JUN 17 2004

K040719

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**510(k) Summary**

Submission Information

| | |
|---|---|
| Name and Address of Sponsor: | Howmedica Osteonics Corp.<br>325 Corporate Drive<br>Mahwah, New Jersey 07430 |
| For Information contact: | Margaret F. Crowe<br>Regulatory Affairs Consultant<br>Howmedica Osteonics Corp.<br>325 Corporate Drive<br>Mahwah, New Jersey 07430 |

Device Identification

| | |
|---|---|
| Proprietary Name: | Modular Replacement System Cemented Stems |
| Common Name: | Proximal Femoral Replacement<br>and<br>Modular Rotating Hinge Knee |
| Classification Name and Reference: | Prosthesis, Hip, Semi-constrained Metal/Polymer Porous Uncemented<br>21 CFR §888.3358<br>and<br>Knee joint femorotibial metal/polymer constrained cemented prosthesis<br>21 CFR §888.3510 |
| Proposed Regulatory Class: | Class II |
| Device Product Code: | OR(87) LPH and KRO |

**Intended Use**

The Modular Replacement System (MRS – found substantially equivalent in K952970, K965164 and K972[illegible]1) has been successfully used in clinical situations where there is extensive bone loss due to tumor resection, and/or failed previous prosthesis, or trauma. These components can be used to replace the proximal femur, the distal femur, the proximal tibia, or to reconstruct the total femur in extreme clinical situations.

It is the intention of Howmedica Osteonics Corp. to expand the indications for use of the standard Proximal/Distal Femoral Stems to include use in the proximal tibia. In order to accomplish this change, the product label for these stems will change to "Cemented Stem". In addition, a minor design change is being made - the diameter at the base of the male taper of these stems will be changed from 28mm to 26mm to provide a minimal transition when assembled to a variety of components.

Likewise, it is the intention of Howmedica Osteonics Corp. to expand the indications for use for the Small Distal Femoral Stems to include use in the proximal tibia, and to expand the clinical situations where this product can be used to include failed previous prosthesis and trauma. In order to accomplish this change, the product label description for these devices will be changed to "Small Cemented Stem". In addition, the diameter at the base of the male taper of these small stems will be changed from 24mm to 26mm to provide a minimal transition when assembled to a variety of components.

All of the stems currently cleared for use in the distal femur would also be available for use in the proximal tibia. All of these stems would be indicated for use with the other segments of the Modular Replacement System (MRS) and/or Global Modular Replacement System (GMRS™) in the treatment of extensive bone loss due to tumor resection, and/or failed previous prosthesis, or trauma. These stems are intended for use with bone cement.

Specific indications for these MRS Cemented Stems are discussed below:

**Indications**

Femoral and/or proximal tibial replacement due to

- Trauma
- Failed previous prosthesis
- Tumor resection

**Contraindications**

A. As related to Bone Tumors

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in either local or distant spread of the tumor may be a contraindication. Examples of such conditions include:

- pathological fracture;
- overt infection;
- inopportune placement of biopsy incision; and,
- rapid disease progression beyond a respectable margin.

B. As related to Failed Previous Prosthesis and Trauma

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the prosthesis.

**Device Description**

The following configurations of MRS Cemented Stems will be available:

**Standard Cemented Stems:**

- Straight stem with 40mm porous coated body - distal diameters/seat diameters are 11mm/24mm, 13mm/28mm, 15mm/32mm, 17mm/36mm - 127mm in length
- Straight stem without body - distal diameters/seat diameters are 11mm/24mm, 13mm/28mm, 15mm/32mm, 17mm/36mm - 127mm in length
- Curved stem with 40mm porous coated body - distal diameters/seat diameters are 11mm/24mm, 13mm/28mm, 15mm/32mm, 17mm/36mm - 127mm in length
- Curved stem without body - distal diameters/seat diameters are 11mm/24mm, 13mm/28mm, 15mm/32mm, 17mm/36mm - 127mm in length
- Curved stem with 40mm porous coated body - distal diameters/seat diameters are 11mm/24mm, 13mm/28mm, 15mm/32mm, 17mm/36mm - 203mm in length

- Curved stem without body - distal diameters/seat diameters are 11mm/24mm, 13mm/28mm, 15mm/32mm, 17mm/36mm - 203mm in length

Standard cemented femoral stems will be used in the proximal femur, distal femur, and proximal tibia. These stems may be used with the standard and small distal femoral component, and standard and small proximal tibial component of the MRS and/or GMRS™ systems.

**Small Cemented Stems:**

- Straight stem with 40mm porous coated body - distal diameters/seat diameters are 8mm/24mm, 9mm/24mm, 10mm/24mm - 102mm in length
- Straight stem without body - distal diameters/seat diameters are 8mm/24mm, 9mm/24mm, 10mm/24mm - 102mm in length
- Curved stem with 40mm porous coated body - distal diameters/seat diameters are 8mm/24mm, 9mm/24mm, 10mm/24mm - 102mm in length
- Curved stem without body - distal diameters/seat diameters are 8mm/24mm, 9mm/24mm, 10mm/24mm - 102mm in length

These stems may be used with the small Distal Femoral component, and small proximal tibial component of the MRS and/or GMRS™ systems.

All of the stems utilize a Morse taper to connect to the proximal femoral/distal femoral or proximal tibial components. The taper angle is 2 degrees 52 minutes. At the distal end of the larger stems is a recessed hole to allow the optional use of a cement centralizer.

Equivalent products include the existing MRS Proximal Femoral Stems, Distal Femoral Stems and Proximal Tibial Stems.

An engineering analysis was presented to support a claim of substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K040749
Trade/Device Name: Modular Replacement System (MRS) Cemented Stems
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: March 19, 2004
Received: March 23, 2004

Dear Ms. Crowe:

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

510(k) Number (if known): K040749

Device Name: Modular Replacement System (MRS) Cemented Stems

Femoral and/or proximal tibial replacement due to

- Trauma
- Failed previous prosthesis
- Tumor resection

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____ (Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milleen

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

**510(k) Number** K040749