December 7, 2018

Zimmer, Inc.
% Neha Sreenath
Regulatory Affairs Specialist
Zimmer GmbH
Sulzerallee 8
Winterthur, 8404 Switzerland

Re: K182048
Trade/Device Name: Avenir Complete Hip System
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: November 1, 2018
Received: November 5, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2018.12.07 14:53:45 -05'00'

FOR 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182048

Device Name
Avenir Complete™ Hip System

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 Regulatory Affairs Specialist Telephone: +41 58 854 88 14
Date:	July 27, 2018
Subject Device:	**Trade Name:** Avenir Complete™ Hip System **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).
Predicate Device(s):	Primary Predicate Device: Avenir® Müller Stem, manufactured by Zimmer GmbH, K123392, cleared March 4, 2013. Additional Predicate Device: Corail AMT™ Hip Prosthesis, manufactured by DePuy Orthopaedics, Inc., K042992, cleared February 11, 2005

Purpose and Device Description:

Avenir Complete Hip System consists of femoral hip stems intended for use in total or hemi hip arthroplasty. The stem is 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 manufactured from a forged titanium alloy Ti-6Al-4V and have a wedge-shaped design, with a proximal-to-distal taper and a reduced distal geometry. Apart from the highly polished femoral neck region, the entire surface of the stem is grit-blasted and plasma sprayed with commercially pure titanium (CP-Ti) followed by hydroxyapatite (HA) coating. Offered in multiple sizes and neck lengths, the stems are available in Standard, High Offset, and Coxa Vara offsets and as collared or collarless stems in each offset to accommodate various patient anatomies. The hip stems are provided sterile and are for single-use only. System-specific instrumentation is available to prepare the femur for implantation of the Avenir Complete Hip System femoral stems.

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:

Avenir Complete Hip System has the same intended use and fundamental scientific technology as its predicate devices. The technological characteristics (material, sizing, indications, coating, design features, sterilization) of the Avenir Complete Hip System are substantially equivalent to the predicate devices. The differences in design have been demonstrated to not raise any new

concerns of safety or effectiveness through non-clinical performance data and analyses.

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

- Intended Use: Identical to the predicate devices.
- Indications for Use: Similar to the predicate devices.
- Overall Design: Similar to the predicate devices. Both the subject and predicate devices mate with a variety of femoral heads and adapters equipped with 12/14 tapered necks. The range of stem lengths, femoral offset options, and collared geometry is similar to the predicate devices.
- Fixation Method: Identical to the predicate devices.
- Materials: Similar to the predicate devices.
- Sterilization: Identical to the predicate devices.

Summary of Performance Data (Nonclinical and/or Clinical)

Non-Clinical Testing:
Non-clinical performance testing and evaluations have demonstrated that the Avenir Complete Hip System meets the performance requirements as defined by Design Control activities and supports its substantial equivalence claim to the predicate devices in terms of safety and performance. Therefore, the subject device is as safe and effective as the legally marketed predicates.

1. Finite Element Analysis for Fatigue Testing
2. Proximal Stem Fatigue Testing
3. Distal 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 subject device has the same intended use and similar indications for use as the predicate devices. The subject device is made of an identical material using a similar manufacturing process as the primary predicate device. In addition, the subject device has similar technological characteristics to the predicate devices, 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 subject device is at least as safe and effective as the legally marketed predicate device.