December 18, 2019

Zimmer, Inc.
% Neha Sreenath
Senior Specialist, Regulatory Affairs
Zimmer GmbH
Sulzerallee 8
WINTERTHUR 8404
SWITZERLAND

Re: K192189
Trade/Device Name: Avenir Complete Hip System, Size 0 Coxa Vara
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, KWY, KWZ, LWJ
Dated: December 4, 2019
Received: December 5, 2019

Dear Neha Sreenath:

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)*

K192189

Device Name

Avenir Complete™ Hip System, Size 0 Coxa Vara

Indications for Use *(Describe)*

Avenir Complete Hip System is intended for total or hemi hip arthroplasty and is indicated for the following conditions:

• Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
• Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemi-arthroplasty or total hip replacement (THR).
• Acute traumatic fracture of the femoral head or neck.
• Avascular necrosis of the femoral head.

Avenir Complete Hip System is for cementless use only.

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

Contact Person:
Neha Sreenath
Senior Specialist, Regulatory Affairs
Telephone: +41 58 854 88 14
Email: Neha.Sreenath@zimmerbiomet.com

Date: August 09, 2019

Subject Device:
Trade Name: Avenir Complete™ Hip System, Size 0 Coxa Vara
Common Name: Hip Prosthesis

Classification Name:
LZO - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR §888.3353).

MEH - Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium Phosphate (21 CFR §888.3353).

KWZ - Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer (21 CFR §888.3310).

KWY - Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented (21 CFR §888.3390).

LWJ - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (21 CFR §888.3360).

Legally Marketed Predicate Device to which Substantial Equivalence is claimed:	K182048 (cleared 12/07/2018)	Avenir Complete™ Hip System	Zimmer Inc.
Legally Marketed Reference Device used to support Substantial Equivalence:	K120030 (cleared 08/17/2012)	Taperloc Complete Size 4mm and XR 123°	Biomet Manufacturing Corp.

Purpose and Device Description:

The purpose of this 510(k) premarket notification is to introduce two Size 0 Coxa Vara Avenir Complete™ Hip System femoral stems; one with a collar and one without a collar. The stems are manufactured from a forged titanium alloy Ti-6Al-4V and feature a wedge-shaped design with a proximal-to-distal taper and reduced distal geometry. The Coxa Vara offset provides a 126.5° neck angle. Below the highly polished femoral neck region, the surface is grit-blasted and plasma sprayed with commercially pure titanium (CP-Ti) and hydroxyapatite (HA) coating. The stems are designed for cementless implantation into the proximal femur and mates with compatible femoral heads and adapters for use in total or hemi hip arthroplasty through a 12/14 male taper connection. The stems are provided sterile and are for single-use only.

Intended Use and Indications for Use:

Avenir Complete™ Hip System is intended for total or hemi hip arthroplasty and is indicated for the following conditions:

- Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
- Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemi-arthroplasty or total hip replacement (THR).
- Acute traumatic fracture of the femoral head or neck.
- Avascular necrosis of the femoral head.

Avenir Complete™ Hip System is for cementless use only.

Summary of Technological Characteristics:

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

- **Intended Use:** Identical to the predicate device.
- **Indications for Use:** Identical to the predicate device.
- **Design Features:** The proposed and predicate devices incorporate the same design features and fundamental scientific technology. Both stems mate with a variety of femoral heads and adapters equipped with 12/14 tapered necks. The stem length, femoral offset, and collared geometry are features existing in the predicate device.
- **Fixation Method:** Identical to the predicate device.
- **Materials:** The proposed and predicate devices are manufactured from Ti-6Al-4V alloy and plasma

sprayed with commercially pure titanium (CP-Ti) and hydroxyapatite (HA) using the same manufacturing processes.

- **Sterilization Method:** Identical to the predicate device.

Summary of Performance Data (Nonclinical and/or Clinical)

Non-Clinical Testing:
Non-clinical performance testing and engineering evaluations were conducted to verify that the performance of the proposed device is adequate for anticipated in-vivo use. Non-clinical testing carried out on the proposed device include distal stem fatigue testing and proximal stem fatigue testing. Testing demonstrated that the proposed device is not a new worst-case for proximal stem fatigue testing but presents a greater challenge to distal stem fatigue testing than the previously evaluated predicate Avenir Complete™ Hip System range (K182048). Nevertheless, the proposed device was determined to have a distal stem fatigue strength equivalent to the legally marketed reference device (K120030).

The following non-clinical testing is provided in this 510(k) to support substantial equivalence determination of the proposed device to the predicate device in terms of safety and performance:

1. Finite Element Analysis to identify the worst-case stem size for the mechanical fatigue testing
2. Distal Stem Fatigue Testing
3. Proximal Stem Fatigue Testing
4. Range of Motion Analysis
5. Pull-Off Strength Evaluation
6. Corrosion Fatigue Evaluation
7. Ti/HA Coating Characterization Evaluation
8. Magnetic Resonance Imaging Compatibility (MRI)

Clinical Testing:
Clinical data and conclusions were not needed for this device.

Substantial Equivalence Conclusion

The proposed device has the same intended use and indications for use as the predicate device. The proposed device uses the same operating principle, incorporates the same design and materials, and is manufactured and sterilized using the same manufacturing processes as the predicate device. Technological characteristics of the proposed device are the same as the predicate device and similar to the reference device, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness as established with performance testing; and
- the proposed device is at least as safe and effective as the legally marketed predicate device.