K100048

MAR - 9 2010

510(k) Summary

Date: March 3, 2010

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl
Regulatory Specialist

Proprietary Name: E1™ Antioxidant Infused Technology
(E1™ previously known as E-Poly™)

Common or Usual Name: UHMWPE with antioxidant

Classification Name:

- OIY—knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560)
- OQG—prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (888.3358)
- OQH—prosthesis, hip, semi-constrained, metal/polymer + additive, cemented (888.3350)
- OQI—prosthesis, hip, semi-constrained, metal/ceramic/polymer + additive, cemented or porous uncemented (888.3353)
- JWH —cemented semi-constrained polymer/metal/polymer knee prosthesis (888.3560)
- 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:
The predicate devices are the E-Poly™ Tibial Bearings, K080528, cleared June 17, 2008; E-Poly™ MaxRom™ Acetabular Liners, K070364, cleared May 3, 2007;

E-Poly™ (100kGy) Acetabular Liners-Additional Profiles, K070399, cleared May 4, 2007; Biolox® *delta* Ceramic Heads with 100 kGy E-Poly™ Acetabular Liners, K073102, cleared November 27, 2007; and 100kGy Acetabular Liners Additional Profiles: +3 MaxRom™ and +3 Hi-Wall, K090103, cleared February 11, 2009.

Device Description: The device descriptions of the E1™ Tibial Bearings and the E1 ™ Acetabular Liners have not changed from the original predicate submissions.

Indications For Use:

E1™ Tibial Bearings

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

E1™ Acetabular Liners

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 E1™Antioxidant Infused Technology is identical to that of the predicate devices.

Non-Clinical Testing: Further testing showed no decreases in the mechanical properties after accelerated aging. In contrast to the control materials, the E1™ hip and the E1™ knee materials showed no evidence of oxidation or oxidative degradation.

Clinical Testing: None provided

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

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

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Re: K100048
Trade/Device Name: E1™ Tibial Bearings and E1™ Acetabular Liners
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: OIY, OQG, OQH, OQI, JWH, JDI, LZO, MAY, LPH, LWJ
Dated: January 7, 2010
Received: January 8, 2010

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. 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,

Barbara Buehler
for

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): K100048

Device Name: E1™ Acetabular Liners

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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K100048

Indications for Use

510(k) Number (if known): K100048

Device Name: E1™ Tibial Bearings

Indications for Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

For cemented and un-cemented use.

Prescription Use YES 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)

(Division Sign-Off)
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and Restorative Devices

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