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BIOMET
MANUFACTURING CORP.

510(k) Summary

SEP 30 2011

Preparation Date: September 29, 2011

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: Taperloc® Complete Microplasty System

Common Name: Uncemented porous modular hip prosthesis

Classification Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR §888.3330)

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)

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

KWL—Hip Joint Femoral (Hemi-Hip) Metallic Cemented or Uncemented Prosthesis (21 CFR 888.3360)

OQG—Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (888.3358)

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Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Taperloc® Complete Stems—Biomet—(K101086)

Lateralized Taperloc® Microplasty Femoral Components —Biomet—(K062994)

Taperloc® Complete, Sizes 5mm and 6mm—Biomet—(K103755)

Fitmore® Hip Stem—Zimmer—(K071723)

Device Description:

The Taperloc® Complete Microplasty Stems are an update to the existing Taperloc® Microplasty Stems and are designed to replace the patient's natural hip, femoral neck, and head, due to disease or accident. The Taperloc® Complete Microplasty Stems will combine the design features of the Taperloc® Complete full-length stems to the shortened design of the existing Taperloc® Microplasty Stems. These design features include: a reduced neck angle, shorter/longer neck lengths, reduced Type 1 taper geometry with neck flats, polished neck, standard and high offset versions, two distal profiles, and an updated insertion hole. Stem sizes ranges are within the ranges of legally marketed predicates. The substrate material is Ti-6Al-4V, ASTM F-136. The proximal intramedullary region is sprayed with porous plasma spray.

Intended Use:

Porous coated components are intended for uncemented biological fixation.

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.

Porous coated components are intended for uncemented biological fixation.

Summary of Technologies:

The technological characteristics are the same as the predicates identified in the Legally Marketed Devices to which substantial equivalence is claimed. The subject microplasty stems are designed to update the existing Taperloc® Microplasty implants (K062994) to join the Taperloc® Complete family of stems as a microplasty option. The subject microplasty stems combine the design features of the Taperloc® Complete full-length stems (K101086 and K103755) and the shortened design of the Taperloc® Microplasty stems, both standard and high offset, or lateralized (K062994). Technological characteristics include a tapered wedge, a porous plasma sprayed region, a modified shortened trunnion (Type 1), a reduced neck angle, two distal profiles and an updated insertion/extraction hole, identical to the Taperloc® Complete full-length stem predicates (K101086 and K103755). Stem lengths are within the range of the legally marketed predicates.

Non-Clinical Testing:
Nonclinical performance testing included distal and proximal stem fatigue testing of the worst-case stem, consistent with the "Guidance for Industry and FDA Staff Non-clinical Information for Femoral Stem Prostheses", ISO 7206-4:2002, ASTM F2068-03 and ISO 7206-6:1992, as well as a Range of Motion analysis consistent with ISO 21535:2009. All 6 stems passed distal stem fatigue for 5 million cycles at 67 lbs to 517lbs,

meeting the acceptance criteria. All 6 stems passed 10 million cycles at 120lbs – 1200lbs in proximal fatigue test, meeting the acceptance criteria. The minimum Range of Motion passed its simulation, meeting the acceptance criteria.

Additional Ti-alloy (ASTM F1580) plasma sprayed metallic coating characterization data was performed for clarification per the "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement" and per the "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements." The PPS plasma sprayed coating is the same as the PPS coating previously cleared and meets the regulatory definition of porous coating for the hip construct per 21 CFR 888.3358.

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

The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Biomet Manufacturing Corp.
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Regulatory Specialist
P.O. Box 587
Warsaw, IN 46581

OCT 30 2011

Re: K110400
Trade/Device Name: Taperloc® Complete Microplasty 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, JDL, LZO, KWZ, JDI, KWY, MEH, KWL, OQG
Dated: September 20, 2011
Received: September 21, 2011

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,

Erin S. Keith

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): K110400 (pg 1/1)

Device Name: Taperloc® Complete Microplasty

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.

Porous coated components are intended for uncemented biological fixation.

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 K110400