JUN 1 5 2001

K011623

Special 510(k) Summary – Modified Exeter Hip System with V40™ Taper

Proprietary Name:	Exeter Hip System with V40™ Taper
Common Name :	Artificial Hip System
Classification Name and Reference:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer/Metal, Cemented, 21 CFR §888.3350
Proposed Regulatory Class :	Class II
Device Product Code :	87 JDI
For Information contact:	Nancy J. Rieder Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401 Phone: (201) 934-4364 Fax: (201) 760-8435

Description/Technologicol Comparison

This Special 510(k) covers a modified Exeter Hip System which differs from the existing, predicate Exeter Hip System primarily in that it features a different trunnion known as the V40™ Taper. In addition to the change in Exeter Hip Stems and Heads from the predicate trunnion design to the newer V40™ Taper, this submission includes some additional stem and head sizes, the addition of an insertion dimple on the stems, reduction in stem neck diameter, and a new wingless version of the stem centralizer component.

Intended Use

The subject Exeter V40™ Hip System components are intended for use in total hip replacement. They are intended for cemented use only. The subject components are intended for use with any Howmedica Osteonics Corp. acetabular component featuring a polyethylene bearing surface.

Indications:

- Noninflammatory joint disease including osteoarthritis and avascular necrosis,
- Rheumatoid arthritis,

- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed,
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Testing Summary

The subject modified hip stems have successfully endured testing in accordance with ISO 7206-4 and 7206-6. Testing of commercially available Zirconia V40™ Femoral Heads demonstrated their suitability for use with the subject hip stems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2001

Ms. Nancy J. Rieder
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K011623
Trade Name: Exeter Hip System with V40™ Taper
Regulation Number: 888.3350
Regulatory Class: II
Product Code: JDI
Dated: May 24, 2001
Received: May 25, 2001

Dear Ms. Rieder:

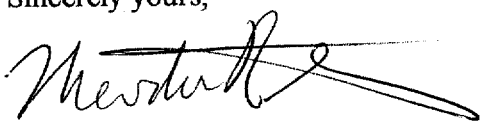
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011623

Device Name: Modified Exeter Hip System with V40™ Taper

The subject Exeter V40™ Hip System components are intended for use in total hip replacement. They are intended for cemented use only. The subject components are intended for use with any Howmedica Osteonics Corp. acetabular component featuring a polyethylene bearing surface.

Indications:

- Noninflammatory joint disease including osteoarthritis and avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed,
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

(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 and Neurological Devices

510(k) Number K011623