K110290

SEP 27 2011

510(k) Summary of Safety and Effectiveness

Sponsor	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
For Information contact:	Valerie Giambanco Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201)-831-6275 Fax: (201)-831-3275
Proprietary Name:	Exeter® Hip Stem
Common Name:	Artificial Hip Replacement Components - Femoral Stem
Classification Name and Reference:	21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II
Product Codes:	JDI
Predicate Device:	Exeter V40 Hip System
Date Prepared:	September 20, 2011

Description:
The currently marketed Exeter® Hip Stem is equivalent to the stainless steel hip stem with a V40™ trunnion approved via K011623. The Exeter® Hip Stem continues to be manufactured from the same design, the same materials, and the same manufacturing process.

Intended Use:
The Exeter® hip is intended for use in total hip arthroplasty. They are intended for cemented use only. The Exeter® hip is provided sterile for single-use.

The Exeter® Femoral Stems are currently cleared for use with femoral heads manufactured from Zirconia, alumina ceramic, Biolox® delta ceramic, and stainless steel. The purpose of this 510(k) is that the Exeter® stems will now be marketed as compatible with Howmedica Osteonics' V40™ cobalt chrome alloy femoral heads and Universal Taper Biolox® Delta Ceramic heads when using a titanium alloy sleeve. Thus, Exeter® stem size range cleared in K011623 will be compatible with V40™ Taper femoral heads manufactured from cobalt chrome alloy, alumina ceramic, Biolox® delta ceramic (Zirconia toughened), and stainless steel and a Universal Taper femoral heads manufactured from Biolox® delta ceramic only when using a titanium alloy adaptor sleeve.

Indications:
The Exeter® V40™ hip stem is intended for use in total hip replacement. It is intended for cemented use only.

The Exeter® Hip is indicated for:

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- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Substantial Equivalence:
The Exeter® hip stem continues to be manufactured from the same material via the same process and same design as the Exeter® hips that were cleared in K011623. The Exeter® Hip Stems are substantially equivalent to other commercially available hip arthroplasty systems in regards to indications for use design, materials, and operational principles. The femoral head compatibility of the Exeter Hip Stem is substantially equivalent to Meridian TMZF Femoral Hip Stem that was cleared via K972228 .The following devices are examples of predicate systems currently cleared for use that will now be intend for compatible usage with the Exeter® stems: Howmedica Osteonics' V40™ taper cobalt chrome alloy femoral heads (K993601, K022077, K061434, K010757) and Universal Taper Biolox® Delta Ceramic heads with a titanium alloy adaptor sleeve (K070885).

Summary of Technologies: The technological characteristics (material, design, sizes, and operational principles) of the Exeter® V40™ Hip Stem are similar or identical to the predicate devices.

Summary of Non-Clinical Testing and Evaluation:
Testing has been performed to demonstrate equivalence of the subject device intended use compared to its predicate device intended use. Additional testing was conducted on the cobalt chrome alloy and Universal taper Biolox® delta ceramic femoral heads with the corresponding titanium alloy sleeves when used with Exeter® stainless steel femoral stems.

New testing to support this additional compatibility for the Exeter® Femoral Stem with cobalt chrome femoral heads includes an Axial Pull-off testing.

New testing to support this additional compatibility for the Exeter® Femoral Stem with the Universal taper Biolox® delta ceramic femoral heads with titanium sleeve includes Axial fatigue & post fatigue ultimate compression testing (according to ISO 7206-10), Axial pull-off testing (according to ISO 7206-10) and ultimate compression testing on both new and "damaged or used" femoral stem tapers (per ISO 7206-6).

For both the cobalt chrome alloy heads and titanium alloy sleeves when used with stainless steel Exeter Stems, testing for galvanic corrosion (according to ASTM G 71-81) was conducted and fretting was evaluated as compared to the predicate device.

Clinical Testing
None provided as a basis for substantial equivalence

Conclusion
The Exeter® V40™ Hip Stem is 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 Room -W066-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Valerie Giambanco
325 Corporate Drive
Regulatory Affairs Specialist
Mahwah, New Jersey 07430

SEP 27 2011

Re: K110290
Trade/Device Name: The Exeter® V40 hip stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: JDI
Dated: August 16, 2011
Received: August 17, 2011

Dear Ms. Giambanco:

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 Keith

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

Enclosure

Indications for Use

510(k) Number (if known): K110290

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Owens for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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