K093549 #1/2

DEC 16 2009

BIOMET®
MANUFACTURING CORP.

510(k) Summary

Date: November 16, 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl
Regulatory Specialist

Proprietary Name: 44mm E1™ Acetabular Liner* with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
(**also known as E-Poly™ Acetabular Liners)*

Common or Usual Name: UHMWPE Liners

Classification Name:

- LPH—prosthesis, hip, semi-constrained, metal/polymer, Porous uncemented (888.3358);
- JDI—prosthesis, hip, semi-constrained, metal/polymer, Cemented (888.3350);
- LWJ—prosthesis, hip, semi-constrained, metal/polymer, Uncemented (888.3360);
- MAY—prosthesis, hip, semi-constrained, metal/ceramic/ Polymer, cemented or non-porous cemented, osteophilic finish (888.3353);
- LZO—prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (888.3353)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: 100 kGy E-Poly™ Acetabular Liners – K070399 and K090103, Biolox® *delta* Option Ceramic Heads – K082996.

Device Description: Biomet Manufacturing Corp. is adding a size 44mm liner to their line of E1™ Acetabular Liners to allow the surgeon more options. Additionally, the 44mm Biolox® *delta* Option Ceramic Head is added to the ceramic option line. The 44mm M²a Magnum™ may be used when a Co-Cr-Mo option is needed. This submission is a line extension of the previously cleared systems.

Mailing Address:
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Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

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44mm E1™ Acetabular Liner* with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
Biomet Manufacturing Corp.
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Indications For Use: The 44mm E1™ Acetabular Liners are for use in total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2) Rheumatoid arthritis.
3) Correction of functional deformity.
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5) Revision procedures where other treatment or devices have failed.

Specific indications for compatible components that can be used with the Biolox® *delta* Option Ceramic Head include:

Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrosis. (K974558, K002757, K021380, K033871)

Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard-type hip replacement prosthesis. (K990830, K042774)

Summary of Technologies: The 44mm E1™ Liner and 44mm Biolox® *delta* Option Ceramic Head are technologically similar to the predicate devices.

Non-Clinical Testing: All parameters of the "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" were met for the devices contained in this 510(k).

Clinical Testing: None provided

Biolox is a trademark of CeramTec AG

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

DEC 16 2009

Biomet Manufacturing Corp.
% Ms. Becky Earl
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K093549
Trade/Device Name: 44mm E1™ Acetabular Liner with 44mm Biolox® delta Option Ceramic Head or 44mm M²a Magnum Modular Head
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, LPH, JDI, LWJ, MAY
Dated: November 16, 2009
Received: November 17, 2009

Dear Ms. Earl:

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): K093549

Device Name: 44mm E1™ Acetabular Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head

Indications For Use: The 44mm E1™ Acetabuler Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head is for use in total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

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

510(k) Number K093549