K093235

BIOMET MANUFACTURING CORP.

APR 30 2010

510(k) Summary

Preparation Date: 8 April, 2010

Applicant/Sponsor:
Biomet Manufacturing Corp.
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P.O. Box 587
Warsaw, IN 46581-0587

Contact Person:
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Biomet Manufacturing Corp.
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Proprietary Name: Porous Plasma Spray (PPS) Ringloc®+ Acetabular System

Common Name: Acetabular System

Classification Name:
Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis. 21 CFR §888.3330
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. 21 CFR §888.3358
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR §888.3353

Product Code: KWA, LPH, LZO

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

M2a Ringloc® Acetabular Liners – K002379
Regenerex Ringloc®+ Modular Acetabular Shell – K070369

Device Description: The Porous Plasma Spray (PPS) Ringloc®+ Acetabular System is a series of acetabular shells that incorporate the Ringloc®+ locking mechanism design of the predicate Regenerex Ringloc®+ Modular Acetabular Shells. The Porous Plasma Spray (PPS) Ringloc®+ Acetabular System shells are compatible with Biomet's M2a Ringloc® Acetabular Liners or the conventional Ringloc® UHMWPE liners that are currently on the market.

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K093235

Intended Use: The Porous Plasma Spray (PPS) Ringloc®+ Acetabular System is intended to replace the natural acetabulum damaged by disease, trauma or revision of previous arthroplasty.

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 by other techniques.
5. Revision procedures where other treatment or devices have failed.

The Porous Plasma Spray (PPS) Ringloc®+ Acetabular System is intended for uncemented use only.

Summary of Technologies: The subject Porous Plasma Spray (PPS) Ringloc®+ Acetabular System shells are made of titanium alloy conforming to ASTM F-136 with a porous plasma spray outer surface coating of titanium alloy powder conforming to ASTM F-1580.

Testing: Since the locking mechanism of the subject and predicate devices is identical, no testing was required to demonstrate substantial equivalence of the Porous Plasma Spray (PPS) Ringloc®+ Acetabular System to the predicate Regenerex Ringloc®+ Modular Acetabular Shell – K070369

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

APR 30 2010

Biomet Manufacturing Corp.
% Mr. Gary Baker, MS RAC
Regulatory Affairs Project Manager
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K093235
Trade/Device Name: Porous Plasma Spray (PPS) Ringloc®+ Acetabular System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, LPH, LZO
Dated: April 08, 2010
Received: April 13, 2010

Dear Mr. Baker:

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.

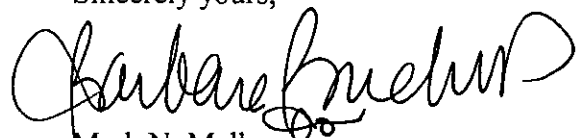
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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

Indications for Use

510(k) Number (if known): K093235

Device Name: Porous Plasma Spray (PPS) Ringloc®+ Acetabular System

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 by other techniques.
5. Revision procedures where other treatment or devices have failed.

The Porous Plasma Spray (PPS) Ringloc®+ Acetabular System is intended for uncemented use only.

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)

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

510(k) Number K093235