510(k) Summary
K023087
Global Modular Replacement System

Submission Information

DEC 1 6 2002

Name and Address of Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401

Device Identification

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

Intended Use

The Global Modular Replacement System (herein referred to as the GMRS) is intended to be used with the components of the Howmedica Osteonics Modular Replacement System (MRS), the Howmedica Osteonics Modular Rotating Hinge Knee System (MRH), and/or the Howmedica Osteonics Kinematic Rotating Hinge Knee System

(KRH) in situations where replacement of extensive bone loss in the femur and/or proximal tibia is required. The Proximal Femoral Module and Distal Femoral Module of the GMRS may be used together, or with the components of the MRS, in replacement of the total femur. Indications and contraindications for this type of replacement are listed below:

Indications

Femoral and/or proximal tibial replacement and total femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of the bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications.

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.

For the use of GMRS Press Fit stems with PureFix™ HA Coating, the following additional contraindication should be noted:

- Inadequate bone stock to allow the use of a press fit stem

The Proximal Femoral Module of the GMRS is intended to be used in a cemented or press fit mode. The components of the Distal Femoral/Proximal Tibial Module are intended to be used with bone cement.

Device Description

The GMRS is comprised of a number of components that are intended to be used in conjunction with each other, or in conjunction with components of Howmedica Osteonics' Modular Rotating Hinge Knee, Kinematic Rotating Hinge Knee, and/or the Modular Replacement System. There are three modules of the GMRS:

- Proximal Femoral Module
- Distal Femoral/Proximal Tibial Module
- Total Femur

Each of these modules is comprised of different components. The modules, and their individual components, are described below:

Proximal Femoral Module

The Proximal Femoral Module of the GMRS contains the following components:

- Proximal Femoral Components
- Extension Pieces
- GMRS Press Fit Stems with PureFix™ HA

Distal Femoral/Proximal Tibial Module

The Distal Femoral/Proximal Tibial Module of the GMRS contains the following new components:

- Distal Femoral Components
- Extension Pieces (as described in the section above)
- Small bushings

- Small Axle
- Proximal Tibial Component
- Proximal Tibial Inserts
- Proximal Tibia Rotating Components

Total Femur

Replacement of the total femur is accomplished by combining the following components of the GMRS:

- Proximal Femoral Component
- Extension Pieces
- Connection Pieces
- Distal Femoral Component (with appropriate bushings, axle, etc.)
- Proximal Tibial Component (with appropriate tibial rotating component, tibial insert component)

Equivalent products include:

1. Modular Replacement System -Howmedica Osteonics Corp.
2. Distal Stems of the Restoration™ Hip System - Howmedica Osteonics Corp.
3. Modular Rotating Hinge Knee System - Howmedica Osteonics Corp.
4. Kinematic® Rotating Hinge Knee System - Howmedica Osteonics Corp.
5. MOST System - Sulzer Orthopaedics

Testing 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

Mr. William J. Cymbaluk
Vice President
Stryker Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401

DEC 16 2002

Re: K023087
Trade/Device Name: Global Modular Replacement System
Regulation Number: 21 CFR 888.3350 and 888.3510
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis; and
Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI and KRO
Dated: September 16, 2002
Received: September 17, 2002

Dear Mr. Cymbaluk :

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

GMRS - Distal Femoral/Proximal Tibial Module 510(k) Premarket Notification
Confidential

510(k) Number (if known): K023087

Device Name: Global Modular Replacement System (GMRS)

Intended Use

The Global Modular Replacement System (herein referred to as the GMRS) is intended to be used with the components of Howmedica Osteonics' Modular Replacement System, Modular Rotating Hinge Knee System, and/or Kinematic® Rotating Hinge Knee System in situations where replacement of extensive bone loss in the femur and/or proximal tibia is required. The Proximal Femoral Module and Distal Femoral Module of the GMRS may be used together, or with the components of the MRS, in replacement of the total femur. Indications and contraindications for this type of replacement are listed below:

Indications

Femoral and/or proximal tibial replacement and total femoral replacement in Oncology cases where radical resection and replacement of bone is required, and in limb salvage procedures where radical resection and replacement of bone is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous prosthesis, and/or Oncology indications.

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.

For the use of GMRS Press Fit stems with PureFix™ HA Coating, the following additional contraindication should be noted:

- Inadequate bone stock to allow the use of a press fit stem

The Proximal Femoral Module of the GMRS is intended to be used in a cemented or press fit mode. The components of the Distal Femoral/Proximal Tibial Module are intended to be used with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-the Counter-Use No (per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023087