K122015 1/2

510(k) Summary of Safety and Effectiveness

FEB 2 2 2013

Proprietary Name:	Distal Femoral Growing Prosthesis System
Common Name:	Knee Replacement Prosthesis and Modular Rotating Hinge Knee
Classification Name and Reference:	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer 21 CFR § 888.3510
Proposed Regulatory Class:	Class II
Product Codes:	87KRO: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
For Information Contact:	Christie Pencinger Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365; Fax (201)831-3365
Legally Marketed Devices to Which Substantial Equivalence Is Claimed:	K020381: Expandable Knee K023087: Global Modular Replacement System (GMRS) K965164: Howmedica Modular Replacement System-Proximal Femur
Date Prepared:	November 26, 2012

Description

The Distal Femoral Growing Prosthesis System provides a means to reconstruct large bone defects resulting from bone resection in skeletally immature patients. The device can be expanded as a patient grows so that leg-length equality can be achieved. The device utilizes a rotating hinge design. The expansion process is mechanical and is conducted with subsequent minimally invasive procedures following the initial implantation surgery.

Intended Use

The Distal Femoral Growing Prosthesis System offers a treatment option for patients requiring distal femoral replacement who have not achieved full skeletal maturity (open epiphysis). The devices are single use implants.

Indications
The Distal Femoral Growing Prosthesis is indicated for pediatric patients who have not achieved full skeletal maturity (open epiphysis), where radical resection and replacement of the distal femur and or/proximal tibia is required with the following conditions:

- Oncology indications
- Severe trauma
- Noninflammatory degenerative joint disease including osteoarthritis
- Correction of functional deformity
- Rheumatoid arthritis
- Revision procedures where other treatments or devices have failed

The devices are single use implants and intended only for implantation with bone cement.

Compatible components of the GMRS, MRH, MRS, and KRH when used with the Distal Femoral Growing Prosthesis are intended for use in pediatric patients for the above-mentioned indications.

Summary of Technologies
The technological characteristics (material, design, sizes, and operational principles) of the Distal Femoral Growing Prosthesis System are similar or identical to its predicate devices.

Non-Clinical Testing
Non-clinical laboratory testing was performed to determine substantial equivalence. Single-axis and multi-axis life cycle testing of the Distal Femoral Growing Prosthesis was conducted to verify that the expansion feature of the device will not cause the subject component to collapse/retract before, after and during physiological loading. All specimens tested ran out without evidence of collapse of the device. Fatigue testing was also conducted on the Distal Femoral Growing Prosthesis crossover bearing component. All test specimens withstood physiological loading as compared to the predicate device.

Clinical Testing
Clinical testing was not required for this submission.

Conclusion
The Distal Femoral Growing Prosthesis System devices are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Howmedica Osteonics Corporation
% Ms. Christie Pencinger
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K122015
Trade/Device Name: Distal Femoral Growing Prosthesis System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: December 20, 2012
Received: December 21, 2012

Dear Ms. Pencinger:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122015

Device Name: Distal Femoral Growing Prosthesis System

Indications

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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