Records processed under FOIA Request 2011-6802; Released 12/14/12

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K023087 - 336 pages
COMPANY:	HOWMEDICA OSTEONICS CORP. (HOWMOSTEA)
PRODUCT:	PROSTHESIS, KNEE, FEMOROTIBIAL, CONSTRAINED, CEMENTED, METAL/POLYMER (KRO)
SUMMARY:	Product: GLOBAL MODULAR REPLACEMENT SYSTEM (GMRS)
DATE REQUESTED:	Dec 10, 2012
DATE PRINTED:	Dec 10, 2012
Note:	Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

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 1 6 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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

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:

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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.

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

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Records processed under FOIA Request 2011-6802; Released 12/14/12

K023087

page 2 of 2

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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POS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 12/16/02

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K023.087/A1

To: Division Director: OR/DGRND

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____Additional information requires a new 510(k); however, the information submitted is incomplete; (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

_____Additional information requires a new 510(k); please process [This information will be made into a new 510(k)

X No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Pi Sung
Date: 12/18/02

Draft #2 : 9/8/99
Draft #3: 1/3/00

DMC 12/27

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

K023087/A1

stryker
Howmedica
OSTEONICS

59 Route 17
Allendale, NJ 07401-1677
Phone: (201) 825-4900
Fax: (201) 934-4369

FDA/CDRH/CDE/PMO
2007 OCT 9 A 10:14
RECEIVED

(b) (4) [redacted]

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, MD 20850

Re: (b) (4) [redacted]

Dear Sir/Madam:

Attached please find the additional information requested by Dr. Pei Sung regarding the above-referenced premarket notification. At Dr. Sung's request, this information was sent via facsimile transmission to Dr. Sung on (b) (4) [redacted]

If you require any additional information regarding the above-referenced premarket notification please contact the undersigned at (b) (6) [redacted] Thank you.

Sincerely,

(b) (6) [redacted]

2

SKO

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

stryker
Howmedica
OSTEONICS

59 Route 17
Allendale, NJ 07401-1677
Phone: (201) 825-4900
Fax: (201) 934-4369

(b) (4) [redacted]

Pei Sung, Ph.D.
Office of Device Evaluation
Orthopaedics Branch
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: (b) (4) [redacted]

Dear Dr. Sung:

(b) (4) [redacted]

3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix A

Premarket Notification Clearance Letter

K022403

GMRS Press Fit Stems with PureFix® HA

5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

RECEIVED
OCT 21 2002
REGULATORY AFFAIRS

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401

Re: K022403
Trade/Device Name: GMRS Press Fit Stems with PureFix® HA
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint/metal/ceramic/polymer/semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Codes: LZO
Dated: July 22, 2002
Received: July 23, 2002

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

6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

Mark N Melkerson

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

510(k) Number (if known): K022403

Device Name: GMRS Press Fit Stems with PureFix® HA

Intended Use

The Global Modular Replacement System (referred to from this point on as the GMRS) Press Fit Stems with PureFix® HA Coating are intended to be used with components of the proximal femoral segment of the Howmedica Modular Replacement System in total hip arthroplasty. These devices are intended for use in total hip arthroplasty indicated as a result of extensive proximal femoral bone loss (from trauma, failed previous arthroplasty, or tumor resection). Adequate bone stock must be present to allow the use of the GMRS Press Fit Stems with PureFix® HA Coating.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K022403

8

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Appendix B

Appendix B-1 - 510(k) Summary

Appendix B-2 - Indications for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Appendix B-1

510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

510(k) Summary
K023087
Global Modular Replacement System

Submission Information

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

- 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix B-2

Indications for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

510(k) Number (if known): K023087

Device Name: Global Modular Replacement System (GMRS)

Intended Use

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

16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix C

Amendment to Technical Report (b) (4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Technical Testing

(b)(4) Technical Testing

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BLL 4203

Catalog No. **6495-5-011**

BLL4203
ID# : SAMPLE
CAT : 6495-5-011
Expire : 2007-12
FMT : GMRS4
CASE : TEST
W/O : 123456
REL : 123
0090-9-590
10:19:16 AM
12-11-2002
Dose Family : E

GLOBAL MRS
Straight Fluted Press-Fit Stem

- Diameter -11mm
- Length -125mm
- Not for use with +16mm V40™ Head
- 100 lbs. (45.4 Kg) maximum weight patient

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

Made in USA

+H825649550110I
+$$8011207TESTI+

2007-12

Ti
CPTi
$Ca_5(PO_4)_3(OH)$

STERILE R

CE0050

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

I.D.#
SN
SAMPLE

HOW / OST
No.: **6495-5-011**
GLOBAL MRS Straight Fluted Press-Fit Stem

CASE CODE: TEST
ID#: **SAMPLE**

I.D.#
SN
SAMPLE

Catalog No.
REF
6495-5-011

Case Code
LOT
TEST

RECORD / REORDER
HOW / OST # **6495-5-011**
GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#:
SAMPLE

RECORD / REORDER
HOW / OST # **6495-5-011**
GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#:
SAMPLE

RECORD / REORDER
HOW / OST # **6495-5-011**
GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#:
SAMPLE

REC ORDER
HOW / OST # **6495-5-011**
GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#:
SAMPLE

RECORD / REORDER
HOW / OST # **6495-5-011**
GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#:
SAMPLE

GLOBAL MRS

REF **6495-5-011**

Tige Press-Fit cannelée droite
· Diamètre -11mm· Longueur -125mm· Ne pas utiliser avec une tête V40™ +16mm · Poids maximum du patient: 45,4 kg

Gerader kannelieter Press-Fit-Schaft
· Durchmesser -11mm· Länge -125mm· Nicht zur Verwendung mit dem +16mm-V40™-Kopf · Maximales Patientengewicht 100 lbs. (45,4 kg)

Stelo scanalato diritto a pressione
· Diametro -11mm· Lunghezza -125mm· Non utilizzare con teste V40™ di misura +16mm · Paziente di peso massimo 45,4 kg. (100 libbre)

Vástago recto estriado, moldeado a presión
· Diámetro -11mm· Longitud -125mm· No utilizar con cabeza V40™ +16mm · Paciente de 100 lbs. (45,4 kg) de peso máximo

Rechte gegroefde press-fit steel
· Diameter -11mm· Lengte -125mm· Niet gebruiken met +16mm V40™-kopje · maximaal gewicht patiënt 45,4 kg. (100 lbs.)

Rak, räfflad pressanpassad stam
· Diameter -11mm· Lång -125mm· Får ej användas med +16mm V40™ huvud · Maxvikt för patient 45,4 kg.

21

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 1 6 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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K023087

page 2 of 2

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

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

K023087

stryker
Howmedica
OSTEONICS

59 Route 17
Allendale, NJ 07401-1677
Phone: (201) 825-4900
Fax: (201) 934-4369

September 16, 2002

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

RECEIVED
SEP 17 4 15 PM '02
FDA/CDRH/ODE/DMC

Attention: Division of General, Restorative and Neurological Devices

Re: 510(k) Premarket Notification
Global Modular Replacement System (GMRS)

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended. and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this 510(k) Premarket Notification is being submitted prior to the date when Howmedica Osteonics Corp. proposes to introduce into interstate commerce, for commercial distribution, the Global Modular Replacement System (GMRS).

The information submitted herein is in support of substantial equivalence of the Global Modular Replacement System. This data is organized in accordance with the following FDA DRAFT guideline: "Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices, The Basic Elements, April 9, 1993".

To provide FDA with knowledge of the material composition, manufacturing methods and relevant testing methods utilized to ensure that the safety and quality standards of this device are in keeping with Quality System Requirements, specific data relevant to these issues are presented in the body of the 510(k) and the related Appendices. Please note, specific pages are confidential and are so marked.

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

OR II

SK22 41

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Indications for Use Form for the Global Modular Replacement System is included in Appendix F, the Truthful and Accurate Statement is included in Appendix G, and the 510(k) Summary follows the Table of Contents.

We understand that the submission to the government of false information is prohibited by Title 18 of the United States Code (USC), Part 1001 and Title 21 of the USC, Part 331 (q).

To the best of my knowledge, the data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

Although the Global Modular Replacement System is substantially equivalent to the predicate devices within the meaning of Section 513(i)(1)(A) of the Federal Food, Drug and Cosmetic Act, nothing in this submission in any way reflects upon the completely unrelated federal patent law "doctrine of equivalents".

If there are any questions or if further information is needed please contact Ms. Margaret F. Crowe at (201)831-5580.

Sincerely,
Howmedica Osteonics Corp.

William J. Cymbaluk
Vice President, Quality Assurance/Regulatory Affairs/Clinical Research

Enclosures: 510(k) Premarket Notification Application (One Volume Submitted in Duplicate)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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HOWMEDICA OSTEONICS CORP.
59 Route 17
Allendale, New Jersey 07401

510(k) Premarket Notification

GLOBAL MODULAR REPLACEMENT SYSTEM

(GMRS)

September 16, 2002

43

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) – Premarket Notification

Global Modular Replacement System
Table of Contents

510(k) Summary 2

SECTION I
ADMINISTRATIVE INFORMATION 6
Name and Address of Sponsor 7
Name and Address of Manufacturer 7
Establishment Registration Number 7
Contact Person 7

SECTION II
DEVICE IDENTIFICATION 8
Proprietary Name 9
Common Name 9
Classification Name and Reference 9
Proposed Regulatory Class 9
Device Product Code 9

SECTION III
DEVICE DESCRIPTIVE INFORMATION 10
Intended Use 11
Indications 12
Contraindications 12
Device Description 13
Testing 26
Material 30
Clinical Data 31
Sterility 31
Packaging 32
Labeling 34
Basis of Equivalence 34

APPENDICES 38
Appendix A Drawing, Catalog Numbers, Schematics, Chart 39
Appendix B Testing 44
Appendix C Testing 50
Appendix D Labeling 57
Appendix E Equivalent Product Information 60
Appendix F Indications for Use 66
Appendix G Truthful and Accurate Statement 67

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

Submission Information

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 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.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- 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

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- 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I

ADMINISTRATIVE INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sponsor
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401
Registration Number: 2243265

Manufacturing Location
Design controls for the GMRS will reside in our Limerick, Ireland facility. The following locations may be involved in the manufacture of the components:

Howmedica International
Raheen Industrial Estate
Limerick, Ireland
Registration No.: 80100106B

Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401
Establishment Registration Number: 2243265

Howmedica Osteonics Corp.
300 Commerce Court
Mahwah, New Jersey 07430
Establishment Registration Number: 2249697

Stryker Ireland, LTD. Osteonics
Carrigtwohill Industrial Estate
Carrigtwohill, County Cork, Ireland
Establishment Registration Number: 9616680

Distributor
Howmedica Osteonics Corp.
300 Commerce Court
Mahwah, New Jersey 07430
Establishment Registration No.: 2249697

Official Contact Person
Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401
Telephone: 201-831-5580
Facsimile: 201-831-6454

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION II

DEVICE IDENTIFICATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

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

Purpose of the Submission

Introduction of a new device into commercial distribution.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION III

DEVICE DESCRIPTIVE INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Introduction

The Howmedica Osteonics Modular Replacement System (MRS – found substantially equivalent in K952970, K965164 and K972041) has been successfully used in clinical situations where there is extensive bone loss due to tumor resection, 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. The Distal Femoral and Proximal Tibial components of the MRS system may be used with components of the Kinematic® Rotating Hinge (KRH) Knee and the Modular Rotating Hinge (MRH) Knee Systems.

Howmedica Osteonics Corp. seeks regulatory clearance for a second-generation modular replacement system – the Global Modular Replacement System (GMRS). These components may be used with components of the Modular Rotating Hinge Knee System (MRH), Kinematic® Rotating Hinge (KRH) Knee System, the Duracon® Total Knee system, and the original MRS System. The Global Modular Replacement System (GMRS) consists of three modules:

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

A full discussion follows.

Intended Use

The Global Modular Replacement System (herein referred to as the GMRS) is intended to be used with the components of the Modular Replacement System (MRS - previously cleared in premarket notifications K952970, K965164 and K972401) the Modular Rotating Hinge Knee System (MRH - previously cleared in premarket notification K994207 and K002552) and/or the Kinematic® Rotating Hinge Knee System (KRH-previously cleared in premarket notification K792089)) 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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 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.

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

55

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Proximal Femoral Module is intended to be used in a press fit or cemented application. The Distal Femoral/Proximal Tibial Module is 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 the Modular Rotating Hinge Knee, Kinematic® Rotating Hinge Knee, and 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, or combinations of these 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

Proximal Femoral Components

The GMRS Proximal Femoral Components are available in two styles: standard and trochanteric. These components are each available in one size. These components are fabricated from cast cobalt-chromium alloy which meets the requirements of ASTM standard F-75. The components have the following features:

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

The Standard and Trochanteric Proximal Femoral Components of the GMRS may be used with the GMRS Connection Pieces, Extension Pieces and the Press Fit Stems with PureFix™ HA Coating in proximal femoral replacement. These products may also be used with the MRS Body components, and modular stems in proximal femoral replacement.

A comparison to the Proximal Femoral Components of the MRS is presented below:

Component	Proximal Femoral Components GMRS (subject)	Proximal Femoral Components MRS (K952970 and K965164)
Feature		
Materials	Cast Cobalt Chromium Alloy (ASTM F-75)	Cast Cobalt Chromium Alloy (ASTM F-75)
Styles	Standard Trochanteric	Standard HNR
Sizes	One Size	One size
Dimensions	(b) (4) [redacted]	
Compatability	• GMRS Connection Pieces • GMRS Extension Pieces • GMRS Press Fit Stems with PureFix™ HA [pending 510(k)] • MRS Body Pieces • MRS Stems	• GMRS Connection Pieces • GMRS Extension Pieces • GMRS Press Fit Stems with PureFix™ HA [pending 510(k)] • MRS Body Pieces • MRS Stems

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Extension Pieces

The Extension Pieces of the Global Modular Replacement System are intended to be used with the Proximal Femoral components, Distal Femoral components and/or the Proximal Tibial component of the GMRS in situations where a longer replacement length is required. (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted]. The Extension Pieces of the GMRS are available in multiple lengths: 30, 40, 50, 60, 70, 80, 100, 120, 140, 160, 180, 200 and 220 mm. The 30mm Extension Pieces are fabricated from GADS (b) (4) [redacted] cobalt-chromium alloy which meets the requirements of ASTM standard F-1537. The 40mm Extension Pieces are fabricated from wrought cobalt-chromium alloy which meets the requirements of ASTM standard F-1537. (b) (4) [redacted] Extension Piece is fabricated from titanium alloy (Titanium-6 Aluminum-4 Vanadium) which meets the requirements of ASTM standard F-136, (b) (4) [redacted] cobalt-chromium alloy which meets the requirements of ASTM standard F-1537. (b) (4) [redacted] (b) (4) [redacted]

(b) (4) [redacted]

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A comparison of the Extension Pieces to the bodies of the MRS System is presented below.

Component	Extension Pieces of GMRS (subject)	Bodies of MRS (K952970; K965164 and K972401)
Feature		
Materials	Cobalt chromium Alloy (ASTM F-1537) Titanium Alloy (ASTM F-136) and cobalt-chromium alloy (ASTM F-799)	Titanium Alloy (ASTM F-136)
Sizes	26mm diameter	Femoral: 24 and 28mm diameter Tibia: 24mm diameter
Lengths	30, 40, 50, 60, 70, 80, 100, 120, 140, 160, 180, 200, 220mm	40, 50, 60, 70, 80, 100, 120, 140, 160, 180, 200, 220mm
Mating Components	• Proximal Femoral Components of GMRS • Distal Femoral Components of GMRS • Proximal Tibia Component of GMRS • GMRS Press Fit Stems with PureFix™ HA [pending 510(k)] • Distal Femoral/Proximal Tibial Segments of MRS • Proximal Femoral Segment of MRS • Stems of MRS • GMRS Connection pieces • MRS Total femoral bodies	• Proximal Femoral Components of GMRS • Distal Femoral Components of GMRS • Proximal Tibia Component of GMRS • GMRS Press Fit Stems with PureFix™ HA [pending 510(k)] • Distal Femoral/Proximal Tibial Segments of MRS • Proximal Femoral Segment of MRS • Stems of MRS • GMRS Connection pieces • MRS Total femoral bodies

59

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GMRS Press Fit Stems with PureFix™ HA

The GMRS Press Fit Stems with PureFix™ HA Coating are machined from titanium alloy (Titanium-6Aluminum-4Vanadium) which meets the requirements of ASTM standard F-136. The stems are coated with commercially pure titanium (CP titanium) plasma spray coating that conforms to ASTM standard F-1580. (b) (4) [redacted] stem is also coated with PureFix™ HA coating which meets ASTM standard F-1185.

(b) (4) [redacted]

The GMRS Press Fit Stems with PureFix™ HA Coating are available in four styles:

- Straight Stems: These stems are available in a 125mm length, and diameters from 11mm to 19mm in one millimeter increments. The seat diameter varies from 22 to 36mm, and the seat radius ranges from 8mm to 9.25mm.
- Straight Fluted Stems: These stems are also available in a 125mm length, and diameters from 11mm to 19mm in one millimeter increments. This stem design has four flutes that extend from the seat down 25mm of the length of the stem. These flutes are located 90 degrees apart on the body of the stem. The seat diameter varies from 22mm to 36mm, and the seat radius ranges from 8mm to 9.25mm.
- Curved Stem (150mm): These stems are available in a 150mm length, and diameters from 11mm to 19mm in one millimeter increments. (b) (4) [redacted]
- Curved Stem (200mm): These stems are available in a 200mm length, and diameters from 11mm to 19mm in one millimeter increments. (b) (4) [redacted]

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These GMRS Press Fit Stems with PureFix™ HA may be used with the Proximal Femoral Component and the Extension Pieces of the GMRS in press fit applications. These stems may be used when there is adequate bone stock present for press fit application.

A comparison to the cemented stems of the MRS and the distal femoral stems of the Restoration™ Modular Hip System (found substantially equivalent in K013106) is presented below:

Product	GMRS Press Fit Stems with PureFix™ HA (subject)	MRS Cemented Stems (K952970 and K965164)	Distal Femoral Stems of Restoration™ Modular Hip System (K013106)
Feature			
Material	• Titanium Alloy • CP Titanium Plasma Spray • Hydroxylapatite Coating	• Cobalt chromium Alloy	• Titanium Alloy • CP Titanium Plasma Spray • Hydroxylapatite Coating
Design	Multiple styles: Straight Fluted Curved	Multiple Styles: Straight Curved	Multiple styles: Straight Fluted Curved
Compatability	• Proximal Femoral Component of GMRS • Extension Pieces of GMRS • Proximal Femoral Component of MRS (in pending 510(k)	• Proximal Femoral of MRS and GMRS • Distal Femoral of MRS and GMRS • Proximal Tibia of MRS and GMRS	• Proximal Femoral Component of Restoration™ Modular Hip System

Distal Femoral/Proximal Tibial Module

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

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- Distal Femoral Components
- Extension Pieces (as described in the section above)
- Small bushings
- Small Axle
- Proximal Tibial Component
- Small Proximal Tibial Inserts
- Small Proximal Tibia Rotating Components

These components are described below:

Distal Femoral Component

The Distal Femoral Component is intended to be used in situations where there is extensive bone loss in the distal femur. This component is fabricated from cast cobalt-chromium alloy that conforms to ASTM standard F-75. The Distal Femoral component is available in two sizes: standard and small, and in right and left configurations. The standard component is available in a replacement length of 65mm. The small Distal Femoral Components are available in replacement lengths of 65mm, 75mm, 85mm, and 95mm. (b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

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A chart comparing the dimensions, materials, and mating components for the Distal Femoral Components follows:

Component	Distal Femoral Component of GMRS (subject)	Distal Femur of MRS (K952970 and K972041)
Feature		
Material	Cast Cobalt-Chromium Alloy ASTM F-75	Cast Cobalt-Chromium Alloy ASTM F-75
Sizes	Standard Small Left and Right Configurations	Standard Small Left and Right Configurations
Dimensions	Standard: A/P: 54mm M/L: 60mm Replacement Length: 65mm Proximal diameter: 26mm Small: A/P: 45mm M/L: 52mm Replacement Lengths: 65, 75, 85 and 95mm Proximal diameter: 26mm	Standard: A/P: 54mm M/L: 64mm Replacement Length: 65mm Proximal diameter: 28mm Small: A/P: 43mm M/L: 58mm Replacement Lengths: 65, 75, 85 and 95mm Proximal diameter: 24mm
Mating Components	Standard: Mates with MRH bumper, bushings, and axleand MRS stems and MRS/GMRS extension pieces Small: Mates with MRH bumper, and new axle and bushings and MRS stems and MRS/GMRS Extension Pieces Uses Duracon® patellar components	Standard: Mates with KRH bumper, bushings and axle and MRS stems and MRS/GMRS extension pieces Small: Mates with KRH bumper, small bushings and small axle and MRS stems and MRS/GMRS Extension Pieces Uses Kinematic® patellar components

Small Bushings

The Small Bushings of the GMRS are intended to be used with the small Distal Femoral components of the GMRS (described above). The Small Bushings are fabricated from ultra-high molecular weight polyethylene, which meets the requirements of ASTM standard F-648. The design of the Small Bushing of the GMRS is based on the design of

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the bushing of the Modular Rotating Hinge Knee System. The Small Bushing of the GMRS has been reduced in overall length due to the reduced M-L width of the small Distal Femoral Components of the GMRS. The dimensions of the Small Bushings of the GMRS are outlined below with a comparison to the dimensions of the MRH bushings.

Component	Small Bushing of GMRS (subject)	Bushing of MRH (K994207 and K002552)
Feature		
Material	UHMWPE ASTM F-648 Duration® Stabilized	UHMWPE ASTM F-648 Duration® Stabilized
Sizes	Small	Standard
Dimensions	Length: 16mm Internal Diameter: 10mm External Diameter: 16mm	Length: 20mm Internal Diameter: 10mm External Diameter: 16mm
Mating Components	Small Distal Femoral component of GMRS	Femoral Components of MRH System GMRS standard distal femur

It should be noted that the Kinematic® Rotating Hinge Knee System has a bushing available in a small size.

Small Axle

The Small Axle of the GMRS system is available in one size and is fabricated from wrought cobalt-chromium alloy that conforms to ASTM standard F- 1537. (b) (4) [redacted]

(b) (4) [redacted]

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Component	Small Axle of GMRS (subject)	Axle of MRH (b) (4) [redacted]
Feature		
Material	Wrought Cobalt-Chromium Alloy ASTM F-1537	Wrought Cobalt-Chromium Alloy ASTM F-1537
Sizes	Small	Standard
Dimensions	Length: 52mm Diameter: 10mm	Length: 60mm Diameter: 10mm
Mating Components	Small Distal Femoral component of GMRS	Femoral Components of MRH System GMRS standard distal femur

It should be noted that the Kinematic® Rotating Hinge Knee System has a small axle component.

Proximal Tibial Component

The Proximal Tibial Component of the GMRS is available in two sizes: standard and small and is fabricated from cast cobalt-chromium alloy that meets the requirements of ASTM standard F-75. (b) (4) [redacted]

(b) (4) [redacted]

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Component	Proximal Tibial component of GMRS (subject)	Proximal Tibia of MRS (K952970 and K972041)
Feature		
Material	Cast Cobalt-Chromium Alloy ASTM F-75	Cast Cobalt-Chromium Alloy ASTM F-75
Sizes	Standard Small	Standard
Dimensions	Standard: A/P: 42mm M/L: 67mm Replacement Length: 80mm With thinnest poly insert Distal diameter: 26mm Small: A/P: 41mm M/L: 52mm Replacement Length: 80mm with thinnest poly insert (b) (4) [redacted]	Standard: A/P: 43mm M/L: 64mm Replacement Length: 95mm With thinnest poly insert Distal diameter: 24mm Small: Not Available
Mating Components	Standard: Mates with MRH tibial sleeve, MRH S1/S2 tibial inserts, and MRH rotating tibial components Mates with MRS stems and MRS/GMRS Extension Pieces Small: Mates with MRH tibial sleeve, new Proximal Tibial Inserts, and Small Tibial Rotating Component	Standard: Mates with KRH tibial bearing and inserts Mates with MRS stems and MRS/GMRS Extension Pieces Small: Not available

Small Proximal Tibial Inserts

The Small Proximal Tibial Inserts of the GMRS are fabricated from ultra-high molecular weight polyethylene that meets the requirements of ASTM standard F-648. The inserts are available in varying thicknesses from 10mm to 24mm (the thickness call out

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represents the thickness of the tibial insert-tibial baseplate construct - the inserts vary in thicknesses from 6mm to 20mm). (b) (4) [redacted]

(b) (4) [redacted]

Component	Small Proximal Tibial Inserts of GMRS (subject)	Tibial Inserts of MRH (K994207 and K002552)
Feature		
Material	UHMWPE ASTM F-648 Duration® Stabilized	UHMWPE ASTM F-648 Duration® Stabilized
Sizes	Small	S1/S2
Dimensions	A/P: 41mm M/L: 52mm Thicknesses: 10-24mm	A/P: 41mm M/L: 65.4mm Thicknesses: 10-24mm
Mating Components	Small Proximal Tibial Component of GMRS	S1 and S2 Tibial Baseplate of MRH GMRS standard proximal tibia

Small Proximal Tibial Rotating Component

The Small Proximal Tibial Rotating Component of the GMRS is intended to link the Distal Femoral Component of the GMRS (small or standard) or the MRH femoral components, to the small Proximal Tibial Component and Small Proximal Tibial Inserts of the GMRS. (b) (4) [redacted]

(b) (4) [redacted]

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(b) (4) The Small Proximal Tibial Rotating Component is fabricated from forged cobalt-chromium alloy which meets the requirements of ASTM standard F-799.

Component	Small Proximal Tibial Rotating Component of GMRS (subject)	Tibial Rotating Component of MRH (K994207 and K002552)
Feature		
Material	Forged Cobalt-Chromium Alloy ASTM F-799	Forged Cobalt-Chromium Alloy ASTM F-799
Sizes	Small	XS/S/M L/XL
Dimensions	Anterior-posterior: 38mm Medial-lateral: 47mm	Anterior-posterior: 38mm Medial-lateral: 63.4mm
Mating Components	Small Proximal Tibial Component of GMRS	Tibial Components of MRH System GMRS standard proximal tibia

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)

The Connection Piece of the GMRS is described below:

Connection Piece

The GMRS Connection Pieces are available in left and right orientations and two lengths: 80mm and 90mm. The GMRS Connection Pieces are fabricated from titanium alloy

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(titanium-6 Aluminum- 4 Vanadium) which meets the requirements of ASTM standard F-136. (b) (4) [redacted]

(b) (4) [redacted]

Component	GMRS Connection Piece (subject)	Male-male Bodies of the MRS (952970)
Material	Titanium Alloy	Titanium Alloy
Design	Male Male Taper 26mm diameter 2 lengths (b) (4) [redacted] left and right versions	Male Male Taper 28mm diameter multiple lengths (b) (4) [redacted] left and right versions
Mating Components	• GMRS Proximal Femoral Component • GMRS Distal Femoral Component • GMRS Extension Pieces • MRS Distal Femur • MRS Proximal Femur • MRS Femoral Bodies	• MRS Proximal Femoral Component • MRS Distal Femoral Component • MRS Extension Pieces • GMRS Distal Femoral Component (subject) • GMRS Proximal Femoral Component (subject device) • GMRS Extension Pieces (subject device)

Engineering drawings for the various components are included in Appendix A. Catalog numbers are also included in Appendix A. Schematics that depict the various configurations of the Proximal Femoral, Distal Femoral/Proximal Tibial and Total Femur Modules of the GMRS are included in Appendix A.

Testing

Proximal Femoral Module Testing

Finite element analyses were used to evaluate the strength of the neck region of the GMRS Standard and Trochanteric Proximal Femoral Components. (b) (4) [redacted]

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(b)(4) Testing

[redacted]

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(b)(4) Testing

[redacted]

Distal Femoral Module Testing

(b)(4) Testing [redacted]

(b)(4) Testing [redacted]

Testing was presented in premarket notification K994207 to characterize the contact characteristics and constraint characteristics of the patellofemoral articulation. (b)(4) Testing [redacted]

(b)(4) Testing

[redacted]

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(b)(4) Testing

[redacted]

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(b)(4) Testing

[redacted]

Materials

A chart that details component, material and corresponding ASTM standard follows:

Component	Material	ASTM Standard
Proximal Femoral Component	Cast Cobalt-Chromium Alloy	F-75
Extension Pieces	Wrought or Forged cobalt chromium Alloy Titanium Alloy and cobalt-chromium alloy	F-1537 F-136 and F-1537
Press Fit Stems with PureFix® HA Coating	Titanium Alloy CP Titanium Plasma Spray Hydroxylapatite Coating	F-136 F-1580 F-1185
Distal Femoral (Standard and Small)	Cast Cobalt-Chromium Alloy	F-75
Small Bushings	Ultra-high Molecular Weight Polyethylene	F-648
Small Axle	Wrought Cobalt-Chromium Alloy	F-1537
Proximal Tibial component (standard and small)	Cast Cobalt-Chromium Alloy	F-75

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Small Proximal Tibial Inserts	Ultra-high Molecular Weight Polyethylene	F-648
Small Proximal Tibial Rotating Component	Forged Cobalt-Chromium Alloy	F-799
Connection Pieces	Titanium Alloy	F-136

Clinical Data

The subject components of the GMRS do not employ any new materials, new intended uses, or substantially different design features. Therefore, this product does not raise any new safety or effectiveness issues and do not require clinical data in order to demonstrate their substantial equivalence to the cited predicate devices.

Sterility Information

The components of the GMRS are single use devices that are sold sterile.

Sterility and packaging information are for metallic components is listed below:

Method of Sterilization: This device is terminally sterilized by exposure to a minimum of 25 kiloGrays (2.5 megarads) of gamma radiation from a Cobalt-60 source.

(b) (4) [redacted]

Lot Release: (b) (4) [redacted]
(b) (4) [redacted]
[redacted] Upon review and acceptance of all applicable criteria, each lot of devices is released for distribution.

Validation: The sterilization dose is validated in accordance with EN 552. Method and study parameters are chosen to assure that the sterilization dose provides a minimum

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Sterility Assurance Level of 10^{-6}. Further aspects of sterilization, validation, e.g. product loading pattern and dose mapping, are also performed in conformance with EN 552.

Pyrogenicity Testing: (b) (4) [redacted]

Packaging Information: The packaging is a double blister type utilizing lids that are heat sealed to rigid co-polymer blisters or pouches. These sealed blisters or pouches are placed in individual cartons, and the entire package is then shrink-wrapped.

Sterility and packaging information for the ultra-high molecular weight polyethylene components is listed below:

(b) (4) [redacted]

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(b) (4)

[redacted]

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Labeling

Sample package labels and draft package insert for the subject device are included in Appendix D.

Basis of Equivalence

The Global Modular Replacement System is substantially equivalent to other legally marketed devices. Examples of these devices are listed below, and a discussion of the equivalent features follows. Additional information regarding these components may be found in Appendix E.

1. Modular Replacement System -Howmedica Osteonics Corp. (K952970, K965164 and K972401)
2. Distal Stems of the Restoration™ Hip System - Howmedica Osteonics Corp. (K013106)
3. Modular Rotating Hinge Knee System - Howmedica Osteonics Corp. (K994207 and K002552)
4. Kinematic® Rotating Hinge Knee System - Howmedica Osteonics Corp. (K792089 and K972863)
5. MOST System - Sulzer Orthopaedics (K964350, K973087, K013031)

Intended Uses:

The intended use of the GMRS (subject device) is the same as the intended use of the MRS (K952970, K965164 and K972401) and the MOST System (K964350, K973087, K013031): replacement of extensive bone loss in the proximal and/or distal femur and proximal tibia as a result of tumor, failed previous prosthesis or trauma. In cases of extensive femoral bone loss replacement of the total femur is possible. The Proximal Femoral Components of all of the named systems may be used in a cemented or press fit mode. The Distal Femoral/Proximal Tibial Components are intended to be used with bone cement.

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Materials:

Similar materials are used in the fabrication of all of the above-named systems: cast or wrought cobalt-chromium alloy, titanium alloy and ultra-high molecular weight polyethylene. These materials have a long history of usage in orthopaedic applications.

The GMRS Press Fit Stems with PureFix™ HA incorporate CP titanium plasma spray coating and hydroxylapatite coating. These coatings are also used with the Distal Femoral Stems of the Restoration™ Modular Hip System.

The UHMWPE components of the subject system, the MRS, MRH and KRH systems are all available in Duration® style UHMWPE.

Design:

In general, the design features of the GMRS are equivalent to the design features of the MRS and MRH Systems. Tabular presentations of similarities among components have been presented in the Device Description section of this premarket notification.

In general, the design features of the subject GMRS are also equivalent to the design features of the MOST system: both consist of Proximal and Distal Femoral and Proximal Tibial Components, and Connection Pieces that connect the components. The MOST system, as well as the GMRS, features a rotating hinge knee for distal femoral/proximal tibial replacement. Both systems have the ability to allow for replacement of a total femur if indicated. (b) (4) [redacted]

Summary:

Based upon the similarities presented above, along with the testing included in Appendices B and C, the substantial equivalence of the Global Modular Replacement System to other legally marketed, Class II, segmental replacement systems is demonstrated. A chart outlining the similarities of the components of the GMRS to other legally marketed devices has been included in the Device Description section of this

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premarket notification. An overall tabular presentation addressing intended use, design, and materials follows on the next page. The 510(k) Summary follows the Table of Contents. The Indications for Use page is included in Appendix F. The Truthful and Accurate Statement is included in Appendix G.

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Equivalent System Features

Component	GMRS (subject)	MRS (K952970, K965164 and K972401)	MRH (K994207 and K002552)	MOST System (K964350, K973087, K013031)
Feature				
Intended Use:	Replacement of Proximal Femur, Distal Femur, Proximal Tibia and Total Femur in situations where radical bone loss/resection is required.	Replacement of Proximal Femur, Distal Femur, Proximal Tibia and Total Femur in situations where radical bone loss/resection is required	Replacement of Distal Femur, and Proximal Tibia in situations where radical bone loss/resection is required	Replacement of Proximal Femur, Distal Femur, Proximal Tibia and Total Femur in situations where radical bone loss/resection is required
Materials	Cobalt Chromium Alloy Titanium Alloy Ultra high molecular weight polyethylene	Cobalt Chromium Alloy Titanium Alloy Ultra high molecular weight polyethylene	Cobalt Chromium Alloy Ultra high molecular weight polyethylene	Cobalt Chromium Alloy Titanium Alloy Ultra high molecular weight polyethylene
Design	[redacted] (b) (4)			

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80

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Appendices

Appendix A: Engineering Drawings, Catalog Number Designations, Schematics and Compatability Chart

Appendix B: Testing

Appendix C: Testing

Appendix D: Package Labels, Package Insert

Appendix E: Equivalent Product Information

Appendix F: Indications for Use

Appendix G: Truthful and Accurate Statement

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Appendix A

Appendix A-1: Engineering Drawings

Appendix A-2: Catalog Number Designations

Appendix A-3: Schematics of Subject Device

Appendix A-4: Compatability Chart

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Appendix A-1

Engineering Drawings

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GMRS PROXIMAL FEMUR

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84

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(b)(4) Design

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GMRS EXTENSION PIECES

ENGINEERING DRAWINGS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Design

(b)(4) Design

(b)(4) Design

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GMRS PRESS FIT STEMS WITH PUREFIX® HA

ENGINEERING DRAWINGS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Design

(b)(4) Design

(b)(4) Design

(b)(4) Design

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GMRS DISTAL FEMORAL COMPONENT

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(b)(4) Design

(b)(4) Design

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GMRS SMALL BUSHING

ENGINEERING DRAWING

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Design

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GMRS SMALL AXLE

ENGINEERING DRAWING

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(b)(4) Design

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GMRS PROXIMAL TIBIA COMPONENT

ENGINEERING DRAWINGS

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(b)(4) Design

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GMRS SMALL TIBIAL INSERT

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GMRS SMALL TIBIAL ROTATING COMPONENT

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GMRS CONNECTION PIECES

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(b)(4) Design

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Appendix A-2

Catalog Number Designations

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Catalog Number Designations

Global Modular Replacement System

Proximal Femoral Components Standard and Trochanteric Styles	
Catalog Number	**Description**
6495-1-001	Proximal Femoral Component Standard Style
6495-1-002	Proximal Femoral Component Trochanteric Style

Extension Pieces	
Catalog Number	**Description**
6495-6-030	Extension Piece 30mm
6495-6-040	Extension Piece 40mm
6495-6-050	Extension Piece 50mm
6495-6-060	Extension Piece 60mm
6495-6-070	Extension Piece 70mm
6495-6-080	Extension Piece 80mm
6495-6-100	Extension Piece 100mm
6495-6-120	Extension Piece 120mm
6495-6-140	Extension Piece 1400mm
6495-6-160	Extension Piece 160mm
6495-6-180	Extension Piece 180mm
6495-6-200	Extension Piece 200mm
6495-6-220	Extension Piece 220mm

GMRS Press Fit Stems - Straight	
Diameter x Length	**Catalog Number**
11mm x 150mm	6495-5-311
12mm x 150mm	6495-5-312
13mm x 150mm	6495-5-313
14mm x 150mm	6495-5-314
15mm x 150mm	6495-5-315
16mm x 150mm	6495-5-316
17mm x 150mm	6495-5-317
18mm x 150mm	6495-5-318
19mm x 150mm	6495-5-319

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GMRS Press Fit Stems - Fluted	
Diameter x Length	**Catalog Number**
11mm x 150mm	6495-5-011
12mm x 150mm	6495-5-012
13mm x 150mm	6495-5-013
14mm x 150mm	6495-5-014
15mm x 150mm	6495-5-015
16mm x 150mm	6495-5-016
17mm x 150mm	6495-5-017
18mm x 150mm	6495-5-018
19mm x 150mm	6495-5-019

GMRS Press Fit Stems - Curved 150mm Long	
Diameter x Length	**Catalog Number**
11mm x 150mm	6495-5-211
12mm x 150mm	6495-5-212
13mm x 150mm	6495-5-213
14mm x 150mm	6495-5-214
15mm x 150mm	6495-5-215
16mm x 150mm	6495-5-216
17mm x 150mm	6495-5-217
18mm x 150mm	6495-5-218
19mm x 150mm	6495-5-219

GMRS Press Fit Stems - Curved 200mm Long	
Diameter x Length	**Catalog Number**
11mm x 150mm	6495-5-111
12mm x 150mm	6495-5-112
13mm x 150mm	6495-5-113
14mm x 150mm	6495-5-114
15mm x 150mm	6495-5-115
16mm x 150mm	6495-5-116
17mm x 150mm	6495-5-117
18mm x 150mm	6495-5-118
19mm x 150mm	6495-5-119

115

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Distal Femoral Component GMRS	
Catalog Number	**Description**
6495-2-010	Distal Femoral Component Small Left 65mm Replacement
6495-2-011	Distal Femoral Component Small Left 75mm Replacement
6495-2-012	Distal Femoral Component Small Left 85mm Replacement
6495-2-013	Distal Femoral Component Small Left 95mm Replacement
6495-2-020	Distal Femoral Component Small Right 65mm Replacement
6495-2-021	Distal Femoral Component Small Right 75mm Replacement
6495-2-022	Distal Femoral Component Small Right 85mm Replacement
6495-2-023	Distal Femoral Component Small Right 95mm Replacement
6495-2-030	Distal Femoral Component Standard Left 65mm Replacement
6495-2-040	Distal Femoral Component Standard Right 65mm Component

GMRS Bushing - Small Femur	
Catalog Number	**Description**
6496-2-105	Bushing for Small Distal Femur

GMRS Axle for Small Distal Femur	
Catalog Number	**Description**
6496-2-115	Axle for Small Distal Femur

Proximal Tibial Component	
Catalog Number	**Description**
6495-3-101	Proximal Tibial Component Small 80mm Replacement Length
6495-3-102	Proximal Tibial Component Standard 80mm Replacement Length

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Inserts for Proximal Tibia	
Catalog Number	**Description**
6495-3-010	Insert for Small Proximal Tibia 10mm thickness
6495-3-013	Insert for Small Proximal Tibia 13mm thickness
6495-3-016	Insert for Small Proximal Tibia 16mm thickness
6495-3-020	Insert for Small Proximal Tibia 20mm thickness
6495-3-024	Insert for Small Proximal Tibia 24mm thickness

Tibial Rotating Component for Small Proximal Tibia	
Catalog Number	**Description**
6495-3-601	Tibial Rotating Component for Small Proximal Tibial Component

Connection Pieces	
Catalog Number	**Description**
6495-6-008	Left Connection Piece - 80mm
6495-6-009	Left Connection Piece - 90mm
6495-6-018	Right Connection Piece - 80mm
6495-6-019	Right Connection Piece - 90mm

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Appendix A-3

Schematic of the Components of the GMRS

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Appendix A-4:

Compatability Chart

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GMRS/MRS Compatibility Chart

120

	Application	GMRS Proximal Femur 6495-1-001/002	GMRS Connection Pieces 6495-6-008/019	GMRS Extension Pieces 6495-6-030/220	GMRS Small Distal Femur 6495-2-010/023	GMRS Standard Distal Femur 6495-2-030/040	GMRS Press-fit Stem 6496-5-011/319	GMRS Proximal Tibia 6495-3-101/102	MRS Proximal Femur 6485-0-000/001/006	MRS Total Femoral Bodies 6485-1/2-080/300	MRS Standard Femoral Bodies 6485-0-041/221	MRS Small Femoral Bodies 6485-0-039/139	MRS Standard Distal Femur 6485-0-010/020	MRS Small Distal Femur 6485-0-005/075	MRS Cemented Femoral Stems 6485-3-000/817	MRS Proximal Tibia 6485-6-000	MRS Tibial Bodies 6485-6-340/360	MRS Cemented Tibial Stems 6485-6-409/513	MRS Cemented Femoral Stems W/ Female Taper (Intercalary) 6485-3-211/217
GMRS Proximal Femur 6495-1-001/002	PF, TF		■	■			■			■	■	■			■		■	■	
GMRS Connection Pieces 6495-6-008/019	TF	■		■	■	■			■		■	■	■	■					■
GMRS Extension Pieces 6495-6-030/220	PF, DF, TF, PT, IN	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
GMRS Small Distal Femur 6495-2-010/023	DF, TF		■	■				*		■	■	■			■	*			
GMRS Standard Distal Femur 6495-2-030/040	DF, TF		■	■				*		■	■	■			■	*			
GMRS Press-fit Stem 6496-5-011/319	PF	■		■					■		■	■							
GMRS Proximal Tibia 6495-3-101/102	PT			■	*	*							*	*			■	■	
MRS Proximal Femur 6485-0-000/001/006	PF, TF		■	■			■			■	■	■			■				
MRS Total Femoral Bodies 6485-1/2-080/300	TF	■		■	■	■			■		■	■	■	■					■
MRS Standard Femoral Bodies 6485-0-041/221	PF, DF, TF, IN	■	■	■	■	■	■		■	■	■	■	■	■	■				■
MRS Small Femoral Bodies 6485-0-039/139	PF, DF, TF, IN	■	■	■	■	■	■		■	■	■	■	■	■	■				■
MRS Standard Distal Femur 6485-0-010/020	DF, TF		■	■				*		■	■	■			■	*			
MRS Small Distal Femur 6485-0-005/075	DF, TF		■	■				*		■	■	■			■	*			
MRS Cemented Femoral Stems 6485-3-000/817	PF, DF, IN	■		■	■	■			■		■	■	■	■					■
MRS Proximal Tibia 6485-6-000	PT			■	*	*							*	*			■	■	
MRS Tibial Bodies 6485-6-340/360	PT	■		■				■								■	■	■	■
MRS Cemented Tibial Stems 6485-6-409/513	PT	■		■				■								■	■		■
MRS Cemented Femoral Stems W/ Female Taper (Intercalary) 6485-3-211/217	IN		■	■						■	■	■			■		■	■	

	GMRS subject of this submission
	Modular Replacement System (MRS) found substantially equivalent in K952970, K965164 and K972041
*	Reference Tibial Rotating Component Compatibility Chart
■	Indicates product above is compatible with product to the left

Application Definitions	
PF	Proximal Femoral Replacement
TF	Total Femoral Replacement
DF	Distal Femoral Replacement
PT	Proximal Tibial Replacement
IN	Femoral Intercalary Replacement

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Tibial Rotating Component Compatibility Chart

				TIBIA					
				KRH All Poly Tibia 6485-2-008/421	KRH Small Metal Encapsulated Tibial Baseplate 6485-7-005/020 or MRS Proximal Tibial Replacement 6485-6-000 Inserts 6485-4-111/121	MRH S1/S2 Tibial Baseplate 6481-3-110/111 or GMRS Standard Proximal Tibial Replacement 6495-3-102 Inserts 6481-3-210/224	Tibial Sleeve 6481-2-140	GMRS Small Proximal Tibial Replacement 6495-3-101 Inserts 6495-3-010/024	Tibial Sleeve 6481-2-140
FEMUR	GMRS Small Distal Femur 6495-2-010/020	Bushings	6495-2-105	6481-2-103	6481-2-104	6481-2-100		6495-3-601	
		Axle	6495-2-115						
		Bumper	6481-2-130/133						
	MRH Femoral Component 6481-1-100/141or	Bushings	6481-2-110						
		Axle	6481-2-120						
	GMRS Standard Distal Femur 6495-2-030/040	Bumper	6481-2-130/133						
	MRS Small Distal Femur 6485-0-005/075	Bushings	6485-2-465	6475-3-933	6485-8-435	6481-2-108		N/A	
		Axle	6485-8-460						
		Bumper	6485-4-100/200						
	KRH Femoral component 6475-3-931/932 or	Bushings	6485-2-460						
		Axle	6475-3-940						
	MRS Standard Distal Femur 6485-0-010/020	Bumper	6485-4-100/200						

	GMRS subject of this submission
	Modular Replacement System (MRS) found substantially equivalent in K952970, K965164 and K972041
	Kinematic Rotating Hinge (KRH) cleared in premarket notification K792089 and K972863
	Modular Rotating Hinge (MRH) Knee cleared in premarket notification K994207
	Crossover Tibial Bearing Components cleared in premarket notification K001548 and K002552

121

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Appendix B

Testing

Appendix B-1: MT01334
Strength Evaluation of GMRS Standard & Humped Proximal Femoral Components

Appendix B-2: RD-02-029
MRS 30mm Extension Piece - Fatigue Strength Evaluation via Finite Element Analysis

Appendix B-3: MT02160
GMRS Extension Piece Testing

Appendix B-4: Report Number RD-02-017
Modular Replacement System - Fatigue Strength Evaluation of Press-fit Stem Design Variations

Appendix B-5: Report No. MT01016
Characterization of Purefix™ HA/Titanium Plasma Sprayed Coating

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Appendix B-1: MT01334

Strength Evaluation of GMRS Standard & Humped Proximal Femoral Components

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(b)(4) Testing

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Appendix B-2: RD-02-029

MRS 30mm Extension Piece - Fatigue Strength Evaluation via Finite Element Analysis

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Technical Report

Advanced Technology/Technical Services Device Evaluation

MRS 30mm Extension Piece - Fatigue Strength Evaluation via Finite Element Analysis

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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Appendix B-3: MT02160

GMRS Extension Piece Testing

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135

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(b)(4) Testing

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(b)(4) Testing

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Appendix B-4: Report Number RD-02-017

Modular Replacement System - Fatigue Strength Evaluation of Press-fit Stem Design Variations

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Technical Report

Advanced Technology/Technical Services Device Evaluation

MT02057: Modular Replacement System – Fatigue Strength Evaluation of Press-fit Stem Design Variations

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

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(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

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Appendix B-5: Report No. MT01016

Characterization of Purefix™ HA/Titanium Plasma Sprayed Coating

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Technical Report

Advanced Technology/Technical Services

Characterization of Purefix® HA/Titanium Plasma Sprayed Coating

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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APPENDIX I
TENSION TEST

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Advanced Technology Medical Devices Section

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APPENDIX II

SHEAR TEST

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APPENDIX III

Four Point Bend Fatigue

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APPENDIX IV

ABRASION TEST

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Appendix C

Testing

Appendix C-1: Report Number MT99146, MT99240
Testing of the Modular Rotating Hinge Knee

Appendix C-2: Mt00153
Technical Memo

Appendix C-3: Report Number RD-02-008
MRS Rotating Hinge Knee Bushing Contact Analyses: A Finite Element Analysis Study

Appendix C-4: Report Number RD-02007
GMRS Rotating Hinge Knee Small Bushing Contact Analyses: A Finite Element Analysis Study

Appendix C-5: Report Number MT02139
KRH vs. GMRS Axle Comparison

Appendix C-6: Report 02L/CASA003
Validation of SHO Limerick Double Layer Sintering

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Appendix C-1:

Report Number MT99146, MT99240

Testing of the Modular Rotating Hinge Knee

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Technical Report

Advanced Technology Technical Service
Device Evaluation

Testing of the Modular Rotating Hinge Knee

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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Appendix C-2:

Mt00153

Technical Memo

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Appendix C-3:

Report Number RD-02-008

MRS Rotating Hinge Knee Bushing Contact Analyses: A Finite Element Analysis Study

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Technical Report

Advanced Technology/Technical Services Device Evaluation

MRS Rotating Hinge Knee Bushing Contact Analyses: A Finite Element Analysis Study

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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Appendix C-4:

Report Number RD-02007

GMRS Rotating Hinge Knee Small Bushing Contact Analyses: A Finite Element Analysis Study

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Technical Report

Advanced Technology/Technical Services Device Evaluation

GMRS Rotating Hinge Knee Small Bushing Contact Analyses: A Finite Element Analysis Study

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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Appendix C-5:

Report Number MT02139

KRH vs. GMRS Axle Comparison

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Technical Report

Advanced Technology/Technical Services Device Evaluation

Comparison of GMRS and KRH Rotating Hinge Axle Strength

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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Appendix C-6:

Mechanical Test Report 02L/CASA003

Validation of SHO Limerick Double Layer Sintering

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Appendix VI

FM 1000 Adhesive

Mechanical test data sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

(b)(4) Testing

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Appendix D

Labeling

Appendix D-1: Draft Product Labels

Appendix D-2: Draft Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix D-1

Draft Package Labels

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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stryker
Howmedica
OSTEONICS

CE 0050

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

REF 6495-1-001 STERILE R Vitallium® LOT C1212 SAMPLE

Global MRS Proximal Femoral Component Standard	Spanish Text Spanish Text Spanish Text
French Text French Text French Text	Italian Text Italian Text Italian Text
German Text German Text German Text	Swedish Text Swedish Text Swedish Text

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-08 2 2006-08
Made in IRELAND

stryker
Howmedica
OSTEONICS

CE 0050

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

REF 6495-1-001 STERILE R Vitallium® LOT C1212 SAMPLE

Danish Text Danish Text Danish Text	Dutch Dutch Dutch
Portuguese Portuguese Portuguese	Greek Greek Greek
Finnish Finnish Finnish	Japanese Japanese Japanese

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-08 2 2006-08
Made in IRELAND

+E0256495100113

+$C1212SAMPLE36

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Howmedica
OSTEONICS
REF 6495-1-001

Global MRS Proximal Femoral Component Standard
French Text French Text French Text
German Text German Text German Text
LOT C1212 SAMPLE 2006-08

246

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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stryker
Howmedica
OSTEONICS

CE 0050

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

REF 6495-5-111 STERILE R Titanium LOT C1212 SAMPLE

Global MRS Long Bowed Press-Fit Stem Dia. 11mm x 200mm	Spanish Text Spanish Text Spanish Text
French Text French Text French Text	Italian Text Italian Text Italian Text
German Text German Text German Text	Swedish Text Swedish Text Swedish Text

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-08 2 2006-08
Made in IRELAND

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Howmedica
OSTEONICS

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Howmedica International S.de R.L.
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REF 6495-5-111 STERILE R Titanium LOT C1212 SAMPLE

Danish Text Danish Text Danish Text	Dutch Dutch Dutch
Portuguese Portuguese Portuguese	Greek Greek Greek
Finnish Finnish Finnish	Japanese Japanese Japanese

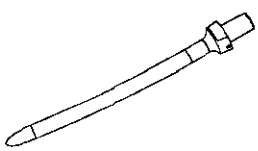
Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-08 2 2006-08
Made in IRELAND

+E0256495511119

+$C1212SAMPLE9C

stryker
Howmedica
OSTEONICS
REF 6495-5-111



Global MRS
Long Bowed Press-Fit Stem
Dia. 11mm x 200mm

French Text
French Text
French Text

German Text
German Text
German Text

LOT C1212 SAMPLE 2006-08

247

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Howmedica International S.de R.L.
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REF 6495 – 6 – 030 STERILE R Vitallium® LOT C1212 SAMPLE

Global MRS Extension Piece 30mm	Spanish Text Spanish Text Spanish Text
French Text French Text French Text	Italian Text Italian Text Italian Text
German Text German Text German Text	Swedish Text Swedish Text Swedish Text

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002 – 08 Made in IRELAND 2 2006 – 08

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OSTEONICS

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

REF 6495 – 6 – 030 STERILE R Vitallium® LOT C1212 SAMPLE

Danish Text Danish Text Danish Text	Dutch Dutch Dutch
Portuguese Portuguese Portuguese	Greek Greek Greek
Finnish Finnish Finnish	Japanese Japanese Japanese

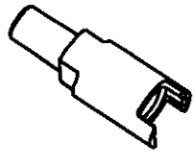
Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002 – 08 Made in IRELAND 2 2006 – 08

+E025649560301A

+$C1212SAMPLEAD

stryker
Howmedica
OSTEONICS
REF 6495 – 6 – 030



Global MRS
Extension Piece 30mm

French Text
French Text
French Text

German Text
German Text
German Text

LOT C1212 SAMPLE 2006 – 08

248

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

REF 6495-2-010 STERILE R Vitallium® LOT C1212 SAMPLE

GMRS Distal Femoral Component Small, Left, 65mm Replacement	Spanish Text Spanish Text Spanish Text
French Text French Text French Text	Italian Text Italian Text Italian Text
German Text German Text German Tex	Swedish Text Swedish Text Swedish Text

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

2002-04 2 2009-04

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

REF 6495-2-010 STERILE R Vitallium® LOT C1212 SAMPLE

Danish Text Danish Text Danish Text	Dutch Text Dutch Text Dutch Text
Portuguese Text Portuguese Text Portuguese Text	Greek Text Greek Text Greek Text
Finish Text Finish Text Finish Text	Japanese Text Japanese Text Japaneses Text

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-04 2 2009-04
Made in IRELAND

+E0256495201014

+$C1212SAMPLE47

249

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OSTEONICS

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

REF 6495-2-010 STERILE R Vitallium® LOT C1212 SAMPLE

Global MRS
Distal Femoral Component
Small Left, 65mm Replacement

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-04 2 2007-04
Made in IRELAND

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

REF 6495-2-010 STERILE R Vitallium® LOT C1212 SAMPLE

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2002-04 2 2007-04
Made in IRELAND

+E0256495201014

+$C1212SAMPLE47

250

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

REF 6495 – 2 – 105 STERILE R UHMWPE LOT C1212 SAMPLE

Global MRC
Bushing for Small Distal Femur

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002 – 04 2 2007 – 04
Made in IRELAND

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Howmedica International S.de R.L.
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REF 6495 – 2 – 105 STERILE R UHMWPE LOT C1212 SAMPLE

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

2002 – 04 2 2007 – 04
Made in IRELAND

+E0256495210519

+$C1212SAMPLE9C

251

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

REF 6495-2-115 STERILE R Vitallium® LOT C1212 SAMPLE

Global MRS
Axle for Small Distal Femur

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-04 Made in IRELAND 2 2007-04

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

REF 6495-2-115 STERILE R Vitallium® LOT C1212 SAMPLE

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-04 Made in IRELAND 2 2007-04

+E025649521151A

+$C1212SAMPLEAD

252

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OSTEONICS

CE 0050

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

REF 6495-3-101 STERILE R Vitallium® LOT C1212 SAMPLE

Global MRS Sml. Prox. Tibia,80mm
replacement if using 10mm Insert
Usec Small Prox. Tibial Inserts

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-04 2 2007-04
Made in IRELAND

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Howmedica International S.de R.L.
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REF 6495-3-101 STERILE R Vitallium® LOT C1212 SAMPLE

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2002-04 2 2007-04
Made in IRELAND

+E0256495310116

+$C1212SAMPLE69

253

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

REF 6495-3-102 STERILE R Vitallium® LOT C1212 SAMPLE

Global MRS Std. Prox. Tibia,80mm
replacement if using 10mm Insert
Uses MRH S1/S2 X-3ml/5ml Inserts

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-04 Made in IRELAND 2 2007-04

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

REF 6495-3-102 STERILE R Vitallium® LOT C1212 SAMPLE

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

2002-04 Made in IRELAND 2 2007-04

+E0256495310217

+$C1212SAMPLE7A

254

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

REF 6495-3-010 STERILE R UHMWPE LOT C1212 SAMPLE

Global MRS
Insert for Small Proximal Tibia
10mm Thickness

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-04 2 2007-04
Made in IRELAND

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

REF 6495-3-010 STERILE R UHMWPE LOT C1212 SAMPLE

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

2002-04 2 2007-04
Made in IRELAND

+E0256495301015

+$C1212SAMPLE58

255

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

REF 6495-3-601 STERILE R Vitallium® LOT C1212 SAMPLE

Global MRS
Tibial Rotating Component for
Small Proximal Tibial Component

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.

2002-04 (2) 2007-04
Made in IRELAND

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

REF 6495-3-601 STERILE R Vitallium® LOT C1212 SAMPLE

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

2002-04 (2) 2007-04
Made in IRELAND

+E025649536011B

+$C1212SAMPLEBE

256

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Appendix D-2

Draft Package Insert

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Howmedica
OSTEONICS

Modular Replacement Systems

Howmedica Osteonics Corp.
Raheen Business Park
Limerick, Ireland
A Subsidiary of Stryker Corp.

2002 Howmedica Osteonics Corp.
Printed in Ireland

XXXX-X-XXX

258

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ATTENTION OPERATING SURGEON

The advancement of modular replacement systems has provided the surgeon with a means to reconstruct large bone defects resulting from tumor resection, failed previous arthroplasty or trauma. These devices, while successful, are manufactured from 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 or bone. The modular replacement system, therefore, will not be as strong, reliable, or durable as a natural human joint or bone.

These procedures are technically demanding and the surgeon should have thorough knowledge and training regarding these devices and surgical procedure. (See **IMPORTANT PHYSICIAN INFORMATION** section for more information.)

In using modular replacement implants, the surgeon must be aware of the following:

A. The correct selection and positioning of the implant is extremely important. Success in segmental replacement requires the selection of the proper size, shape, and configuration of the implants. Segmental replacement prostheses require careful seating, rigid fixation and adequate bone support.

B. In selecting patients for segmental 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 product higher loads on the prostheses that can lead to accelerated 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 that includes significant impact loads (walking, running, lifting or twisting), the resultant forces can cause accelerated 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 replacements. 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) **Substance dependence.** 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.

259

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DESCRIPTION

The Modular Replacement Systems consist of articular sections, connection and extension pieces, and stem components. The system is assembled utilizing a male/female taper locking mechanism. Implant components are available for the Proximal, Distal, Mid-shaft and total Femur; Proximal Tibia and Knee fusions. Many of the components are available in a wide variety of sizes, lengths and geometries to satisfy anatomical requirements and surgeon needs.

Proximal Femur

The Proximal Femoral Replacement System consists of a proximal femoral component, extension pieces and stem components. The proximal femoral component is available in a variety of geometries, with and without porous coatings, with a taper to accept Howmedica Osteonics modular femoral heads with the corresponding taper, and a female taper, with an anti-rotation feature for mating with the extension pieces or stem components. (See **IMPORTANT PHYSICIAN INFORMATION** section for more information.) The proximal femoral component includes a suture attachment feature(s). A suture attachment feature and porous coating provide a means for reattachment of the greater trochanter and other soft tissue structures. The proximal femoral component is manufactured from cast cobalt-chromium-molybdenum alloy (Vitallium® Alloy) conforming to ASTM standard F75.

The extension pieces are available in various lengths and have a male/female taper for assembly with the proximal femoral component and stem components. There is an anti-rotation feature for mating with the component. The extension pieces are manufactured from materials certified to ASTM standards:

Material	ASTM Standard
Vitallium® Alloy	
Wrought	F1537
Gas Atomized Dispersion Strengthened (GADS)	F1537
Wrought Titanium Alloy (Ti 6Al-4V ELI)	F136

The stem components are available in multiple diameters and several lengths, straight or curved, to fit various patient anatomical requirements; with and without coatings. The stem components are available in two designs; one with a porous coated replacement length, and one without the replacement length. The porous coating can used for positioning bone graft for extra-cortical fixation. The stem component without the replacement length allows for shorter resections when mated with a proximal femoral component or distal condyle component. The stem components are manufactured from materials certified to ASTM standards:

Material	ASTM Standard
Vitallium® Alloy	
Cast*	F75
Forged	F799
Wrought	F1537
Gas Atomized Dispersion Strengthened (GADS)	F1537
Wrought Titanium Alloy (Ti 6Al-4V ELI)	F136
Forged Titanium Alloy (Ti 6Al-4V ELI)	F136

** Cast stem components are not available for sale within the US.*

260

The coatings incorporated on the stems and articular components consist of: sintered Vitallium® Alloy beads, Titanium plasma spray or Titanium plasma spray overlaid with a layer of hydroxylapatite. These materials are certified to ASTM Standards:

Material	ASTM Standard
Vitallium® Alloy Beads	F75
Titanium Commercially Pure (CP)	F1580
Hydroxylapatite	F1185

Distal Femurs

The Distal Femoral Replacement System consists of a condyle, extension pieces and stem components. The condylar section is available in various sizes, lengths and in left or right configurations and is compatible with the components of Howmedica Osteonics Rotating Hinge Knee Systems. The Distal Femoral Condyle section is manufactured from cast cobalt-chromium-molybdenum alloy (Vitallium® Alloy) conforming to ASTM standard F75.

The stem components and extension pieces are the same as those used with the proximal femur.

Total Femur

The Total Femoral Replacement System consists of a proximal femoral component, connection piece, extension piece and condyle. The proximal femoral component, extension piece and condyle are the same mentioned previously. The connection pieces are available in left or right configuration and various lengths. There is a male taper on each end that assembles with the proximal femoral component, extension piece or distal condyle section. There are anti-rotation features adjacent to the male tapers for positioning with the other components. The connection pieces are manufactured from Wrought Titanium 6Al-4V Alloy conforming to ASTM standard F136.

Intercalary System

The Intercalary System consists of intercalary stems, extension pieces and stem components. The intercalary stems are available in multiple diameters and several lengths, straight or curved, to fit various patient anatomical requirements; with and without coatings. The intercalary stems include a female taper for mating with the extension pieces and stem components previously mentioned. The intercalary stems are manufactured from the same materials previously listed for the stem components.

Proximal Tibia

The Proximal Tibial Replacement System consists of a proximal tibial replacement section, extension pieces and stem components. The proximal tibial replacement section resembles the anatomy of the proximal tibia and is available in various sizes and lengths. The proximal end flares to a flat surface, having a recess, to allow ultra-high-molecular-weight polyethylene (UHMWPE) inserts to snap-in intraoperativity. These inserts are available in several thicknesses. The proximal portion of the tibia section has suture holes surrounded by porous coating, to allow for tissue reattachment. The proximal replacement section is manufactured for cast cobalt-chromium-molybdenum alloy (Vitallium® Alloy) conforming to

ASTM standard F75. The polyethylene inserts are manufactured from UHMWPE conforming to ASTM standard F648.

The stem components and extension pieces are the same as those mentioned previously.

Label Information

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

INDICATIONS

The Modular Replacement System is intended for use in patients requiring extensive reconstruction of the hip joint and/or knee joint, including knee fusions, necessitated by extensive bone loss due to trauma, failed previous prosthesis and/or tumor resection.

CONTRAINDICTIONS

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:

1) Pathological fracture;

2) Overt infection;

3) Inopportune placement of biopsy incision; and,

4) Rapid disease progression beyond a respectable margin.

Each patient must therefore be individualized and carefully evaluated by appropriate staging techniques prior to consideration of segmental replacement.

B. As related to Failed Previous Prosthesis and Trauma:

1) Any active or suspected latent infection in or about the operative joint.
2) Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
3) Bone stock compromised by disease, infection, or prior implantation, which cannot provide adequate support and fixation of the prosthesis.
4) HA coated stems are contraindicated in situations where bone stock is inadequate to support press fit application.

262

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WARNINGS

Improper selection, placement, positioning or 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 that 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 minimize the risk of accelerated wear of the articular surfaces of the implant.

Press-fit Application. Secure fixation at the time of surgery is critical to the success of the procedure. The stem must be press-fit into the host bone, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture can occur during the seating of the prosthesis. Bone stock must be adequate to support the device.

Prosthetic components, Joint replacement 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.

Metal components. Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures of 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.

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 acetabular, tibial and patella components has been reported following total joint replacement. Higher rates of wear may be initiated by particles of cement, metal or other debris that 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.

Explantation. Removal of an unloosened porous coated, plasma sprayed or hydroxyapatite surface treated implant may require the use of special instruments to disrupt the interface at the implant surface.

PRECAUTIONS

263

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Information for patients. The patients 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 replacement have been implicated in failure of the reconstruction by loosening, fracture and/or accelerated 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.

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

The patient should be warned of the surgical risks, and made aware of possible adverse effects. The patient should be warned that the device cannot and will not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged, particularly as a result of strenuous activity or trauma, and that the device has a finite expected service life and may need to be replaced 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 reduce the risk of infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Component Assembly. Modular Replacement Systems consist of components that are assembled using male/female taper locking mechanisms. Complete cleaning and seating of these tapers is essential to the performance of the system.

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

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

Reuse. An implant must never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity that would reduce its service life.

Handling. Handling of implants is important, particularly hydroxylapatite and porous coated implants. Do not allow porous surfaces to come in contact with cloth or other fibre 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. Handling of the hydroxyapatite treated regions must be avoided as it may compromise the effectiveness of the device.

ADVERSE EFFECTS

1) Infection, which can lead to failure of the joint replacement.

2) Nerve palsy.

264

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

4) Wound dehiscence.

5) Loosening or migration of implants due to trauma or loss of fixation.

6) Pathological fracture.

7) Intravascular extension of the tumor.

8) Amputation due to failure of the procedure.

9) Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. (See **IMPORTANT PHYSICIAN INFORMATION** section for more information).

10) 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.

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

12) 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.

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

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

15) 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;

265

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) 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) acetabular, 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 items contained in the **WARNING** 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 extremely caused by leg length discrepancy;

4) late ligamentous instability;

5) periarticular 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 periarticular 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. **Information for Use.** The information contained in this Package Insert is necessary, but not sufficient for the use of this prosthesis. This information is in no sense intended as a substitute for the professional judgement, skill and experience of the surgeon in:

1) Careful patient selection.

2) Preoperative planning and implant selection.

3) Knowledge of the anatomy and biomechanics of the involved joint and/or 266

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bones.

4) Training and skill in joint replacement, and the use of the associated instruments in cemented and press-fit procedures.

5) Securing the patient's cooperation in following an appropriately defined postoperative management program.

6) Conducting scheduled postoperative follow-up examinations.

B. **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. It has been hypothesized that particulate debris generated by articulation of the components of a prosthesis migrate from the synovial cavity and into 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, TNF3). 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 can be 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 that are progressive may necessitate replacement of the prosthetic component(s).

C. **Polyethylene Thickness**. Theoretical analyses have indicated that contact stresses in the tibial component vary with the thickness and congruity 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.

D. **Femoral Head Compatibility.** Howmedica Osteonics manufactures femoral heads with **SEVERAL** tapers and diameters. Care must be taken to use stems 267

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and heads with the same taper angle and diameter. See product label for the specific taper information, such as angle and diameter.

E. **Ultra-High-Molecular-Weight Polyethylene (UHMWPE).** Pending the completion of additional research, Howmedica Osteonics recommends that its **UHMWPE** orthopaedic implants 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.

F. See **Product Label** for information regarding the specific product reference in the package insert.

STERILIZATION

- This component has been sterilized by gamma radiation to provide sterility throughout the unit.
- The package of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile.
- Care should be taken to prevent contamination of the component. In the event of such contamination this product must be discarded.
- If the package has been opened, but the product is not used, the prosthesis **must not** be resterilized and must therefore be discarded or returned to the supplier.
- Devices containing POLYETHYLENE, PORUOS COATING, PLASMA SPRAY, HYDROXYAPATITE, CERAMICS or METHYMETHACRYLATE SHOULD NOT BE AUTOCLAVED OR RESTERILIZED BY THE USER.

CAUTION

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

See product label for information regarding the specific product referenced in this package insert.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix E

Equivalent Product Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Modular Replacement System

(K952970, K965164 and K972401)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 1996

Ms. Mary C. Spicer
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

JAN 19 1996

Re: K952970
Howmedica® Femoral and Proximal
Tibial Modular Replacement Systems
Regulatory Class: II
Product Code: JDI and KRO
Dated: October 5, 1995
Received: October 6, 1995

Dear Ms. Spicer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). You may, therefore, market your device subject to the general controls provisions of the Act and the following limitation: all labeling for this device system, including the package label and labeling included within the package, must prominently state that the Femoral and Proximal Tibial Modular Replacement Systems are intended only for use with bone cement in "Oncology" patients where radical bone resection and replacement may be required.

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 (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will

271

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

272

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 1997

Ms. Margaret F. Crowe
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K965164
Howmedica® Modular Replacement System - Proximal Femur
Regulatory Class: II
Product Code: LPH and MEH
Dated: December 23, 1996
Received: December 24, 1996

Dear Ms. Crowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

274

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

275

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FILE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OTHER

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 1998

RECEIVED
JUL 15 1998
REGULATORY AFFAIRS

Ms. Margaret F. Crowe
Group Regulatory Affairs Manager
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K972401
Howmedica® Modular Replacement System - Distal Femoral/Proximal Tibial Segments
Regulatory Class: II
Product Code: KRO
Dated: May 13, 1998
Received: May 14, 1998

Dear Ms. Crowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

276

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

277

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Indications for Use

510(k) Number (if known):

Device Name: Howmedica® Modular Replacement System - Distal Femoral/Proximal Tibial Segments

Indications for Use:

The Howmedica® Modular Replacement System - Distal Femoral/Proximal Tibial Segments are presently cleared for use with bone cement in Oncology patients where radical resection and replacement of the distal femur is required (reference premarket notification K952970). Howmedica seeks clearance to expand this indication to include use with bone cement in limb salvage procedures where radical resection and replacement of the distal femur/proximal tibia is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous knee arthroplasties, and/or Oncology indications. All of these surgical interventions have in common the need for radical resection of the distal femur/proximal tibia, and the need for a prosthetic replacement. This device achieves fixation by the use of 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 X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 97240/

(Division Sign-Off)
Restorative Devices
510(k) Number

278

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Distal Stems of the Restoration Hip System

(K013106)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RECEIVED
APR - 5 2002
REGULATORY AFFAIRS

APR 0 3 2002

Jennifer A. Daudelin
Regulatory Affairs
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K013106
Trade/Device Name: 2-Piece Modular Hip Stem
Regulation Number: 21 CFR §888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or porous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: January 24, 2002
Received: January 25, 2002

Dear Ms. Daudelin:

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.

280

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

for Mark N Melkerson

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

281

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Indications for Use

510(k) Number (if known): K013106

Device Name: 2 Piece Modular Hip Stem

Indications for Use:

The 2 Piece Modular Revision Stem Components are intended to be used for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. The stems are intended to be used with Howmedica Osteonics femoral heads, unipolar and bipolar components, and acetabular components. These femoral stems are designed to be press fit into the proximal femur.

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

282

510(k) Number K013106

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Modular Rotating Hinge Knee System

(K994207 and K002552)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2000

Ms. Mary-Catherine Dillon
Regulatory Affairs Team Member
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K994207
Trade Name: Howmedica Osteonics® Modular Rotating Hinge Knee
Regulatory Class: II
Product Code: KRO
Dated: December 10, 1999
Received: December 14, 1999

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

284

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

285

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Indications for Use

510(k) Number (if known): K 994207

Device Name: Howmedica Osteonics® Modular Rotating Hinge Knee

The Modular Rotating Hinge Knee is intended to be implanted with bone cement for the following conditions:

- There is destruction of the joint surfaces, with or without significant bone deformity.
- The cruciate and/or collateral ligaments do not stabilize the knee joint.
- The ligaments are inadequate and/or the musculature is weak.
- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 994207

286

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2000

Ms. Jennifer Daudelin
Regulatory Affairs
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K002552
Trade Name: Howmedica Osteonics Modular Rotating Hinge Knee
Regulatory Class: II
Product Code: KRO
Dated: August 16, 2000
Received: August 17, 2000

Dear Ms. Daudelin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

288

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

289

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Indications for Use

510(k) Number (if known): K002552

Device Name: Howmedica Osteonics Modular Rotating Hinge Knee – Additional Indications

Indications for Use:

The Howmedica Osteonics Modular Rotating Hinge Knee Components is intended for use with bone cement in cases where there is destruction of the joint surfaces, with or without significant bone deformity; the cruciate and/or collateral ligaments do not stabilize the knee joint; the ligaments are inadequate and/or the musculature is weak; and revision is required of a failed prostheses where there has been gross instability, with or without bone loss or inadequate soft tissue.

In addition, expanded indications include for use with bone cement in oncology patients where radical resection and replacement of either the distal femur or proximal tibia is required. Additionally, this device would be intended for use with bone cement in limb salvage procedures where radical resection and replacement of the distal femur/ proximal tibia is required. Limb salvage procedures would include surgical intervention for severe trauma, failed previous knee arthroplasties, infection, and/or Oncology indications. All of these surgical interventions have in common the need for radical resection of the distal femur/ proximal tibia, and the need for a prosthetic replacement.

The Modular Rotating Hinge Knee components are intended to be mated with corresponding components of the Howmedica® Modular Replacement (MRS) System (K952970, K972401) and the Kinematic™ Rotating Hinge Knee (KRH) System (K792089)..

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

for Mark N Melkerson (Optional Format 1-2-96)
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002552

290

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Kinematic® Rotating Hinge Knee System

(K792089)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MARYLAND 20910

MAY 6 1980

Mr. Harry M. Kaufman
Howmedica, Inc.
235 East 42nd Street
New York, New York 10017

Ref: K792089
Howmedica[R] Kinematic[TM]
Knee System

Dear Mr. Kaufman:

We have reviewed the additional data submitted March 17, 1980 concerning the Kinematic[TM] Rotating Hinge Knee Prosthesis. Based on this information we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. This letter supercedes the January 16, 1980 letter notifying you that the Kinematic[TM] Rotating Hinge Knee Prosthesis is non-equivalent.

You may therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

Received Howmedica
MAY 1
Regulatory Affairs

292

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,

David M Link/RSK

David M. Link, Director
Bureau of Medical Devices

293

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

MOST System

(K964350, K973087, K013031)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

JAN-14 97 TUE 10:4 Records processed under FOIA Request 2011-6802; Released 12/14/12

JAN 16 1997 K964350

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Modular Options for Severe bone loss and Trauma (MOST) System.

Submitter:	Intermedics Orthopedics, Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9687
Date:	January 10, 1997
Contact Person:	Jacquelyn Hughes Manager, Regulatory Affairs
Classification Name:	Knee joint femorotibial metal/polymer constrained cemented prosthesis 21CFR 888.3510 Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis 21CFR 888.3353
Common/Usual Name:	Hinge Knee for Total Knee Replacement/Hip Stem for Total Hip Replacements/Total Hip and Knee Replacement
Trade/Proprietary Name:	Modular Options for Severe bone loss and Trauma (MOST) System

PRODUCT DESCRIPTION

The Modular Options for Severe bone loss and Trauma (MOST) System will be used for the replacement of the proximal, distal or total femur. Replacement of the distal femur would also include replacement of the proximal tibia and the possible resurfacing of the patella, if necessary. Unlike primary hip and knee systems, this system will be used where the amount of femoral resection and restoration required is extreme (e.g., in oncology cases). The modularity of this system allows for the resection of varying amounts of the femur (and the proximal tibia and patella, if necessary) before implantation. A total replacement is possible in those cases where no part of the femur can be salvaged. The components of the MOST System include:

- the proximal femoral replacement that is available in two designs to address the presence or absence of the greater trochanter, with suture holes for soft tissue attachment;
- the distal femoral replacement which mates with a tibial component via a hinge-type mechanism, allowing 15 degrees of internal and external rotation;
- intramedullary (I/M) stems with Cancellous Structured Titanium™ (CSTi™) and femoral segments which will be used in conjunction with the proximal and distal replacements, and,
- an all-poly patella.

295

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DIAGNOSTIC INDICATIONS

This device is intended to replace the proximal, distal or total femur, especially in cases that require extensive resection and restoration. Replacement of the distal femur would also include replacement of the proximal tibia and the possible resurfacing of the patella, if necessary. Proximal replacement components are available for press-fit or cemented application. Components used for replacement of the distal femur are for cemented use only. Specific diagnostic indications for use of the MOST include:

- metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur;
- revision cases requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur; and,
- severe conditions of inflammatory or noninflammatory degenerative joint disease that require extensive resection(s) and replacement(s) of the proximal and/or distal femur.

SUBSTANTIAL EQUIVALENCE

The MOST System is substantially equivalent to products offered by Wright Medical Technology, Inc., Waldermar Link, Joint Medical Products Corporation and Howmedica, Inc. The Segmented Oncology System (S.O.S.™) Proximal Femur (Wright Medical) and the MP Reconstruction Prosthesis (Link) are both modular stem designs which allow for necessary length adjustment. This provides surgeon's with intraoperative flexibility in a variety of clinical situations.

The Hinge-Type Knee of the MOST System is substantially equivalent to the Noiles Total Knee Prosthesis (Joint Medical Products Corporation) and the Kinematic II Rotating Hinge (Howmedica).

296

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

510(k) SUMMARY

NOV 14 1997

K973087

August 13, 1997

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a 510(k) summary for the Sulzer Orthopedics Inc. MOST (Modular Options for Severe Bone Loss and Trauma) System Hex I/M Stem.

Submitter: Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, TX 78717
(512)432-9900

Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: 21CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

21CFR 888.3510 - Knee joint femorotibial metal/polymer constrained cemented prosthesis

Common/Usual Name: Cemented stem for modular trauma or oncology applications

Trade/Proprietary Name: MOST Hex Intramedullary (I/M) Stem

PRODUCT DESCRIPTION:

The MOST System is used for the replacement of the proximal, distal and/or total femur. Unlike primary hip and knee systems, this system is used where the amount of femoral resection and restoration required is extreme (e.g., in oncology cases). A total replacement is possible in those cases where no part of the femur can be salvaged.

The Hex I/M stems are hex shaped and designed to serve as the modular stem portion of either the proximal or distal femoral replacement. A taper feature at the end of the stem allows for connection to the mating modular component. The hex shape allows for rotational stability within the femoral canal once the stem is cemented into place. A ring of CSTi coating around the neck of the CoCr stem (ASTM F1537) allows for tissue attachment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

SPECIFIC DIAGNOSTIC INDICATIONS:

The MOST System is intended to replace the proximal, distal and/or total femur, especially in cases that require extensive resection and restoration. The Hex I/M Stem is intended for cemented use only in these situations. Specific diagnostic indications for use of the MOST System include:

- metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement of the proximal and/or distal femur;
- patients suffering from severe arthropathy of the hip and/or knee that does not respond to any conservative therapy or better alternative surgical treatment;
- revision cases requiring extensive resection(s) and replacement(s) of the proximal, distal, or total femur.

SUBSTANTIAL EQUIVALENCE:

Substantial equivalence determination is based on comparison of the MOST Hex I/M Stem to the following legally marketed predicate competitive devices:

- Sulzer Orthopedics MOST System
- Wright Medical Segmented Oncology System (S.O.S.)
- Waldermar Link MP Reconstruction Prosthesis
- Johnson & Johnson/Joint Medical Products Noiles Knee System
- Howmedica Kinematic II Rotating Hinge Knee System

299

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mitchell A. Dhority, RAC
Senior Regulatory Affairs Specialist
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

NOV 14 1997

Re: K973087
Trade Name: MOST System Hex Intramedullary (I/M) Stem
Regulatory Class: II
Product Codes: JDI, LZO, and KRO
Dated: August 14, 1997
Received: August 18, 1997

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

300

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

301

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

510(k) Number (if known): K973087

Device Name: Modular Options for Severe Bone Loss or Trauma (MOST) - Hex I/M Stem

Indications for Use:

The MOST System is intended to replace the proximal, distal and/or total femur, especially in cases that require extensive resection and restoration. The Hex I/M Stem is intended for cemented use only in these situations. Specific diagnostic indications for use of the MOST System include:

- metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement of the proximal and/or distal femur;
- patients suffering from severe arthropathy of the hip and/or knee that does not respond to any conservative therapy or better alternative surgical treatment;
- revision cases requiring extensive resection(s) and replacement(s) of the proximal, distal, or total femur.

(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 Devices
510(k) Number K973087

Prescription Use X **OR** **Over-the Counter Use** ____

(Optional Format 1-2-96)

302

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEC 0 7 2001

K013031
page 1 of 2

510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics MOST Options™ System

Manufacturer:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	September 7, 2001
Contact Person:	Frances E. Harrison, RAC Senior Regulatory Affairs Specialist
Classification Name:	Knee joint femorotibial metal/polymer constrained cemented prosthesis - 21 CFR Part 888.3510 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis - 21 CFR Part 888.3353
Common/Usual Name:	Total Hinged Knee for Total Knee Replacement Femorotibial Prosthesis
Trade/Proprietary Name:	MOST Options™ System (MOST)

PRODUCT DESCRIPTION

The MOST Options System (MOST) is used for the replacement of the proximal, distal or total femur and/or the proximal tibia. Replacement of the distal femur would also include replacement of the proximal tibia and possible resurfacing of the patella, if necessary. Unlike primary hip and knee systems, this system can be used where extensive femoral and/or tibial resection and restoration is required (e.g., oncology cases). Modularity of the system allows for the resection of varying amounts of the femur and the proximal tibia (and patella, if necessary) before implantation. A total replacement is possible in cases where no part of the femur can be salvaged. Moreover, the system provides additional options for revision or severe bone loss of the tibia. The components of the MOST System include:

- a distal femoral replacement (Condylar End or Hinged Femur) which mates with a tibial component via a hinge type mechanism (Hinge-Kit or 4mm Hinge Kit);
- a proximal femur replacement that is available in two designs to address the presence or absence of the greater trochanter;
- intramedullary (I/M) stems with Cancellous Structured Titanium™ (CSTi™) and MOST segments which will be used in conjunction with the proximal and distal femoral replacements, the Proximal Tibia and the MOST Revision Stem Adapter;
- an all poly patella;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- a proximal tibia replacement (Proximal Tibia or Hinged Tibia) which mates with the Proximal Tibia Insert and Hinged Tibia Insert, respectively and features a distal female taper for attachment of a MOST Revision Stem Adapter, Sulzer Revision Stems or Hinged Tibia Stem Plug (Hinged Tibia only);
- femoral and tibial spacers for use in conjunction with the Hinged Femur and Hinged Tibia, respectively to augment uni-compartmental or bi-compartmental defects; and
- revision stem adapter with and without CSTi coating used to convert the MOST taper to the Sulzer taper.

SPECIFIC DIAGNOSTIC INDICATIONS

Components of the MOST System are intended to replace the proximal, distal or total femur and/or the proximal tibia, especially in cases that require extensive resection and restoration. Specific diagnostic indications for use of the MOST include:

- metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) and trauma requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur and/or proximal tibia;
- patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory (IJD), e.g. rheumatoid arthritis, requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur and/or proximal tibia; and
- revision cases requiring resection(s) and replacement(s) of the proximal, distal or total femur and/or proximal tibia.

SUBSTANTIAL EQUIVALENCE

The MOST Options System is similar to the following commercially available devices in terms of materials, general design features, and intended uses:

- Sulzer Orthopedics MOST™ System
- Johnson & Johnson S-ROM® Noiles™ Rotating Hinge Knee System
- Howmedica Osteonics® Modular Rotating Hinge Knee (MRS)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Frances E. Harrison, RAC
Senior Regulatory Affairs Specialist
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

DEC 0 7 2001

Re: K013031
Trade/Device Name: MOST Options System
Regulation Number: 21 CFR 888.3510; 21 CFR 888.3353
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: KRO, LZO
Dated: September 7, 2001
Received: September 10, 2001

Dear Ms. Harrison:

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.

305

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

for Mark N Melkerson

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

306

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

510(k) Number (if known): K013031

Device Name: MOST System

Indications for Use:

The MOST System is intended to replace the proximal, distal or total femur and/or the proximal tibia, especially in cases that require extensive resection and restoration. Replacement of the distal femur would also include replacement of the proximal tibia and possible resurfacing of the patella, if necessary. Proximal femoral replacement components are available for press-fit or cemented applications. Components used for replacement of the distal femur and proximal tibia are intended for cemented use only. Specific diagnostic indications for use of the MOST include:

1. metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur and/or proximal tibia;

2. patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory (IJD), e.g. rheumatoid arthritis, requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur and/or proximal tibia; and

3. revision cases requiring resection(s) and replacement(s) of the proximal, distal or total femur and/or proximal tibia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Ge[illegible]
and Neurologic[illegible] Devices

510(k) Number K013031

Prescription Use X **OR** **Over-the Counter Use** ____

(Optional Format 1-2-96)

307

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

510(k) Number (if known): K

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 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.

308

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- 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 _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

309

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Records processed under FOIA Request 2011-6802; Released 12/14/12

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

I certify that, in my capacity as Vice President, Quality Assurance/ Regulatory Affairs/Clinical Research of Howmedica Osteonics Corp., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

William J. Cymbaluk
Vice President, Quality Assurance, Regulatory Affairs and
Clinical Research

Date: 9/12/02

Premarket Notification [510(k)] Number:

310

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Document: K023087
Device Name: Global Modular Replacement System (GMRS)
Classification: II, 87/JDI and 87/KRO, §888.3350 and §888.3510
Regulation Name: Hip Joint Metal/Polymer Semi-constrained Cemented Prosthesis; and Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Submitted by: Howmedica Osteonics
Date Decision Due: 12/16/02
Reviewed by: Pei Sung, Ph.D. PS 12/13/02

Recommendation:
This subject 510(k) notification:

- ☒ is substantially equivalent to the marketed devices.
- ☐ requires more data.

Type letter and wording suggested:

- ☒ "SE" Letter Attached
- ☐ "AI" Letter Attached
- ☐ "AI" via Telephone, and/or attached e-mail or FAX
- ☐ "CR" Letter Attached

Summary:
The Howmedica Osteonics Modular Replacement System cleared via K952970, K965164 and K972041 has been used in clinical situations where there is extensive bone loss due to tumor resection, 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 for cancer patients. Howmedica Osteonics Corp. is seeking the regulatory clearance for an expended device system (i.e., the Global Modular Replacement System, GMRS) for:

- The Modular Replacement System, MRS (K952970, K965164 and K972401);
- The Modular Rotating Hinge Knee System (K994207 and K002552);
- The Kinematic® Rotating Hinge (K792089) Knee System.

The intended use of the GMRS (subject device) is the same as the intended use of the MRS (K952970, K965164 and K972401) system: 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.

7

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The sponsor stated that the Proximal Femoral Components (consisting of the Proximal Femoral Body, Extension Pieces, and Press Fit Stems with HA) of the Global Modular Replacement System are intended for cemented and/or press fit use in the proximal femur. Press fit use is accomplished via use of the GMRS Press Fit Stems with PureFix™ HA. The GMRS Press Fit Stems with PureEix™ HA have recently been cleared by the FDA in premarket notification K022403 for use with the proximal femoral component of the previously released Modular Replacement System in total hip arthroplasty as a result of extensive proximal bone loss.

The Distal Femoral Segment Components of the GM.RS (Distal Femoral Component, Proximal Tibial Component, Small bushings, small axle, small proximal tibial inserts, and small proximal tibial rotating components are intended for cemented use only.

In comparison with predicates, this subject Global Modular Replacement System is substantially equivalent to the above legally marketed devices (Please see comparison tables in the Section of the "Device Description")

Proposed Indications for Use:
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.

The proximal femoral module is intended to be used in a cemented or press-fit mode. The distal femoral and proximal tibial module are intended to be used with bone cement. Adequate bone stock must be present to allow the use of the press-fit stems with PureFix® HA coating.

(b) (4)

[redacted]

8

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(b) (4)

[redacted]

Description of the Subject Device(s):

The GMRS is comprised of the following three modules:

1. Proximal Femoral Module
2. Distal Femoral/Proximal Tibial Module
3. Total Femur

1. 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

Proximal Femoral Components

The GMRS Proximal Femoral Components are available in two styles: standard and trochanteric.

A comparison to the Proximal Femoral Components of the MRS (K952970 and K965164) is presented below:

Component/Feature	Proximal Femoral Components GMRS (subject)	Proximal Femoral Components MRS (K952970 and K965164)
Materials	Cast Cobalt Chromium Alloy (ASTM F-75)	Cast Cobalt Chromium Alloy (ASTM F-75)
Styles	Standard /trochanteric	Standard
Sizes	One Size	One size
Dimensions	(b) (4) [redacted]	
Compatability	GMRS Connection Pieces	MRS Connection Pieces

9

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	GMRS Extension Pieces GMRS Press Fit Stems with PureFix™ HA [pending 510(k)] MRS Body Pieces MRS Stems	MRS Extension Pieces MRS Press Fit Stems with PureFix™ HA [pending 510(k)] MRS Body Pieces MRS Stems

Extension Pieces

The Extension Pieces of the Global Modular Replacement System are intended to be used with the Proximal Femoral components, Distal Femoral components and/or the Proximal Tibial component of the GMRS in situations where a longer replacement length is required. A comparison of the Extension Pieces to the bodies of the MRS System is presented below.

Component/Feature	Extension Pieces of GMRS (subject)	Bodies of MRS (K952970, K965 164 and K972401)
Materials	Cobalt chromium Alloy (ASTM F-1537, ASTM F-799) Titanium Alloy (ASTM F-136)	Titanium Alloy (ASTM F-136)
Sizes	26mm diameter	Femoral: 24 and 28mm diameter Tibia: 24mm diameter
Lengths	30, 40, 50, 60, 70, 80, 100, 120, 140, 160, 180, 200, 220mm	40, 50, 60, 70, 80, 100, 120, 140, 160, 180, 200, 220mm
Mating Components	Proximal Femoral Components of GMRS Distal Femoral Components of GMRS Proximal Tibia Component of GMRS GMRS Press Fit Stems with PureFix™ HA [pending 510(k)] Distal Femoral/Proximal Tibial Segments of MRS Proximal Femoral Segment of MRS Stems of MRS GMRS Connection pieces MRS Total femoral bodies	Proximal Femoral Components of MRS Distal Femoral Components of MRS Proximal Tibia Component of MRS MRS Press Fit Stems with PureFix™ HA [pending 510(k)] Distal Femoral/Proximal Tibial Segments of MRS Proximal Femoral Segment of MRS Stems of MRS MRS Connection pieces MRS Total femoral bodies

GMRS Press Fit Stems with PureFix™ HA

The GMRS Press Fit Stems with PureFix™ HA Coating are machined from Ti6Al4V alloy. The stems are plasma sprayed with commercially pure titanium (CP titanium) coating . (b) (4) [redacted] (b) (4) [redacted] stem is also coated with PureFix™ HA coating.

A comparison to the cemented stems of the MRS and the distal femoral stems of the Restoration™ Modular Hip System (found substantially equivalent in K013106) is presented below:

Product	GMRS Press Fit Stems with PureFixTM HA (subject)	MRS Cemented Stems (K952970 and K965164)	Distal Femoral Stems of Restoration™ Modular Hip System (K013106)

10

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Material	Titanium Alloy CP Titanium Plasma Spray Hydroxylapatite Coating	Cobalt chromium Alloy	Titanium Alloy CP Titanium Plasma Spray Hydroxylapatite Coating
Design	Straight Straight Fluted Curved	Straight Curved	Straight Straight Fluted Curved
Compatability	Proximal Femoral Component of GMRS Extension Pieces of GMRS Proximal Femoral Component of MRS (in pending 510(k)	Proximal Femoral of MRS Distal Femoral of MRS Proximal Tibia of MRS	Proximal Femoral Component of Restoration™ Modular Hip System

2. Distal Femoral/Proximal Tibial Module

The distal femoral/proximal tibial module contains:

- Distal Femoral Components
- Extension Pieces (as described in the section above)
- Small bushings
- Small Axle
- Proximal Tibial Component
- Small Proximal Tibial Inserts
- Small Proximal Tibia Rotating Components

Distal Femoral Components

A chart comparing the dimensions, materials, and mating components for the Distal Femoral Components are as follows:

Component/Feature	Distal Femoral Component of GMRS (subject)	Distal Femur of MRS (K952970 and K972041)
Material	Cast Cobalt-Chromium Alloy ASTM F-75	Cast Cobalt-Chromium Alloy ASTM F-75
Sizes	Standard Small Left and Right Configurations	Standard Small Left and Right Configurations
Dimensions	Standard: A/P: 54mm M/L: 60mm Replacement Length: 65mm Proximal diameter: 26mm Small: A/P: 45mm M/L: 52mm Replacement Lengths: 65, 75, 85 and95mm Proximal diameter: 26mm	Standard: A/P: 54mm M/L: 64mm Replacement Length: 65mm Proximal diameter: 28mm Small: A/P: 43mm M/L: 58mm Replacement Lengths: 65, 75, 85 and95mm Proximal diameter: 24mm
Mating Components	Standard:	Standard:

11

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	Mates with MRH bumper, bushings, axle, MRS stems and MRS/GMIRS extension pieces Small: Mates with MRH bumper, and new axle, bushings, MRS stems and MRS/GMRS Extension Pieces Uses Duracon® patellar components	Mates with KRFI bumper, bushings and axle and MRS stems and MRS extension pieces Small: Mates with KRH bumper, small bushings and small axle and MRS stems and MRS Extension Pieces Uses Kinematic® patellar components

Small Bushings

The Small Bushings of the GMRS are intended to be used with the small Distal Femoral components of the GMRS (described above). The Small Bushings are fabricated from ultra-high molecular weight polyethylene.

The dimensions of the Small Bushings of the GMRS are outlined below with a comparison to the dimensions of the MRH bushings.

Component/Feature	Small Bushing of GMRS (subject)	Bushing of MRH (K994207 and K002552)
Material	UHMWPE ASTM F-648 Duration® Stabilized	UHMWPE ASTM F-648 Duration® Stabilized
Sizes	Small	Standard
Dimensions	Length: 16mm Internal Diameter: 10mm External Diameter: 16mm	Length: 20mm Internal Diameter: 10mm External Diameter: 16mm
Mating Components	Small Distal Femoral component of GMRS	Femoral Components of MRH System

It should be noted that the Kinematic® Rotating Hinge Knee System has a bushing available in a small size.

Small Axle

The Small Axle of the GMRS system is available in one size and is fabricated from wrought cobalt-chromium alloy. A comparison of the Small Axle of the GMRS to the axle of the MRH appears below:

Component	Small Axle of GMRS (subject)	Axle of MRH (b) (4) [redacted]
Material	Wrought Cobalt-Chromium Alloy ASTM F-1537	Wrought Cobalt-Chromium Alloy ASTM F-1537
Sizes	Small	Standard

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Dimensions	Length: 52mm Diameter: 10mm	Length: 60mm Diameter: 10mm
Mating Components	Small Distal Femoral component of GMRS	Femoral Components of MRH System

It should be noted that the Kinematic® Rotating Hinge Knee System has a small axle component.

Proximal Tibial Component

The Proximal Tibial Component of the GMRS is available in two sizes: standard and small and is fabricated from cast cobalt-chromium alloy

Component	Proximal Tibial component of GMRS (subject)	Proximal Tibia of MRS (K952970 and K972041)
Material	Cast Cobalt-Chromium Alloy ASTM F-75	Cast Cobalt-Chromium Alloy ASTM F-75
Sizes	Standard Small	Standard
Dimensions	Standard: A/P: 42mm M/L: 67mm Replacement Length: 80mm With poly insert Distal diameter: 26mm Small: A/P: 41mm M/L: 52mm Replacement Length: 80mm With poly insert (b) (4) [redacted]	Standard: A/P: 43mm M/L: 64mm Replacement Length: 95mm With poly insert Distal diameter: 24mm Small: Not Available
Mating Components	Standard: Mates with MRH tibial sleeve, MRII S1/S2 tibial inserts, and MRH rotating tibial components Mates with MRS stems and MRS/GMRS Extension Pieces Small: Mates with MRH tibial sleeve, new Proximal Tibial Inserts, and Small Tibial Rotating Component	Standard: Mates with KRH tibial bearing and inserts Mates with MRS stems and MRS/GMRS Extension Pieces Small: Not available

Small Proximal Tibial Inserts

The Small Proximal Tibial Inserts of the GMRS are fabricated from ultra-high molecular weight polyethylene that meets the requirements of ASTM standard F-648. The inserts vary in

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thicknesses from 6mm to 20mm. (b) (4) [redacted]

Component	Small Proximal Tibial Inserts of GMRS (subject)	Tibial Inserts of MRH (K994207 and K002552)
Material	UHMWPE ASTM F-648 Duration® Stabilized	UHMWPE ASTM F-648 Duration® Stabilized
Sizes	Small	S1/S2
Dimensions	A/P: 41mm M/L: 52mm Thicknesses: 10-24mm Minimum thickness: 6mm	A/P: 41mm M/L: 65.4mm Thicknesses: 10-24mm Minimum thickness: 6mm
Mating Components	Small Proximal Tibial Component of GMRS	S1 and S2 Tibial Baseplate of MRH

Small Proximal Tibial Rotating Component

The Small Proximal Tibial Rotating Component of the GMRS is intended to link the Distal Femoral Component of the GMRS (small or standard) or the MRH femoral components, to the small Proximal Tibial Component and Small Proximal Tibial Inserts of the GMRS. (b) [redacted]
(b) (4) [redacted]

Component	Small Proximal Tibial Rotating Component of GMRS (subject)	Tibial Rotating Component of MRH (K994207 and K002552)
Material	Forged Cobalt-Chromium Alloy ASTM F-799	Forged Cobalt-Chromium Alloy ASTM F-799
Sizes	Small	XS/S/M/L/XL
Dimensions	Anterior-posterior: 38mm Medial-lateral: 47mm	Anterior-posterior: 38mm Medial-lateral: 63.4mm
Mating Components	Small Proximal Tibial Component of GMRS	Tibial Components of MRH System

3. Total Femur

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

- Proximal Femoral Component
- Extension Pieces
- Connection Pieces

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

Connection Piece

The GMRS Connection Pieces are available in left and right orientations and two lengths: 80mm and 90mm. The GMRS Connection Pieces are fabricated from titanium alloy (titanium-6 Aluminum- 4 Vanadium). (b) (4) [redacted]:

Component	GMRS Connection Piece (subject)	Male-male Bodies of the MRS (952970)
Material	Titanium Alloy	Titanium Alloy
Design	Male Male Taper 26mm diameter 2 lengths, 80 and 90mm (b) (4) [redacted] left and right versions	Male Male Taper 28mm diameter multiple lengths (b) (4) [redacted] versions
Mating Components	• GMRS Proximal Femoral Component • GMRS Distal Femoral Component • GMRS Extension Pieces • MRS Distal Femur • MRS Proximal Femur • MRS Femoral Bodies	• MRS Proximal Femoral Component • MRS Distal Femoral Component • MRS Extension Pieces

Engineering drawings for the various components are included in Appendix A. Catalog numbers are also included in Appendix A. Schematics that depict the various configurations of the Proximal Femoral, Distal Femoral/Proximal Tibial and Total Femur Modules of the GMRS are included in Appendix A.

Device Testing and Results:

1. Proximal Femoral Module Testing:

   Based on the ISO 7206-6 standard, finite element analyses were used to evaluate the strength of the neck region of the GMRS Standard and Trochanteric Proximal Femoral Components.

(b) (4) [redacted]

15

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(b) (4)

[redacted]

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(b) (4)

[redacted]

Conclusion:

☐ Additional Information

☒ This subject device is substantially equivalent to legally marketed device(s), i.e., K952970, K965164 and K972401, K994207 and K002552 in terms of design, physical characteristics, and intended use. The sponsor has adequately addressed the request deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Decision Making Documentation

Product to which compared: see review

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

Note: "Yes" responses to questions 4,6,8,11, and every "No" response requires an explanation.

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
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 performances data are needed:
11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		x
2. Did we grant expedited review?		x
3. Have you verified that the Document is labeled Class III for GMP purposes?	x	
4. If, not, has POS been notified?		
5. Is the product a device?	x	
6. Is the device exempt from 510(k) by regulation or policy?		x
7. Is the device subject to review by CDRH?	x	
8. Are you aware that this device has been the subject of a previous NSE decision?		x
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		x
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.		

Screening Checklist

2. GENERAL INFORMATION:							
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class					x		
b) OR a statement that the device is not yet classified	(may be a classification request; see coordinator)						
c) identification of legally marketed equivalent device	NA				x		
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer					x		
f) Truthful and Accurate Statement					x		
g) Indications for Use enclosure					x		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					x		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					x		
k) Proposed Labeling					x		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred)					x		
m) If kit, certification							
5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation					x		
b) Sterilization and expiration dating information					x		
c) Software validation & verification							

Passed Screening: Yes Reviewed by: Pei Sung Concurred by: _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zimmerman, Barbara C.

ɔm: Buch, Barbara D
nt: Friday, December 13, 2002 11:00 AM
Cc: Zimmerman, Barbara C.; Melkerson, Mark N.
Subject: Bone in growth HA coated device

(b) (4)

[redacted]

Barbara Buch, M.D, Orthopaedic Surgeon
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20

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Stryker Howmedica Osteonic
59 Route 17
Allendale, New Jersey 0740

facsimile transmittal

To:	Pei Sung, Ph.D. Office of Device Evaluation	Fax:	301-827-4349
From:	Margaret F. Crowe Regulatory Consultant	Date:	12/11/02
Re:	GMRS K023087	Number of pages :	20 (with cover)
CC:			

Urgent x For Review ☐ Please Comment Please Reply ☐ Please Recycle

Dr. Sung,

Our response to K023087.

Margaret Crowe

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21

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stryker
Howmedica
OSTEONICS

59 Route 17
Allendale, NJ 07401-1677
Phone: (201) 825-4900
Fax: (201) 934-4369

(b) (4) [redacted]

Pei Sung, Ph.D.
Office of Device Evaluation
Orthopaedics Branch
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: (b) (4) [redacted]

Dear Dr. Sung:

(b) (4) [redacted]

22

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix A

Premarket Notification Clearance Letter

K022403

GMRS Press Fit Stems with PureFix® HA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

OCT 17 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RECEIVED
OCT 21 2002
REGULATORY AFFAIRS

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401

Re: K022403
Trade/Device Name: GMRS Press Fit Stems with PureFix® HA
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint/metal/ceramic/polymer/semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Codes: LZO
Dated: July 22, 2002
Received: July 23, 2002

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

25

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

Mark N Melkerson

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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page 1 of 1

GMRS Press Fit Stems with PureFix® HA 510(k) Premarket Notification
Confidential

510(k) Number (if known): K022403

Device Name: GMRS Press Fit Stems with PureFix® HA

Intended Use

The Global Modular Replacement System (referred to from this point on as the GMRS) Press Fit Stems with PureFix® HA Coating are intended to be used with components of the proximal femoral segment of the Howmedica Modular Replacement System in total hip arthroplasty. These devices are intended for use in total hip arthroplasty indicated as a result of extensive proximal femoral bone loss (from trauma, failed previous arthroplasty, or tumor resection). Adequate bone stock must be present to allow the use of the GMRS Press Fit Stems with PureFix® HA Coating.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K022403

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

Appendix B

Appendix B-1 - 510(k) Summary

Appendix B-2 - Indications for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix B-1

510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

510(k) Summary
K023087
Global Modular Replacement System

Submission Information

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix B-2

Indications for Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-6802; Released 12/14/12

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 _____ OR Over-the Counter-Use_____ (per 21 CFR 801.109)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix C

Amendment to Technical Report (b) (4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Technical Testing

(b)(4) Technical Testing

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BLL 4203

BLL4203
ID#: SAMPLE
CAT: 6495-5-011
Expire: 2007-12
IMT: GMRS4
CASE: TEST
W/O: 123456
REL: 123
0090-8-590
10:18:16 AM
12-11-2002
Dose Family: B

Catalog No. **6495-5-011**

GLOBAL MRS
Straight Fluted Press-Fit Stem

- Diameter -11mm
- Length -125mm
- Not for use with +16mm V40™ Head
- 100 lbs. (45.4 Kg) maximum weight patient

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

Made in USA

+H825649550110I
+$$8011207TESTI+

2007-12 | Ti CPTi $Ca_5(PO_4)_3(OH)$

STERILE R ⚠ CE0050 ®

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

I.D.# SN SAMPLE

[redacted]

I.D.# SN SAMPLE

Catalog No. REF 6495-5-011

Case Code LOT TEST

W / OST
6495-5-011
GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#: SAMPLE

RECORD / REORDER
HOW / OST # 6495-5-011
GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#: SAMPLE

RECORD / REORDER
HOW / OST # 6495-5-011
GLOBAL MRS Straight Fluted Press-Fit Stem
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GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#: SAMPLE

RECORD / REORDER
HOW / OST # 6495-5-011
GLOBAL MRS Straight Fluted Press-Fit Stem
CASE CODE: TEST
ID#: SAMPLE

GLOBAL MRS

REF **6495-5-011**

Tige Press-Fit cannelée droite
- Diamètre -11mm- Longueur -125mm- Ne pas utiliser avec une tête V40™ +16mm - Poids maximum du patient: 45,4 kg

Gerader kannelierter Press-Fit-Schaft
- Durchmesser -11mm- Länge -125mm- Nicht zur Verwendung mit dem +16mm-V40™-Kopf - Maximales Patientengewicht 100 lbs. (45,4 kg)

Stelo scanalato diritto a pressione
- Diametro -11mm- Lunghezza -125mm- Non utilizzare con testa V40™ di misura +16mm - Paziente di peso massimo 45,4 kg. (100 libbre)

Vástago recto estriado, moldeado a presión
- Diámetro -11mm- Longitud -125mm- No utilizar con cabeza V40™ +16mm - Paciente de 100 lbs. (45,4 kg) de peso máximo

Rechte gegroefde press-fit steel
- Diameter -11mm- Lengte -125mm- Niet gebruiken met +16mm V40™-kopje - maximaal gewicht patiënt 45,4 kg. (100 lbs.)

Rak, räfflad pressanpassad stam
- Diameter -11mm- Längd -125mm- För ej användas med +16mm V40™ huvud - Maxvikt för patient 45,4 kg.

46

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Pei Sung

Subject: 510(k) Number K023087

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.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ 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: JDI/KRO 888.3350

Additional Product Code(s) with panel (optional): MEH/KRO 888.3510

Review: Barbara Zimmerman (Branch Chief) OCDB (Branch Code) 12/15/02 (Date)

Final Review: for Miriam C. Provost (Division Director) 12/16/02 (Date)

Revised:8/17//99

5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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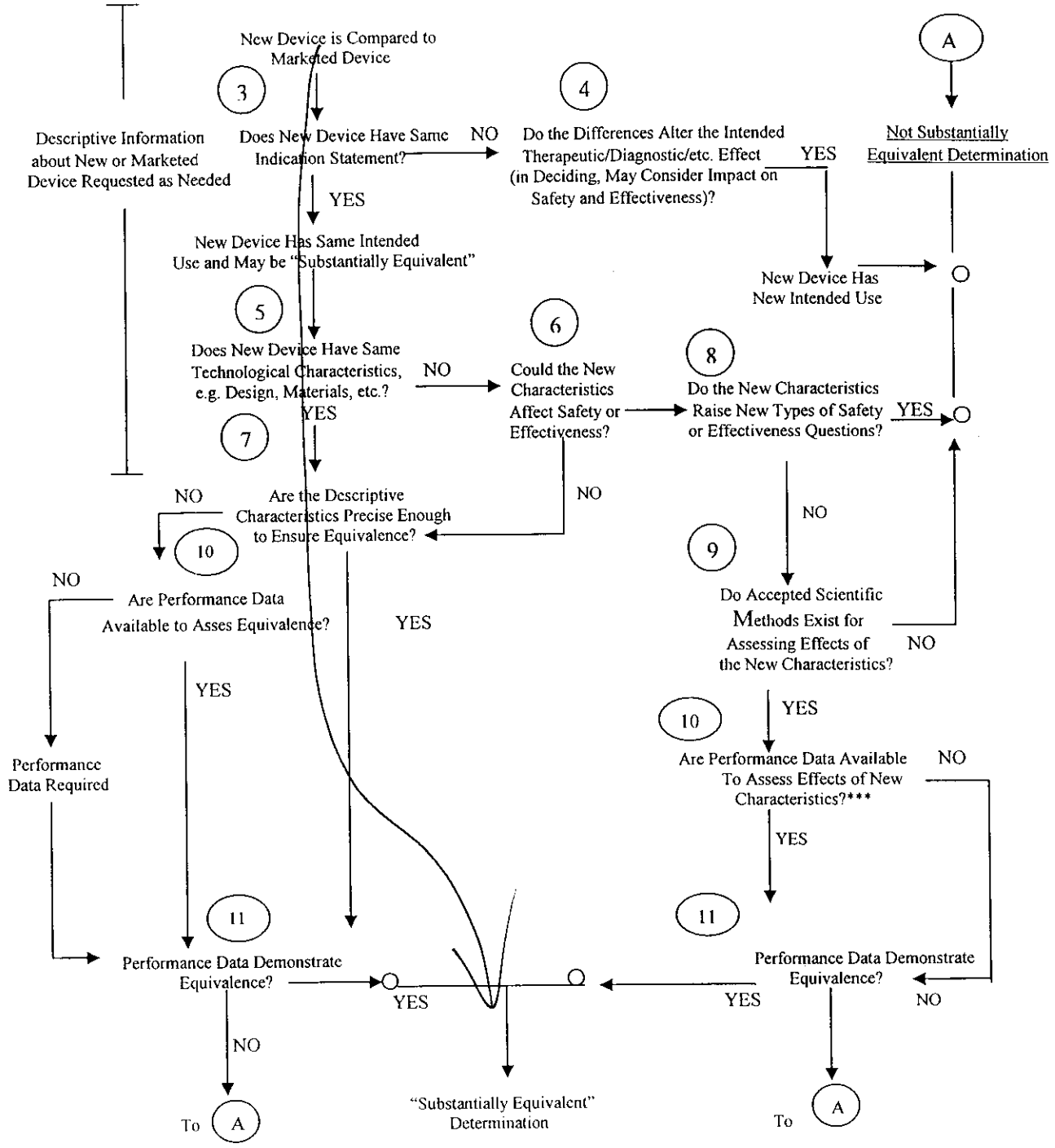
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 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.

6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118