Zimmer, Inc.
% Dean Heit
Global Regulatory Affairs Project Manager
ZimmerBiomet
Waterton Ind Estate
Bridgend, CF31 3XA Gb

November 5, 2019

Re: K183457
Trade/Device Name: Zimmer Biomet 12/14 CoCr Femoral Head and Freedom Head
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, KWZ
Dated: October 4, 2019
Received: October 7, 2019

Dear Dean Heit:

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)*
K183457

Device Name
Zimmer Biomet 12/14 CoCr Femoral Heads and Freedom® Heads

Indications for Use *(Describe)*

• The Zimmer Biomet 12/14 CoCr Femoral Heads are intended for use in total and hemi arthroplasty* in primary and revision patients. Refer to the acetabular system and femoral stem package inserts for the full description of indications for the construct.

* Hemi-Arthroplasty indication is for use with Bipolar Systems only.

• The Zimmer Biomet 12/14 CoCr Freedom® Heads are intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. Refer to the acetabular system and femoral stem package inserts for the full description of indications for the construct.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 Zimmer Biomet 12/14 CoCr Femoral Head and Freedom® Head 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:

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Date:

12th December 2018

Subject Device:

Trade Name: Zimmer Biomet 12/14 CoCr Femoral Head and Freedom® Head

Common Name: Zimmer Biomet 12/14 CoCr Femoral Head and Freedom® Head

Classification Name: Zimmer Biomet 12/14 CoCr Femoral Head.

- 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 - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)

Classification Name: Zimmer Biomet 12/14 CoCr Freedom® Head.

- KWZ - Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)

Primary Predicate Device(s):	K953337 –	Beta Hip Prosthesis	Zimmer Inc.
	K142882	G7 Freedom® And Offset Liners, Freedom® Head, Size 32.	Biomet Inc.
Additional Predicates:	K121874 –	G7 Acetabular System.	Biomet Manufacturing Corp.

Purpose and Device Description:

This traditional 510(k) premarket notification is being submitted to obtain clearance for the Zimmer Biomet 12/14 CoCr Femoral Head and Freedom® Heads. The heads are made from Freedom® Heads cobalt-chromium-molybdenum alloy (CoCrMo) to ISO 5832-12:2007 and ASTM F1537-11.

Intended Use and Indications for Use:

The Zimmer Biomet 12/14 CoCr Femoral Heads are intended for use in total and hemi arthroplasty* in primary and revision patients. Refer to the acetabular system and femoral stem package inserts for the full description of indications for the construct.

* Hemi-Arthroplasty indication is for use with Bipolar Systems only.

The Zimmer Biomet 12/14 CoCr Freedom® Heads are intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. Refer to the acetabular system and femoral stem package inserts for the full description of indications for the construct.

Summary of Technological Characteristics:

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

- **Intended Use:** Equivalent to predicate(s).
- **Indications for Use:** Identical to predicate(s).
- **Materials:** Identical to predicate(s).
- **Design Features:** Both the subject and predicate devices mate with a variety of femoral stems equipped with tapered necks. The variety of head diameters and neck configurations is equivalent although the subject device is available in a larger range of sizes.
- **Sterilization:** Identical to predicate.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Pull Off Testing.
  - Accelerated Corrosion Fatigue.
  - Head Fatigue.
  - Resistance to Wear and Head Retention were considered.
- **Clinical Tests:**
  - N/A

Substantial Equivalence Conclusion

The subject device has the same intended use and equivalent indication for use as the predicate devices. The subject device is made of the identical material using a equivalent manufacturing process as the primary predicate device. In addition, the subject device has equivalent technological characteristics to the predicates and reference device. 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.