DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2016

Biomet, Incorporated
Ms. Emily Manuel
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581-0587

Re: K161190
Trade/Device Name: G7 Dual Mobility System, Active Articulation 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: April 25, 2016
Received: April 27, 2016

Dear Mr. Manuel:

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 Parts 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)*

K161190

Device Name
G7 Dual Mobility System
Active Articulation 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 expanded compatibility of the G7 Dual Mobility System and Active Articulation System 510(k) premarket notification.

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

Contact: Emily Manuel
Regulatory Affairs Specialist
Phone: (574) 371-9632
Email: Emily.manuel@zimmerbiomet.com

Date: April 25, 2016

Subject Device:
Trade Name: G7 Dual Mobility System
Active Articulation System
Common Name: Hip Prosthesis
Product Code(s): LPH, OQG, KWY, LZO
Regulation/Description:

- 21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
- 21 CFR 888.3390 – Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented
- 21 CFR 888.3353 – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented

Legally marketed devices to which substantial equivalence is claimed:

- G7 Dual Mobility System (K150522)
- E1 Avantage Heads (K101336)
- ArComXL Active Articulation Heads (K110555)

Device Description

The G7 Dual Mobility System and Active Articulation System are dual articulation systems wherein there are two articulating surfaces in the same joint space. The systems include an Active Articulation polyethylene (UHMWPE) bearing which is assembled over a femoral head. The femoral head articulates on the inner, concave surface of the bearing. The resultant assembly then articulates within a metal liner (G7 Dual Mobility System) or acetabular shell (Active Articulation System). The G7 Dual Mobility and Active Articulation Systems are designed for both primary and revision surgeries, where all device components associated with the wear couple are removed and replaced.

The Zimmer cobalt chrome and ceramic femoral heads are proposed as compatible femoral head components. As part of this additional compatibility, legally marketed Zimmer stem combinations will be included for system compatibility.

Intended Use and Indications for Use

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular
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 intended use of the proposed compatibility of the G7 Dual Mobility and Active Articulation Systems is identical to the intended use of the predicates. The intended use of the predicates is not impacted by the proposed expanded compatibility.
- **Indications for Use:** The indications for use of the proposed compatibility of the G7 Dual Mobility and Active Articulation Systems is identical to the indications for use of the predicates. The indications for use of the predicates is not impacted by the proposed expanded compatibility.
- **Materials:** The materials of the proposed compatible components of the G7 Dual Mobility and Active Articulation Systems are identical to the materials of the predicates. The materials of the predicates are not impacted by the proposed expanded compatibility.
- **Design Features:** The design features of the proposed compatible components of the G7 Dual Mobility and Active Articulation Systems are identical to the design features of the predicates. There have been no design changes to the originally cleared predicate devices as a result of the proposed expanded compatibility.
- **Sterilization:** Sterilizaiton methods and processes of the proposed compatible components of the G7 Dual Mobility and Active Articulation Systems is identical to the sterilization methods and processes of the predicates. Sterilization methods and processes are not impacted by the proposed expanded compatibility. Subject and predicate devices are provided sterile, single-use only.

Summary of Performance Data

Results from performance tests and engineering analyses demonstrate the subject G7 Dual Mobility and Active Articulation Systems, including proposed new compatible components, remain substantially equivalent to the systems cleared in K150522, K101336 and K110555. No

animal or clinical testing was required to support substantial equivalence. A description of the tests performed on the proposed compatibility is as follows:

- Wear Justification Reports – ISO 7206-2: 2011
- Interference Fit Analyses
- Push-in, Pull-out, Lever-out Analysis – ASTM F1820-13
- Range of Motion Analyses – ISO 21535:2007

Substantial Equivalence Conclusion

The proposed G7 Dual Mobility System and Active Articulation System have the same intended use and indications for use as the predicates. Performance test data and analyses demonstrate the proposed expanded compatibility is as safe and effective and is substantially equivalent to the legally marketed predicates.