AUG 12 1999

K992346

Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the Kinematic II Rotating Hinge Knee

Proprietary Name:	Kinematic II Rotating Hinge Knee
Common Name:	Knee Prosthesis
Classification Name and Reference :	Knee joint, femorotibial, metal/polymer, semi-constrained, cemented prosthesis 21 CFR §888.3530
Proposed Regulatory Class:	Class II
Device Product Code:	87 LGE
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 (201) 760-8187 Fax: (201) 934-4368

This Kinematic II Rotating Hinge Knee XXX-Small Tibial Bearing Component, Kinematic II Rotating Hinge Knee XX-Small Tibial Plug and the Kinematic II Rotating Hinge Knee XXX-Small Tibial Plug are currently marketed devices that are being modified. The modified components, MRS Pediatric Tibial Bearing Component, MRS Pediatric All Poly Tibial Component PT2 (XX-Small) and the MRS Pediatric All Poly Tibial Component PT1 (XXX-Small) are substantially equivalent to features of the predicate devices, which have been cleared for marketing via the 510(k) process. The modifications address both design and material specification changes. The MRS Pediatric Tibial Bearing Component is manufactured from a cobalt-chromium alloy, which conforms to ASTM F-1537. The MRS Pediatric All Poly Tibial Components are manufactured from ultra-high molecular weight polyethylene, which conforms to ASTM F-648. The intended use of the subject MRS Pediatric Tibial Bearing Components and the MRS Pediatric All Poly Tibial Components are identical to that of the Modular Replacement System. These components are intended for cemented use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401

Re: K992346
Trade Name: Kinematic II Rotating Hinge Knee
Regulatory Class: II
Product Code: LGE and KRO
Dated: July 9, 1999
Received: July 13, 1999

Dear Ms. Ariemma:

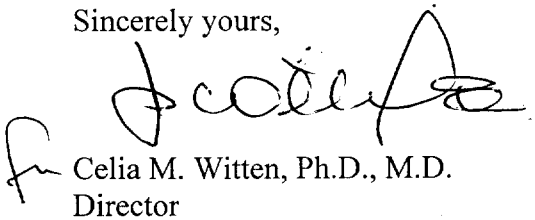
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



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

Indications for Use Page 1 of 1

510(k) Number (if known): K 992346

Device Name: Howmedica MRS Pediatric Tibial Bearing Component and MRS All Poly Tibial Component (modified Kinematic II Rotating Hinge Knee components)

The intended use of the subject MRS Pediatric Tibial Bearing Components and the MRS Pediatric All Poly Tibial Components is identical to that of the Modular Replacement System. The Modular Replacement System was cleared via 510(k) #K952970. A second submission, reference 510(k) #K972401, was found substantially equivalent which expanded the indications for use for the system. The original indications for use were for oncology patients where radical resection of the distal femur/proximal tibia is required. The expanded indications for use are limb salvage procedures where radical resection and replacement of the distal femur/proximal tibia is required. Limb salvage procedure would include surgical intervention for severe trauma, failed previous knee arthroplasties, and/or oncology indications.

As with the predicate Kinematic II Rotating Hinge Knee Metal Tibial Bearing Component and the Kinematic II Rotating Hinge Knee Tibial Plugs, the subject MRS Pediatric Tibial Bearing Components and the MRS Pediatric All Poly Tibial Components are single use devices. They are intended for cemented fixation only. The subject MRS Pediatric Tibial Bearing Components and the MRS Pediatric All Poly Tibial Components are intended to be used in conjunction with the commercially available components of the Modular Replacement System and the Kinematic II Rotating Hinge Knee System.

(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) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992346