510(k) Summary

Date: November 16, 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becký Earl
Regulatory Specialist

Proprietary Name: 44mm E1™ Acetabular Liner* with 44mm Biolox® delta Option Ceramic Head or 44mm M²'a 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 uncedmented (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, uncedmented (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 M²'a Magnum™ may be used when a Co-Cr-Mo option is needed. This submission is a line extension of the previously cleared systems.
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
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" (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,

[Signature]

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 M2™a Magnum™ Modular Head

Indications For Use: The 44mm E1™ Acetabular Liner with 44mm Biolox® delta Option Ceramic Head or 44mm M2™a Magnum™ Modular Head is 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.
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Prescription Use _X_ AND/OR Over-The-Counter Use _No_ (Part 21 CFR 801 Subpart D) (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)

[Signature]

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093549