AUG 2 9 2003

K031730

Special 510(k) Summary - Addition of 36mm Orthinox® V40™ Femoral Heads To The Exeter Series

	SUBJECT DEVICE	PREDICATE DEVICE
Proprietary Name:	36mm Orthinox® V40™ Femoral Head Components	22mm-32mm V40™ Orthinox® Femoral Head Components
Common Name:	Femoral Head Component	Femoral Head Component
Classification Name and Reference:	21 CFR §888.3350 Hip Joint Metal/ Polymer Semi-constrained Cemented Prosthesis	21 CFR §888.3350 Hip Joint Metal/ Polymer Semi-constrained Cemented Prosthesis
Proposed Regulatory Class:	II	II
Device Product Code:	(87) JDI	(87) JDI
For Information contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 (201) 831-5379 Fax: (201) 831-6038 Email: jdaudelin@howost.com	
Date Summary Prepared:	May 27, 2003	

This Special 510(k) submission is intended to add 36mm Orthinox® V40™ femoral head components in –5mm, +0mm, and +5mm offsets to the Exeter Femoral Bearing Series. The intended use, manufacturing methods, materials, packaging and sterilization of the subject device are identical to those of predicate devices. The predicate Orthinox® V40™ femoral bearing components were found substantially equivalent via the 510(k) process in K011623. The Orthinox® V40™ femoral head components are fabricated from Orthinox®, a Stainless Steel Alloy conforming to ASTM F1586 and ISO 5832-9. Like the predicate devices, the subject devices are intended for use with femoral stems and acetabular components in primary or revision total hip arthroplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Ms. Debra Bing
Regulatory Affairs Manager
Howmedica Osteonics Corp.
59 Route17
Allendale, New Jersey 07401

Re: K031730
Trade/Device Name: Addition of 36mm Orthinox® V40™ Femoral Heads to the Exeter Series
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: August 5, 2003
Received: August 5, 2003

Dear Ms. Bing:

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.

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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: 36mm Orthinox® V40™ Femoral Heads

Indications for 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.

(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)

for Mark N Milhous

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

510(k) Number K031730