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

May 1, 2015

Biomet, Incorporated
Ms. Amy Walriven
Manager, Regulatory Affairs
56 East Bell Drive
Warsaw, Indiana 46581

Re: K150522
Trade/Device Name: G7 Dual Mobility System
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, OQG, KWY, LZO
Dated: February 27, 2015
Received: March 2, 2015

Dear Ms. Walriven:

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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150522

Device Name
G7 Dual Mobility System

Indications for Use *(Describe)*

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 of previously failed total hip arthroplasty.
6. Dislocation risks.

The Active Articulation Hip Bearings and G7 Metal Liners are single-use implants, intended for uncemented applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the G7 Dual Mobility system 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact:
Amy L Walriven
Manager, Regulatory Affairs
Phone: (574) 372-6660
Fax: (574) 372-1683

Date:
February 27, 2015

Subject Device:
Trade Name: G7 Dual Mobility System
Common Name: Acetabular Hip Replacement Components
Classification Name:

- LPH – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous, Uncemented (21 CFR 888.3358)
- OQG – Hip Prosthesis, Semi-Constrained, Cemented, Metal/Polymer + Additive, Porous, Uncemented (21 CFR 888.3358)
- KWY – Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented (21 CFR 888.3390)
- LZO – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353)

Legally marketed devices to which substantial equivalence is claimed:

- Biomet E1 Avantage Head (K101336)
- ArComXL Active Articulation Head (K110555)
- Stryker MDM (K103233)
- Biomet Tri-Polar (K991990) - Reference

Device Description

The G7 Dual Mobility system consists of two articulating surfaces in the same joint space. The proposed system includes an UHMWPE Active Articulation Bearing and Cobalt-Chromium Alloy (CoCr) Liner. A femoral head articulates on the inner, concave surface of the Active Articulation Bearing. Once the femoral stem contacts the Active Articulation Bearing, a secondary motion occurs between the Active Articulation Bearing and the CoCr Liner. The G7 Dual Mobility system

is designed for both primary and revision surgeries, where all device components associated with the wear couple are removed and replaced.

The proposed CoCr Liners are manufactured from cast Cobalt-Chromium-Molybdenum per ASTM F75. The proposed G7 Active Articulation Bearings are manufactured from E1® (aka E-Poly) or ArComXL highly cross-linked polyethylene per ASTM F648. The proposed Active Articulation Bearings are available in sizes 32 and 36mm with a 22.2mm inner diameter. The proposed CoCr Liners are available in sizes A-J (sizes 32-60mm).

The proposed CoCr Liners are compatible with the following devices:

- G7 Acetabular Shells - K121874 and K140669
- Biomet E1 Avantage Bearings (38-60mm) - K101336
- ArComXL Active Articulation Bearings (38-60mm) - K110555
- G7 Active Articulation Bearings (32 and 36mm) - included in this submission

The proposed Active Articulation Bearings are compatible with 22.2mm femoral heads (K974558/K030555).

Intended Use and 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 of previously failed total hip arthroplasty.
6. Dislocation risks.

The Active Articulation Hip Bearings and G7 Metal Liners are single-use implants, intended for uncemented applications.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The proposed G7 Dual Mobility system and predicate devices have the same intended use.
- **Indications for Use:** The proposed G7 Dual Mobility system and predicate devices have the same indications for use.
- **Materials:** The proposed Active Articulation Heads are composed of the same material (100 kGy E1® or ArComXL) as the predicate Biomet E1 Avantage (K101336) and ArComXL Active Articulation Heads (K110555). The proposed CoCr Liners are composed of the same material (Co-Cr-Mo) as the predicate Stryker MDM liner (K103233).
- **Design Features:** The proposed G7 Dual Mobility system incorporate similar design features as the predicate devices.

- **Sterilization:** The proposed G7 Dual Mobility system and the predicate devices are provided sterile for single-use.

Summary of Performance Data

Results from mechanical tests and engineering analyses demonstrate the proposed G7 Dual Mobility system is substantially equivalent to the predicate devices. No animal or clinical testing was required to support substantial equivalence. A description of these tests and analyses are listed below.

- Liner axial push-out per ASTM F1820, ASTM F2068 and ISO 7206-6
- Liner lever-out per ASTM F1820, ASTM F2068 and ISO 7206-6
- Liner torque per ASTM F1820, ASTM F2068 and ISO 7206-6
- Wear per engineering analysis
- Fretting and Corrosion per ASTM F1875
- Range of Motion per ISO 21535
- Rim Impingement per ASTM F2582
- Femoral head lever-out per Biomet standard
- Femoral head pull-out per ASTM F1820

Substantial Equivalence Conclusion

The proposed G7 Dual Mobility system has the same intended use and indications for use as the predicate devices. Performance test data and analyses demonstrate the device is as safe and effective and is substantially equivalent to the legally marketed predicate devices.