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JUL 22 2008

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Tritanium®Acetabular Shell System
Common Name:	Artificial Hip Replacement Components - Acetabular
Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR §888.3358
Proposed Regulatory Class:	Class II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
For Information contact:	Kimberly Lane Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5185 Fax: (201) 831-4185
Date Prepared:	April 23, 2008

Description:

The Tritanium® Acetabular Shell consists of a hemispherical acetabular shell in both solid-backed and cluster screw-hole design and is compatible with all polyethylene Trident inserts. Both shell designs will be available in sizes 44-72 mm outside diameter (OD) in 2 mm increments. The Trident shell is being modified to include a proprietary porous coating, Particle Sintered Foam. The particle sintered foam (PSF) porous metal technology offers net-shape coatings on acetabular shells from which devices can be fabricated.

Intended Use:

The Tritanium® Acetabular Shell is a sterile, single-use device intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function.

Indications:

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

This acetabular shell is intended for cementless use only.

Substantial Equivalence:

The Tritanium® Acetabular Shell system is substantially equivalent to other commercially available acetabular systems in regards to intended use, design, materials, and operational principles. The following devices are examples of predicate systems: Trident® Acetabular Systems (K013676 and K010170) and Implex/Zimmer's Hedrocel® Revision Cup (K001759).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2008

Howmedica Osteonics Corp.
% Ms. Kimberly Lane
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, NJ 07430

Re: K081171
Trade/Device Name: Tritanium® Acetabular Shell System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: April 23, 2008
Received: April 24, 2008

Dear Ms. Lane:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
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): K081171

Device Name: Tritanium® Acetabular Shell System

Indications for Use:

The indications for use of the total hip replacement prostheses include:

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

   This acetabular shell is intended for cementless use only.

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)

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

510(k) Number K081171