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BIOMET MANUFACTURING CORP.

FEB 11 2009

510(k) Summary

Preparation Date: January 13, 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl

Proprietary Name: 100 kGy E-Poly™Acetabular Liners- Additional Profiles: +3 MaxRom™ and +3 Hi-Wall

Common Name: UHMWPE Liners

Classification Name(s):

- 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: K070399, 100 kGy E-Poly™ Acetabular Liners—Additional Profiles.

Device Description: Biomet Manufacturing Corp. is adding new +3 MaxRom™ and +3 Hi-Wall profiles to their line of 100 kGy E-Poly™ Acetabular Liners to allow the surgeon an option for achieving more range of motion and joint stability in smaller patients.

Intended Use:

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 using other techniques.
5. Revision of previously failed total hip arthroplasty.

Cemented and Uncemented Applications

Summary of Technologies: The intended use, indications, contraindications and materials of the subject components remain identical to its predicate counterpart, with the exception of the additional profiles. The safety and effectiveness of this cross-linked polyethylene in acetabular applications are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

Mailing Address:
P.O. Box 587
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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Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet, Inc.
% Ms. Becky Earl
Regulatory Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581

FEB 11 2009

Re: K090103
Trade/Device Name: 100kGy E-Poly Acetabular Liners – Additional Profiles; +3 MaxRom™ and +3 Hi-Wall
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: Class II
Product Code: MAY, LZO, LWJ, JDI, LPH
Dated: January 13, 2009
Received: January 15, 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.

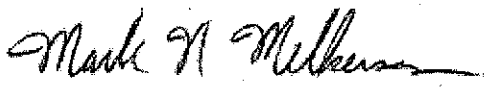
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K090103 (pg 1/1)

Device Name: 100kGy E-Poly™ Acetabular Liners—Additional Profiles: +3 MaxRom™ and +3 Hi-Wall

Indications for Use:

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 using other techniques.
5. Revision of previously failed total hip arthroplasty.

Cemented and Uncemented Applications (as based on mating shell)

Prescription Use ___YES___ (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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090103