FEB 1 1 2000 K993889

510(k) Summary

Device: Exeter Ceramic Femoral Heads

This device is a modular femoral head component which is affixed to a femoral stem component and articulates with a polyethylene acetabular cup or a metal backed polyethylene acetabular cup to reconstruct painful and/or severely disabled hip joints resulting from osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis, subcapital fracture or a revision of a failed femoral prosthesis. The Exeter Ceramic Femoral Heads described in this submission are a modification of a previously cleared Zirconia head (K972361) and Orthinox® head (K891454). The modification is a slight change in the taper angle of the device.

The substantial equivalence is based on an equivalence in intended use, materials, design, operational principles, and relative indications and contraindications to devices currently in commercial distribution including: V40™ Zirconia Femoral Heads (K972361) and Exeter II Total Hip System (K891454).

All of the named devices are intended to be used as the modular femoral head component of a total hip replacement. The basic design of these devices is generally the same, with varying diameters and lengths of internal tapers to accommodate individual patient needs. The material used in the manufacture of these femoral heads is also the same as the V40™ Zirconia Femoral Heads.

Assembly of all the named femoral head components to an appropriate femoral stem component requires similar instrumentation and preparation. All of the named Exeter Ceramic Femoral Heads are intended to articulate with the femoral components of the previously released Exeter Orthinox® (Rex 734 stainless steel) hip stems with a 5° 43' taper. Relative indications and contraindications for all of the zirconia heads named are the same.

Testing of the Exeter Ceramic Femoral Heads included ultimate compression strength testing. All heads tested for ultimate compression strength exceeded loads greater than 46 kN as specified in the FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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FEB 1 1 2000

Ms. Elizabeth A. Staub
Vice President
Quality Assurance, Regulatory Affairs and Clinical Research
Howmedica Osteonics Corporation
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Rutherford, New Jersey 07070

Re: K993889
Trade Name: Exeter Ceramic Femoral Heads
Regulatory Class: II
Product Code: LZO
Dated: November 11, 1999
Received: November 16, 1999

Dear Ms. Staub:

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,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K993889

Device Name: Exeter Ceramic Femoral Heads

Indications for Use:

The Exeter Ceramic Femoral Heads are intended to be used with modular femoral components in primary and secondary cemented or cementless total hip replacement procedures. These devices are intended to articulate with a polyethylene cup or a metal backed polyethylene cup component to reconstruct painful and/or severely disabled hip joints resulting from osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis, subcapital fracture, or a revision of a failed femoral prosthesis. The Exeter Ceramic Femoral Heads are intended to be used with the femoral components of the previously released Exeter hip stems - and Exeter II Total Hip System (K891454).

(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 K993889