K072020

OCT 18 2007

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Restoration™ ADM System
Common Name:	Artificial Hip Replacement Components - Acetabular
Classification Name and Reference:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353
Proposed Regulatory Class:	Class II
Product Codes:	87 MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate
For Information contact:	Karen Ariemma Senior Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5718 Fax: (201) 831-6038
Date Prepared:	October 17, 2007

Description:

The Restoration™ Anatomic Dual Mobility (ADM) System consists of an acetabular cup and an acetabular insert. The Restoration™ ADM insert retains a femoral head. The outer diameter of the insert articulates on the inner surface of the polished metal acetabular cup. The polyethylene insert therefore functions as a bipolar head as there are two articulating surfaces.

The Restoration™ ADM Acetabular Cup has a highly polished inner surface to help reduce wear between the cup and the insert and an anatomical shaped rim to limit cup impingement with the stem or the psoas muscle. The Restoration™ ADM Acetabular Cup is manufactured from wrought Cobalt Chromium alloy with a Commercially Pure Titanium and Hydroxylapatite coating.

Intended Use
The Restoration™ ADM is a sterile, single-use device intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function. This device is

intended to be used only with any currently available Howmedica Osteonics 22.2 and 28 mm diameter femoral heads.

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

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

This acetabular cup is intended for cementless use only.

Substantial Equivalence:

The Restoration™ ADM Acetabular 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 System, Biomet Tri-Polar System, Plus Orthopaedics Ag Polarcup Dual Mobility System -and UHR Bipolar System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

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

Re: K072020
Trade/Device Name: Restoration Anatomic™ Dual Mobility (ADM) System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code(s): MEH, LZO
Dated: July 20, 2007
Received: July 23, 2007

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 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K072020

Device Name: Restoration™ ADM System

Indications for Use:

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

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

This acetabular cup 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 K072020