K103233

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510(k) Summary of Safety and Effectiveness

Proprietary Name:	Modular Dual Mobility (MDM™) Liner and X3®Acetabular Insert
Common Name:	Artificial Hip Replacement Components - Acetabular
Classification Name	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:	Avital Merl-Margulies Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365 Fax: (201) 831-3365
Date Prepared:	February 3, 2011

Description:
The Modular Dual Mobility (MDM™) liner is a highly polished cobalt chrome liner that features a Trident® locking mechanism. This feature will allow for compatibility with other acetabular cups containing the same locking mechanism. A Duration® or X3® polyethylene insert will articulate within the MDM™ liner. The additional X3® Acetabular Inserts are intended to accommodate the size range of the MDM™ liner device.

Intended Use:
The MDM™ liner and X3® Acetabular Inserts are a sterile, single-use device 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.

Indications:
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 MDM™ liners are intended for cementless use only.

Substantial Equivalence:
Testing has been performed to demonstrate equivalence of the subject device compared to its predicate device. Predicate devices include Restoration® ADM System (K072020), Restoration® X3® Acetabular Insert (K093644), and Trident® Porous Titanium Acetabular Component (K010170). The testing conducted includes disassembly force evaluation including push-out strength according to ASTM F1820-03 and lever-out and pull-out force testing. An engineering analysis of range of motion, jump distance, and fretting wear were also performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

FEB - 3 2011

Re: K103233
Trade/Device Name: Modular Dual Mobility (MDM™) Liner and X3® Acetabular Insert
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: LZO, MEH
Dated: January 28, 2011
Received: January 31, 2011

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. 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" (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

K103233

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Indications for Use

510(k) Number (if known): _____

Device Name: Modular Dual Mobility (MDM™) liner and X3® Acetabular Insert

Indications for Use:

The indications for use of the 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 MDM™ liners are 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)

for M. Mellerson

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

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