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510(k) Summary of Safety and Effectiveness: SEP 28 2011
Restoration[®] Anatomic Dual Mobility[™] and Modular Dual Mobility[™] Systems
Duration[®] and X3[®] Acetabular Inserts

Proprietary Name: Restoration[®] Anatomic Dual Mobility[™] (ADM) and Modular Dual
Mobility[™] (MDM) Systems Duration[®] and X3[®] Acetabular Inserts

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, 87 LZO

For Information contact: Valerie Giambanco
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-6275 Fax: (201) 831-3275

Date Prepared: 9/1/2011

Description:

The Restoration[®] Anatomic Dual Mobility (ADM) and Modular Dual Mobility (MDM) Systems utilize Duration[®] and X3[®] Polyethylene Acetabular Inserts that retain a femoral head. The outer diameter of the insert articulates on the inner surface of either the polished ADM Acetabular Cup or, for certain sizes of inserts, the MDM Acetabular Liner. The Duration[®] and X3[®] polyethylene inserts therefore function as a dual mobility device as there are two articulating surfaces.

Intended Use:

The modification does not alter the intended use of the predicate systems as cleared in the referenced premarket notifications. The subject ADM and ADM/MDM Acetabular Inserts are sterile, single-use devices intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function. These devices are intended to be used only with currently available Howmedica Osteonics 22.2 mm and 28 mm diameter femoral heads.

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Indications for Use:

The indications for use for total hip arthroplasty 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

The ADM and MDM Systems are intended for cementless use only.

Devices for which Substantial Equivalence is claimed:

- Howmedica Osteonics Restoration® ADM System: K072020
- Howmedica Osteonics Restoration® ADM X3® Acetabular Insert: K093644
- Howmedica Osteonics Restoration MDM System: K103233

Proposed Modification:

The subject ADM Inserts and ADM/MDM Inserts maintain the same indications for and intended use, material, and operational principles as the previously cleared ADM/MDM Acetabular Inserts, cleared for use with ADM under K072020 and K093644, and certain sizes cleared for use with MDM under K103233. The subject ADM insert and ADM/MDM Insert devices consist of a modification to their inner bore design.

Summary of Technologies: Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate device. Device comparison showed that the modified device is substantially equivalent in intended use, materials and performance characteristics to the predicate device. Engineering and risk analysis has been performed to demonstrate equivalence of the subject products to the predicate devices. Laboratory testing was performed for the hip system to determine substantial equivalence. Wear, lever-out and pull out force testing, and range of motion analysis have been established for the modified design.

Clinical Testing: Clinical testing was not required for this submission.

Conclusion: The ADM Inserts and ADM/MDM Inserts are substantially equivalent to the predicate devices identified in this premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Valerie Giambanco
325 Corporate Drive
Mahwah, NJ 07430

SEP 28 2011

Re: K112556

Trade/Device Name: Restoration® Anatomic Dual Mobility™ (ADM) and Modular Dual Mobility™ (MDM) Systems Duration® and X3® Acetabular Inserts

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class: II

Product Code: MEH, LZO

Dated: September 1st, 2011

Received: September 2nd, 2011

Dear Ms. Giambanco:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

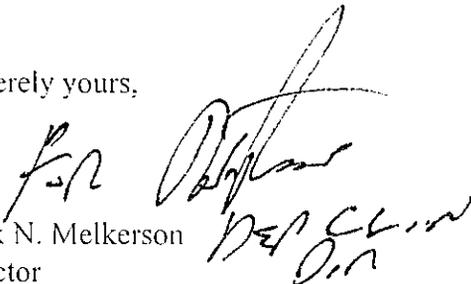
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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" (21 CFR 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): K112556

Device Name: ADM and ADM/MDM Acetabular Inserts

Indications for Use:

The indications for use for total hip arthroplasty include:

- 1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- 2) Rheumatoid arthritis;
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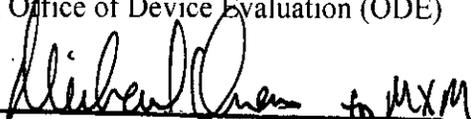
The ADM and MDM Systems are intended for cementless use only.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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