K090897

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510(k) Summary of Safety and Effectiveness
Tritanium® Non-Modular Shell & X3® All-Poly Insert

OCT 23 2009

Proprietary Name:	Tritanium® Non-Modular Shell & X3® All-Poly Insert
Common Name:	Artificial Hip Replacement Components- Acetabular
Classification Name/Reference:	Hip joint metal/polymer/metal semi constrained porous coated uncemented prosthesis Hip joint metal/polymer semi-constrained cemented prosthesis. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Device Product Code:	87 LPH, 87LZO, 87MEH, 87JDI
Proposed Regulatory Class:	Class II
For Information contact:	Avital Merl-Margulies Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365 Fax: (201) 831-3365
Date Summary Prepared:	October 19, 2009

Description:

The Tritanium® Non-Modular Shell described in this Traditional 510(k) submission consist of single use devices which is intended for cementless fixation within the prepared acetabulum. The X3® All-Poly Insert, also single use devices, are intended to mate only with the Tritanium® Non-Modular Shell and must be fixed with bone cement within the metal shell.

The assembled acetabulum component is used in conjunction with any appropriately sized Howmedica Osteonics stem with a compatible head size, excluding bi-polar and uni-polar heads, to that of the respective insert, to achieve total reconstructive replacement of the hip joint.

Intended Use:

The Tritanium® Non-Modular Shell & X3® All-Poly Insert are a sterile, single use device intended for use in both primary and revision applications.

Indications:

1. Noninflammatory degenerative joint disease incuding osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis (excepting the OSTEOLOCK HA Acetabular Cup);
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and,
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques

The Tritanium® Non-Modular Shell is intended for cementless use, while the X3® All-Poly Insert is intended for cemented use only.

Substantial Equivalence:

The Tritanium® Non-Modular Shell & X3® All-Poly Insert is substantially equivalent to other commercially available acetabular systems in regards to intended use, design features, materials, and operational principles. The following devices are examples of predicate systems: TridentTM Porous Titanium Acetabular Shell, Zimmer Trabecular MetalTM Acetabular Revision System, Trident® Constrained Acetabular Insert, & Trident® Large Diameter Acetabular Inserts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Avital Merl-Margulies
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

OCT 23 2009

Re: K090897
Trade/Device Name: Tritanium Non-Modular Shell & X3 All-Poly Insert
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, MEH, JDI
Dated: October 19, 2009
Received: October 21, 2009

Dear Ms. Merl-Margulies:

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 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,

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): K090897

Device Name: Tritanium® Non-Modular Shell & X3® All-Poly Insert

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)

Janette L for NKM

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

510(k) Number K090897