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

February 22, 2015

Biomet, Incorporated
Ms. Becky Earl
Senior Regulatory Specialist
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581

Re: K140669
Trade/Device Name: G7 OsseoTi™ Acetabular Shells
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, OQG, KWZ, JDI, OQH, OQI, PBI
Dated: November 10, 2014
Received: November 12, 2014

Dear Ms. Earl:

This letter corrects our substantially equivalent letter of December 11, 2014.

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

for
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): K140669

Device Name: G7 OsseoTi™ Acetabular Shells

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 acetabular shells and femoral stems are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

Additional indications for Biomet G7 *Freedom™* Constrained Liners:
The Biomet G7 *Freedom™* Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability, and for whom all other options to constrained acetabular components have been considered.

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)

510(k) Summary

Preparation Date: December 10, 2014

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
Senior Regulatory Specialist
574-372-1518
Fax: 574-372-1683

Proprietary Name: G7 OsseoTi™ Acetabular Shells

Common Name: Acetabular Shells

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)

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

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)

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)

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

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

G7 Acetabular System—K121874 (Biomet)
Exactech Novation Crown Cup with InteGrip—K102975 and K122798 (Exactech)

Reference predicates include K122770, Biomet Reconstructive Wedges, which first introduced Biomet's additive manufacturing process and Regenerex Porous Titanium Acetabular Shells, K052996, which served as a comparison in unsupported fatigue testing.

Device Description:

The G7 OssetoTi™ Acetabular Shells are part of the G7™ Acetabular System, designed to provide numerous options for surgeons and patients in one modular compatible system. The OsseoTi™ Shell utilizes an outer surface porous region produced by additive manufacturing using titanium alloy powder (ASTM F2924). This structure leads to a highly interconnected volume of porosity and promotes biological fixation through tissue ingrowth. The shell is available in either a limited hole or multi-hole design. The inner diameter and locking mechanisms are identical to the previously cleared shells of the G7™ Acetabular System, K121874, and will be compatible with the G7™ Acetabular System's E1™ and ArComXL™ polyethylene acetabular liners, as well as all modular components and instrumentation included in K121874.

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Summary of Technologies:

The technological characteristics of the proposed devices, produced by additive manufacturing, are the same as or similar to the predicates. The outer porous structure of the OsseoTi™ shell is manufactured similarly to the Exactech Novation Crown Cup with InteGrip. The inner shell incorporates the G7™ acetabular shell design, dimensions, locking mechanisms, and intended use.

Non-Clinical Testing:

Previous testing was completed on the G7™ Acetabular System, K121874, to support substantial equivalence. The testing is applicable to the OsseoTi™ Shells as the sizing and mating features are identical.

New Testing on G7 OsseoTi™ Acetabular Shells:

- Deformation Testing
- Torsional Testing
- Fatigue Testing (both anatomic and unsupported fatigue)
- Poly Push Out Testing
- Poly Lever Out Testing
- Poly Torque Out Testing

OsseoTi™ Material Characterization:

- Chemical Composition
- Interconnected Porosity
- Average Pore Size
- Porosity Volume
- Roughness
- Tensile Adhesion
- Abrasion Resistance
- Static Shear Strength
- Shear Fatigue
- Compressive Strength
- Elastic Modulus

Other:

- Animal Data

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

The culmination of the results of the mechanical testing, OsseoTi characterization and animal data indicate that the devices perform within the intended use and are substantially equivalent to the predicate devices.