the tibial component to ensure adequate thickness under the*

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femoral condyle. Finally, the material will change from the current polyethylene material to the polyethylene material used in the Scorpio Knee System (K962152).

(b) (4)

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

*The new 8-12mm components are identical to the old components except that they lack a central keel and are manufacture from the polyethylene used for the Scorpio Total Knee System.*

(b) (4)

- 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
  - 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.

*The sponsor has nreformed* (b) (4)

(b) (4) Results showed that (b) (4)

*12mm components is statistically equivalent to the (b) (4) components. The (b) (4)*

(b) (4)

- c) A declaration of conformity with design controls. The declaration of conformity should include:
  - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
  - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

- 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 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

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recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

*Jonathan Beck*

12/23/03

(Reviewer's Signature)

(Date)

**Correspondence:**

I spoke with Denise Duchene on 12/16/03 and asked her to provide (b) (4)  
(b) (4)

I spoke with Denise Duchene on 12/18/03 to discuss options for the file such as an AI hold or (b) (4)  
She told me on 12/19/03 that she would prefer the submission be placed on hold.

(b) (4)

- a. A legally marketed predicate unicondylar (b) (4) tibial component with a (b) (4)
- b. A revised Design Verification Summary which assesses the following risks associated (b) (4)  
(b) (4) These risks could be assessed by performing the following Design Verification Activities and providing appropriate acceptance criteria in the Design Verification Summary:

(b) (4)

If the performance data you supply does not adequately demonstrate the substantial equivalence of the components in question, you may be required to supply clinical data. Please be advised that prior to initiating a clinical study in the United States, an investigational device exemption (IDE) must be submitted for review and approval by FDA.

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**SCREENING CHECKLIST  
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K033769

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

\* - May not be applicable for Special 510(k)s.

\*\* - Required for Class III devices, only.

\*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
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 required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
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. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)\* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

\* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL	✓	
iv) packaging	✓	
v) specify pyrogen free	✓	
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

*Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.*

Passed Screening  Yes  No  
 Reviewer: Jessica Peck  
 Concurrence by Review Branch: \_\_\_\_\_

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Date: \_\_\_\_\_

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

*See Memo*

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REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: Jonathan Peck K 033769

Division/Branch: DGRND/ORDB

Device Name: E1US Unicompartmental Knee System

Product To Which Compared (510(K) Number If Known): K992287

	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?	X		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NE
9. Accepted Scientific Methods Exist?	X		If NO = Stop NE
10. Performance Data Available?		X	If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision: <u>AI</u>

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.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

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 technological characteristics:  
De(b) (4)
6. Explain how new characteristics could or could not be used:  
ef(b) (4)
7. Explain how descriptive characteristics are used:
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:  
(b) (4)
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
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?		✓
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?		✓
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.		
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.		

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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

January 21, 2004

HOWMEDICA OSTEONICS CORP  
325 CORPORATE DR.  
MAHWAH, NJ 07430  
ATTN: DENISE DUCHENE

510(k) Number: K033769  
Product: EIUS  
UNICOMPARTMENTAL  
KNEE SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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](http://www.fda.gov/cdrh/ode/a02-01.html).

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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K033769/S'

stryker®

Howmedica  
OSTEONICS

325 Corporate Drive  
Mahwah, NJ 07430

January 16, 2004

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

SK-71

FOI...  
2004 JAN 20 P 2:46

RE: EIUS Tibia 510(k) Submission – K033769

Document Mail Center Staff,

Attached please find the response to the questions received regarding the EIUS Tibial Component 510(k) Submission K033769. Included in the response is a technical report (b) (4)



This submission contains methods, data, and analysis of these data that 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 the Freedom of Information (FOI) Act.

I hope this information address your needs, please feel to contact me if you have additional questions. I look forward to hearing from you.

Best Regards,

Denise Duchene  
Sr. Regulatory Affairs Specialist  
Howmedica Osteonics Corp.  
325 Corporate Dr.  
Mahwah, NJ 07430  
(201) 831-5612  
[denise.duchene@stryker.com](mailto:denise.duchene@stryker.com)

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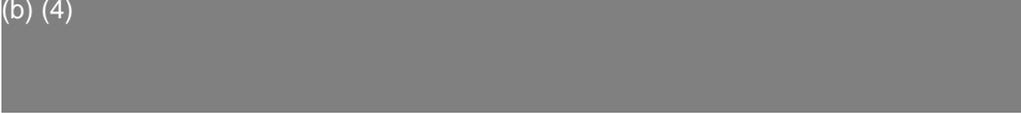
**Question:**

(b) (4)



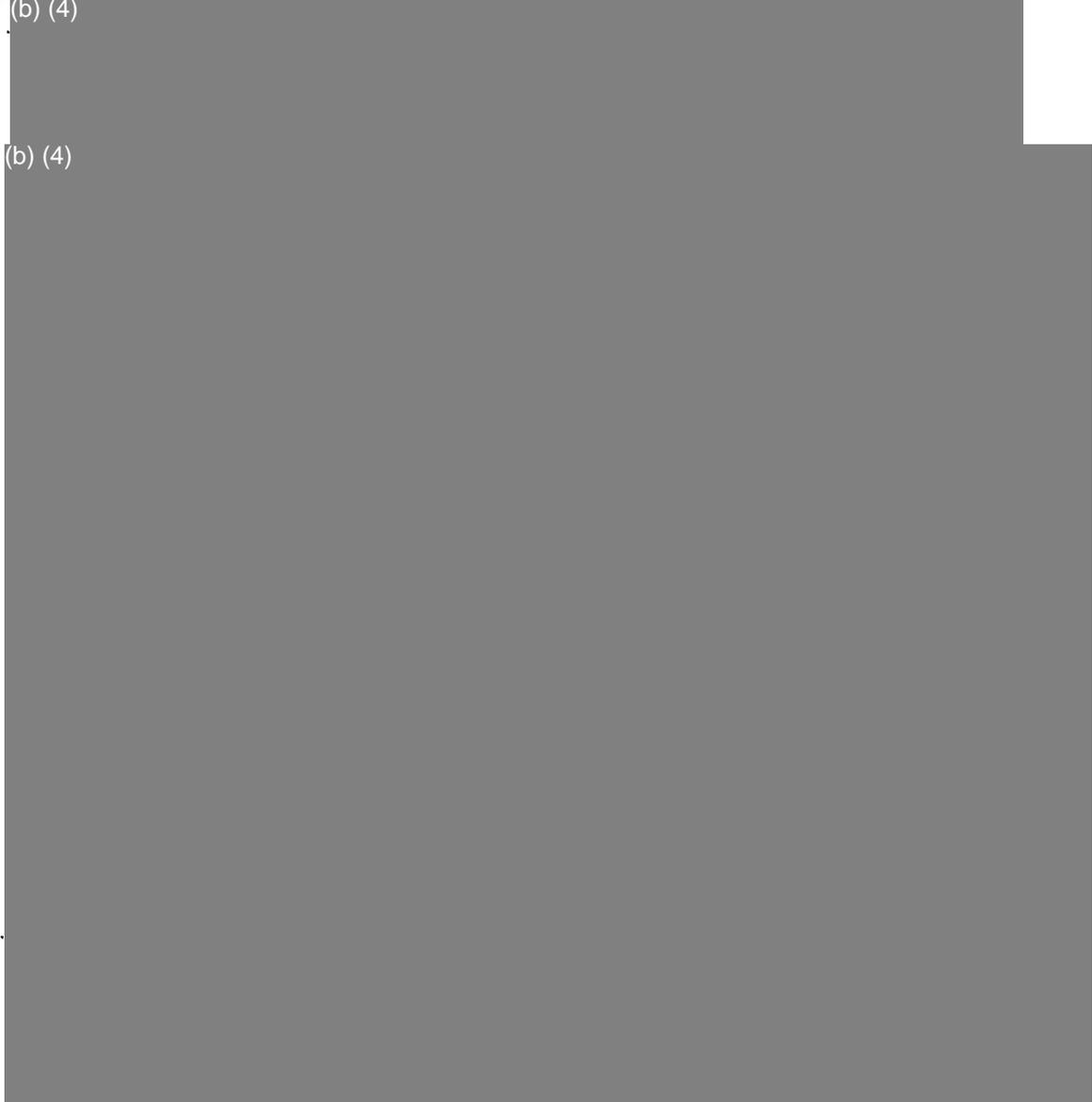
a.) A legally marketed predicate (b) (4) tibial component  
(b) (4)

b.) A revised Design Verification Summary, which assesses the following risks.  
(b) (4)



**Response:**

1. (b) (4)



(b) (4)

2.

(3)

3. Finally, please change the contact for this submission to:  
Ms. Karen Ariemma  
Stryker Orthopaedics  
325 Corporate Drive  
Mahwah, NJ 07430  
(201) 831-5718  
(201) 831-6038 (Fax)  
[Karen.ariemma@stryker.com](mailto:Karen.ariemma@stryker.com)

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510(k) Response EIUS Tibial Component

K033769

APPENDIX A  
PRODUCT DRAWINGS

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APPENDIX B

ANALYTICAL AND PHYSICAL MEASUREMENT OF (b) (4)  
IN THE EIUS TIBIAL INSERT (b) (4)

CS

