Zimmer Inc.
Charles Neitzel
Senior Regulatory Affairs Specialist
P.O. Box 708
Warsaw, Indiana 46581-0708

December 6, 2019

Re: K190656
Trade/Device Name: Dual Mobility - Longevity and Vivacit-E Polyethylene Hip Bearings
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: November 6, 2019
Received: November 7, 2019

Dear Charles Neitzel:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FOR Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190656

Device Name

Dual Mobility - Longevity and Vivacit-E Polyethylene Hip Bearings

Indications for Use *(Describe)*

• Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
• Rheumatoid arthritis.
• Correction of functional deformity.
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
• Revision procedures where other treatment or devices have failed.
• Dislocation risks.

Dual Mobility Hip Bearings 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 Dual Mobility Longevity and Vivacit-E Hip Bearings 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:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person:

Charles Neitzel
Specialist, Regulatory Affairs
Telephone: (262) -716-3243
Fax: (574) 372-4605

Date:

13-March-2019

Subject Device:

Trade Name: Dual Mobility Longevity and Vivacit-E Polyethylene Hip Bearings

Common Name: Hip Prosthesis

Classification Name:

- LPH – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)
- OQG – Prosthesis, hip, semi-constrained, 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)

Predicate Device(s):

Primary Predicates

K161190	G7 Dual Mobility System, Active Articulation System	Biomet Inc.

Secondary Predicates

K151448	Continuum And Trilogy Integrated Taper (IT) Acetabular Systems	Zimmer Inc.
K120370	Continuum-Trilogy IT Acetabular System: Vivacit-E Vitamin E Highly Crosslinked Polyethylene IT Neutral and Elevated Liners	Zimmer Inc.

Purpose and Device Description:

The purpose of this subject 510(k) is to introduce a new set of acetabular bearings within the G7 Dual Mobility and Active Articulation Systems. There are no changes to the other components within the systems.

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 a 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.

Intended Use and Indications for Use:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Correction of functional deformity.
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- Revision procedures where other treatment or devices have failed.

- Dislocation risks.

Dual Mobility Hip Bearings 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:** Identical to the predicates
- **Indications for Use:** Same as the G7 Dual Mobility System and Active Articulation System predicates, similar to the Continuum/Trilogy IT predicate
- **Materials:** Same polyethylene material as the Continuum/Trilogy IT predicate
- **Design Features:** Identical to the G7 Dual Mobility System and Active Articulation System predicates, similar to the Continuum/Trilogy IT predicate
- **Sterilization:** Same as the Continuum/Trilogy IT predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:** Mechanical testing and engineering analysis was conducted to demonstrate that the modifications did not adversely affect safety and efficacy, and to demonstrate substantial equivalence to the predicate components. The test reports are listed below:
  - Push In / Pull Out Testing
  - Lever Out Testing
  - Anatomic Fatigue Testing
  - Rim Impingement Testing
  - Range of Motion Evaluation
  - Laser Etch Verification
  - Wear Justification
  - MRI compatibility
  - Shelf Life Justification
  - Dimensional Stability Justification
- **Clinical Tests:**
  - Clinical data was not deemed necessary for the subject device.

Substantial Equivalence

Conclusion	The subject device has the same intended use and the same indications for use as the G7 Dual Mobility System and Active Articulation System predicate devices. The subject device has similar technological characteristics to the predicates, and the performance data and analyses demonstrate that: • any differences do not raise new questions of safety and effectiveness; and • the proposed device is at least as safe and effective as the legally marketed predicate devices.