K090757

BIOMET MANUFACTURING CORP.

SEP 25 2009

510(k) Summary

Preparation Date: March 20, 2009

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
Establishment Registration Number: 1825034

Contact Person:
Becky Earl
Regulatory Specialist

Proprietary Name: Biomet® Modular Femoral Revision System

Common Name: Femoral Hip Revision System

Classification Name:

LPH— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)

KWA—Prosthesis, Hip, Semi-Constrained (Metal Uncemented Acetabular Component) (21 CFR 888.3330)

JDL— Prosthesis, Hip, Semi-Constrained (Metal Cemented Acetabular Component) (21 CFR 888.3320)

LZO—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353)

KWZ—Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer (21 CFR 888.3310)

JDI— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350)

KWY—Prosthesis, Hip, Hemi-Femoral, Metal/Polymer, Cemented or Uncemented (21 CFR 888.3390)

MAY—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous Cemented, Osteophilic Finish (21 CFR 888.3353)

MEH—Prosthesis, Hip, Semi-constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate (21 CFR 888.3353)

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

K090757

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K031693	Mallory-Head® Modular Calcar with and without HA—Biomet
K042774	Mallory-Head® Modular Calcar Stems with Interlocking Slots—Biomet
K013106, K022549	Restoration™ Modular System—Stryker
K994038	Modular Reach® Hip--Biomet

Device Description:
The Biomet® Modular Revision Femoral System is a comprehensive, press-fit revision stem design that provides the surgeon with multiple styles of modular proximal and distal bodies for reconstruction of various defects commonly seen in femoral revision surgery. The proximal bodies will consist of broached, calcar-replacing, and cone-style implants. The system also includes auxiliary implants to aid in fixation. A single set of instrumentation is provided for all styles. The system is intended for uncemented applications

Intended Use:
Indications for the Biomet® Modular Revision Femoral System include:

1. Noninflammatory 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.

The Biomet® Modular Revision Femoral System hip components are single-use implants, intended for uncemented applications.

Summary of Technologies:
The Biomet® Modular Revision Femoral System has the same technological haracteristics as the predicates listed above.

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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

SEP 2 5 2009

Re: K090757
Trade/Device Name: Biomet® Modular Femoral Revision System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA, LPH, JDL, LZO, KWZ, JDI, KWY, MAY and MEH
Dated: September 19, 2009
Received: September 21, 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,

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): K090757

Device Name: Biomet® Modular Femoral Revision System

Indications For Use:

1. Noninflammatory 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.

The Biomet® Modular Revision Femoral System hip components are single-use implants, intended for uncemented applications.

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)

Joanne Z for MKN
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090757