FEB 1 3 2004

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

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| Proprietary Name: | EIUS® Unicompartmental Knee System |
| Common Name: | Unicompartmental Knee System |
| Proposed Regulatory Class: | Class II<br>Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer, 21 CFR 888.3520 |
| Device Product Code: | 87 HSX |
| For Information contact: | Denise Duchene<br>Sr. Regulatory Affairs Specialist<br>Howmedica Osteonics Corp.<br>325 Corporate Dr.<br>Mahwah, NJ 07430<br>Telephone: (201) 831-5612<br>Fax: (201) 831-6038<br>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.

**Intended Use:**

The EIUS® 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2004

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

Re: K033769
Trade/Device Name: EIUS® 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.

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,

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___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

for Mark N. Melkerson

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



510(k) Number K033769