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K103755

BIOMET
MANUFACTURING CORP.

510(k) Summary

Preparation Date: December 22, 2010

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

Contact Person:
Becky Earl
Regulatory Specialist
Biomet Manufacturing Corp.
Phone: (574) 267-6639
Fax: (574) 372-1683
becky.earl@biomet.com

Proprietary Name: Taperloc® Complete, Sizes 5mm and 6mm

Common Name: Uncemented porous modular hip prosthesis.

Classification Code(s)/Name(s):
LZO - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
KWA - Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR §888.3330)
KWZ - Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR§888.3310)
JDL - Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR §888.3320)
JDI - Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3350)
MAY - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
MEH - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
LPH- Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR §888.3358)

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
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Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 E. Bell Drive
Warsaw, IN 46582

KWL - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR§888.3360)
LWJ - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR§888.3360)
KWY - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR §888.3390)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Taperloc® Complete, K101086

Device Description:

The Taperloc® Complete hip stems are a line extension of the legally marketed Taperloc® Complete stems cleared in K101086.

Intended Use:

The Taperloc® Complete hip stems are intended for uncemented biological fixation. This is the same intended use as the predicate Taperloc® stems cleared in K101086.

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 Taperloc® Complete, Size 5mm and 6mm hip stems are a line extension to the predicate Taperloc® hip stems cleared in K101086.. The subject stems are manufactured from the same materials, conforming to the same standards, as the predicate Taperloc® stems. The Indications for Use have remained the same.

Non-Clinical Testing:

Non-clinical fatigue testing was conducted to demonstrate that the modifications proposed in this submission raise no new issues of safety and effectiveness of the modified components as compared to the predicate hip stems.

Distal Pot Fatigue testing was conducted in accordance with ASTM F-1612-95, Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion. All components passed distal pot cyclic fatigue testing.

Proximal Pot Fatigue testing was conducted in accordance with ASTM F-2068-03 Standard Specification for Femoral Prostheses – Metallic Implants. All components passed distal pot cyclic fatigue testing.

Clinical Testing:

Clinical testing is not necessary to demonstrate substantial equivalence to the predicate components.

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

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Re: K103755
Trade/Device Name: Taperloc® Complete, Sizes 5mm and 6mm
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, LZO, KWZ, JDL, JDI, MAY, MEH, LPH, KWL, LWJ, KWY
Dated: December 22, 2010
Received: December 23, 2010

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.

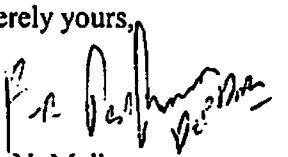
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



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

Enclosure

K103755

Indications for Use

510(k) Number (if known):_____

Device Name: Taperloc® Complete, Sizes 5mm and 6mm

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)

for M. Melkerson

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

510(k) Number K103755

3