MAR 13 2000

K994207

510(k) - Premarket Notification
Summary of Safety and Effectiveness for the
Howmedica Osteonics® Modular Rotating Hinge Knee

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Mary-Catherine Dillon Regulatory Affairs Team Member
Date of Summary Preparation:	December 10, 1999

Device Identification

Proprietary Name:	Howmedica Osteonics® Modular Rotating Hinge Knee
Common Name:	Modular Rotating Hinge Knee
Classification Name and Reference:	Prosthesis, Knee, Femorotibial, Semi-constrained

Predicate Device Identification

The features of the Howmedica Osteonics® Modular Rotating Hinge Knee are substantially equivalent to features of the following Howmedica Osteonics predicate devices, which have been cleared for marketing via the 510(k) process (K811630, K932070, and K910500 respectively):

- Howmedica Kinematic Rotating Hinge Total Knee PR.
- Howmedica Duracon Total Stabilizer Knee
- Howmedica Kinemax Plus Total Knee System

Device Description

The Modular Rotating Hinge Knee is a tricompartmental knee system. It consists of a stemmed femoral component and a stemmed tibial rotating component connected by a set of bushings and an axle. A bumper locks this assembly. This assembly provides motion through the axle/bushing combination in the flexion/extension plane. The articulation between the cylindrical bearing surfaces

on the underside of the tibial rotating component and a tibial insert provide motion in the rotation plane. The tibial insert is assembled to a tibial stemmed tray which incorporates a longitudinal bore to accept a tibial sleeve. The metallic components are manufactured from cast cobalt-chromium-molybdenum alloy (Vitallium® Alloy) conforming to ASTM F-75. The polyethylene components are manufactured from Ultra-High Molecular-Weight Polyethylene (UHMWPE) conforming to standard ASTM F648.

Intended Use:

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.

Statement of Technological Comparison:

The components of the Modular Rotating Hinge Knee share the same material, intended uses, and basic design concepts as those of the predicate devices, the Kinematic Rotating Hinge Knee, Kinemax Plus, and the Duracon Total Stabilizer Knee. Mechanical and multi-axis static testing demonstrate the comparable contact and constraint properties of these components.

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.

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

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

Device Name: Howmedica Osteonics® Modular Rotating Hinge Knee

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- The ligaments are inadequate and/or the musculature is weak.
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(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