AUG 17 2012

BIOMET
MANUFACTURING CORP.

510(k) Summary

Preparation Date: August 14, 2012

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 Size 4mm and XR 123

Common Name: Uncemented porous modular hip prosthesis

Classification Name:

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)

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)

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

Taperloc® Complete Microplasty Stems—Biomet—(K110400)

Device Description:

Taperloc® Complete Size 4mm Stems

The Taperloc® Complete Size 4mm stems will combine the design features of the Taperloc® Complete full-length stems (K101086 and K103755) and the shortened design of the new Taperloc® Complete Microplasty, K110400. This submission is extending the implant size range to 4mm for the Full Profile (full-length and Microplasty), the Reduced Distal Profile (full-length and Microplasty), and the Traditional Reduced Distal Profile (full-length only). The design characteristics of the size 4mm full-length stems and Microplasty stems are identical to the Taperloc® Complete implants (K101086, K103755 and K110400); this is simply a line extension of our current offerings. These characteristics include: trapezoidal neck design, short taper, 133° neck angle, same material properties of the stem and plasma spray, a reduced profile distal stem, and an updated insertion/extraction hole.

Taperloc® Complete XR 123° Stems

The Taperloc® Complete XR 123° implants incorporate all the benefits of the Taperloc® Complete system, both full-length and Microplasty, as mentioned above, with a single offset neck option for the Full Profile and the Reduced Distal Profile. The only change is the 123° offset option, which was developed to reduce vertical offset (leg length), while maximizing horizontal offset. This option is supported through additional mechanical testing.

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 intramedullary plasma sprayed region of the

Taperloc® Complete Size 4mm stems and the XR 123° stems have remained unchanged from the predicate Biomet Taperloc® Complete Stems (K101086, K103755, and K110400). The trunnion for the XR 123° has been modified to include a reduced neck angle of 123°, as compared to 133° of the predicate Taperloc® Complete Stems (K101086, K103755 and K110400). The trapezoidal design, taper junction and fine sisal buff surface finish of the Taperloc® Complete 4mm and the XR 123° stems are the exact same used with the predicate Biomet Taperloc® Complete Stems (K101086, K103755 and K110400). Additionally, the updated insertion/extraction hole is identical to the Taperloc® Complete stem predicates (K101086, K103755 and K110400). Stem lengths are within the range of the legally marketed predicates.

Non-Clinical Testing:

Taperloc 4mm 133°

MT6461—Taperloc Complete 4mm 133° Proximal Pot Fatigue Test

The proximal pot test was conducted on the 4mm High Offset Taperloc® Complete Microplasty Stems that included the new design modifications, determined to be worst case by Finite Element Analysis (FEA). Six stems, combined with +12 modular heads, were tested and passed the 10 million cycles to 120lbs – 1,200lbs. The results meet the acceptance criteria set forth by ASTM F2068-03. Since the worst-case 4mm 133° High Offset passed the mechanical test, it can be expected that the 4mm 133° Standard Offset implant will also pass this proximal pot mechanical test.

MT6540—Taperloc Complete 4mm 133° Distal Pot Fatigue Test

Six 4mm 133° Standard Offset Microplasty Stems represented the worst-case, as determined by FEA, simulating the distal pot loading scenario. (The worst-case stress conditions were shown in the High Offset stems, but since the High Offset stems are not included in this submission, the second worst stem, the 4mm 133° Standard Offset was tested.) All six stems tested passed 5 million cycles to

67lbs – 517lbs, meeting acceptance criteria as set forth in FDA guidance.

Taperloc Complete XR 123°

MT6579—Taperloc Complete XR 123° Proximal Pot Fatigue Test

Based on the FEA results of the twelve smallest stem sizes, as expected, the smallest stem was the worst-case. FEA showed that both Full-Length sizes and Microplasty sizes were found to perform the same, because the only differences between the two are their distal geometries which are potted deep in the potting media and have no effect on the strength of the proximal geometry. Therefore, six, of the 4mm XR 123° Microplasty stems, combined with +12 modular heads were tested. All six stems passed 10 million cycles to 120lbs – 1,200lbs. These results meet the acceptance criteria set forth by ASTM F2068-03, and it can be said that the entire Taperloc Complete XR 123° hip system will withstand the same loading conditions.

MT6609—Taperloc Complete XR 123° Distal Pot Fatigue Test

As determined by FEA, the worst-case stem is the combination of the smallest diameter stem (4mm) with a large horizontal offset and low vertical offset, combined with a femoral head that has the highest available offset (28mm +12). The XR 123° worst-case stem was potted at the same level as the other Taperloc Complete stems (K101086, K103755, K110400) relative to the intersection of the medial curve and resection level. The first round of testing encountered some issues due to potting media breakdown. After this problem was corrected, six samples withstood the loading for 5,000,000 cycles. Upon the completion of the test, the stems were found to be in their original condition. All six stems tested passed 5 million cycles to 67lbs – 517lbs, meeting acceptance criteria as set forth ASTM 1612-95 (Reapproved 2005).

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 –WO66-G609
Silver Spring, MD 20993-0002

Biomet Manufacturing Corporation
% Ms. Becky Earl
Regulatory Specialist
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AUG 17 2012

Re: K120030
Trade/Device Name: Taperloc® Complete Size 4mm and XR 123°
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, KWZ, JDI, KWY, MEH, KWL, OQG
Dated: July 13, 2012
Received: July 16, 2012

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

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 D 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): K120030

Device Name: Taperloc® Complete Size 4mm and XR 123°

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 K120030