APR 19 2013

BIOMET
MANUFACTURING CORP.

510(k) Summary

Preparation Date: March 5, 2013

Applicant/Sponsor:
Biomet Manufacturing Corp.
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P.O. Box 587
Warsaw, Indiana 46581-0587
FDA Registration Number: 1825034

Contact Person:
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Biomet Manufacturing Corp.
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Proprietary Name:
Arcos Modular Femoral Revision System
Trochanteric Button

Common Name: Trochanteric bolt washer; hip prosthesis accessory

Classification Code(s)/Name(s):

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

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)

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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)

JDG—Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360).

OQG—Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (21 CFR 888.3358)

OQH—Hip, semi-constrained, cemented, metal/polymer + additive, cemented (21 CFR 888.3350)

OQI—Hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented (21 CFR 888.3353)

PBI—Prosthesis, hip, constrained, cemented or uncemented, metal/polymer, + additive (21 CFR 888.3310)

LWJ—prosthesis, hip, semi-constrained, metal/polymer, uncemented (888.3360)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

The predicate device is the Biomet Modular Femoral Revision Modular System (Arcos), K090757.

Device Description:

The Arcos Trochanteric Button is being added to the Arcos Modular Femoral Revision System, K090757, to expand surgical options beyond the claw when increased proximal stability is needed, especially when a greater trochanteric osteotomy has been performed. This assembly allows the greater trochanter to be compressed against the prosthesis or for reattaching the greater trochanter in cases where a trochanteric osteotomy has been performed. The Trochanteric Button comes in one size and is manufactured from Ti-6Al-4V. The design is very similar to the cleared Trochanteric Plate cleared for use with the Mallory-Head Modular Calcar System, K031693.

Intended Use:

The Arcos Trochanteric Button is intended for use with the Arcos Modular Femoral Revision System, which is cleared only for uncemented use (K090757), as well as the Arcos Interlocking Stems, a line extension to the Arcos Modular Femoral Revision System, added by Special 510(k) K100469, listed in the compatible component section.

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 Arcos Modular Femoral Revision System Trochanteric Button hip components are single-use implants, intended for uncemented applications.

Summary of Technologies:

The Arcos Trochanteric Button is being added to the line of accessories for use with the Arcos Modular Femoral Revision System. The Arcos Trochanteric Button uses the same technology as the referenced previously cleared Trochanter Plate included in the Revision Mallory-Head® Modular Calcar with and without HA, K031693, which served as a predicate for the Arcos Modular Femoral Revision System. The subject device is manufactured from the same material, conforming to the same standard, as the previously cleared Trochanter Plate.

Non-Clinical Testing:

- Pull-Through Comparison (FEA)
- Cross Section Analysis

Since the stresses are reduced on the new washer due to the smaller hole and larger contact area, the proposed Arcos Modular Femoral Revision System Trochanteric Button should perform as well or better than the referenced cleared Mallory-Head® Trochanter Plate, thus meeting the acceptance criteria, indicating capability to fulfill surgical expectations.

Clinical Testing:

None provided as a basis for substantial equivalence.

Testing and analysis demonstrates that the modifications made to the Arcos Modular Femoral Revision System, by the addition of the Arcos Trochanteric Button, do not introduce any new risks of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

Letter dated: April 19, 2013

Re: K130063
Trade/Device Name: Arcos Modular Femoral Revision System Trochanteric Button
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, KWZ, JDI, KWY, MAY, MEH, JDG, OQG, OQH, OQI, PBI, LWJ
Dated: March 22, 2013
Received: March 25, 2013

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 contact 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. 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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130063

Device Name: Arcos Modular Femoral Revision System Trochanteric Button

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 Arcos Modular Femoral Revision System Trochanteric Button 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)

Elizabeth L. Frank -S

Division of Orthopedic Devices