FEB 1 0 2005 K033716

Summary of Safety and Effectiveness

Contact Person:	Karen Ariemma Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 (201) 831-5718 (Phone) (201) 831-6038 (FAX)
Date:	February 3, 2005
Device:	Trident® Hip System
Classification:	Prosthesis Hip, Semi-Constrained, Porous Coated, Uncemented Prosthesis: 21 CFR 888.3358 Hip Joint Metal/Ceramic/Polymer Semi-constrained cemented or nonporous uncemented prosthesis: 21 CFR 888.3353 Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis, 21 CFR 888.3350
Device Product Codes:	87 JDI, 87 LPH, 87 LWJ, 87 LZO, 87 MEH:
Predicate Devices:	Trident® Hip System
Indications for Use:	The Trident® Acetabular Hip System Polyethylene inserts are intended for use with the mating Trident Acetabular Shells. The Trident® Acetabular Shells are intended for cementless fixation. The Trident® Hip System components are for use in total hip arthroplasty to relieve pain and restore function for indications such as: painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis; revision of previous failed femoral head replacement, cup arthroplasty or other procedure; clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results; where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Proposed Modification:	Addition of new polyethylene components of a modified sequentially crosslinked and annealed material which has undergone a STERRAD gas plasma sterilization.
Device Description:	The device includes the acetabular inserts of a total hip system. These components are used for the replacement of the bearing surface of the acetabulum to relieve pain, instability and the restriction of motion due to degenerative bone disease, including osteoarthritis, rheumatoid arthritis, failure of other devices or trauma.
Summary of Data:	A risk analysis and research and development testing have been performed to demonstrate equivalence of the proposed products to the predicate devices. The testing includes material properties testing; wear testing; the effect of sterilization on the sequentially crosslinked and annealed material; dimensional assessment of the sequentially crosslinked and annealed material; disassembly force evaluation; and contact stresses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2005

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K033716
Trade/Device Name: Trident® Hip System
Regulation Number: 21 CFR 888.3358; 21 CFR 888.3353 and 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis,Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, JDI, MEH and LWJ
Dated: December 14, 2004
Received: December 15, 2004

Dear Ms. Ariemma:

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.

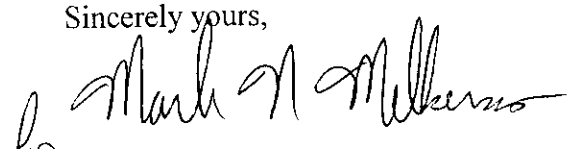
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 240-276-0120. 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/industry/support/index.html.

Sincerely yours,



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): K033716

Device Name: Trident Hip System – Polyethylene Inserts

Indications For Use:

The Trident® Acetabular Hip System Polyethylene inserts are intended for use with the mating Trident® Acetabular Shells. The Trident® Acetabular Shells are intended for cementless fixation. The Trident® Acetabular Hip System Polyethylene inserts are indicated for use in total hip arthroplasty in the following instances:

- Painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis.
- Revision of previous failed femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

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

510(k) Number K033716