Zimmer GmbH
Melanie Mitrov
Regulatory Affairs, Specialist
Sulzerallee 8
Winterthur, 8404 Switzerland

December 6, 2019

Re: K193030
Trade/Device Name: Avenir Muller Stem, Avenir Cemented Hip Stem
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, KWY, KWZ, LWJ, MEH, KWL
Dated: October 24, 2019
Received: October 30, 2019

Dear Melanie Mitrov:

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,

Vesa Vuniqi,
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)*
K193030

Device Name
Avenir® Müller Stem

Indications for Use *(Describe)*

• Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
• Failed previous hip surgery (not THA) where pain, deformity, or dysfunction persists.
• Optional use in revision: in some medical conditions (e.g., early revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.
• Acute traumatic fracture of the femoral head or neck.
• Avascular necrosis of the femoral head.

Avenir® Müller Stems are 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*

K193030

Device Name
Avenir® Cemented Hip Stem

Indications for Use *(Describe)*

The product is intended for total or hemi hip arthroplasty with cemented applications for rehabilitating hips damaged as a result of:

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

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)

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510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Melanie Mitrov Specialist, Regulatory Affairs Telephone: +41 58 854 233 Fax: +41 58 854 233
Date:	November 20, 2019
Trade Name:	Avenir® Müller Stem Avenir® Cemented Hip Stem
Common Name	Femoral Stem
Classification Product Code :	LZO, KWY, KWZ, LWJ, MEH, KWL
Device Classification Name:	prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented prosthesis, hip, constrained, cemented or uncemented, metal/polymer prosthesis, hip, semi-constrained, metal/polymer, uncemented prosthesis, hip, semi-constrained, uncemented, metal / polymer, non-porous, calcium phosphate prosthesis, hip, hemi-, femoral, metal
Regulation Number / Description:	21 CFR § 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR § 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. 21 CFR § 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis. 21 CFR § 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis. 21 CFR § 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR § 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.
Primary Predicate Device:	Avenir® Müller Stem, manufactured by Zimmer GmbH, K123392, cleared March 2013

Reference Device:

Subject Device	Reference Device
Avenir® Cemented Hip Stem (K193030) only.	Avenir® Cemented Hip Stem, manufactured by Zimmer GmbH, K131884, cleared August 2013.

Device Description:

The Avenir® Müller Stem is a titanium alloy femoral stem designed to replace the proximal femur in total or hemi-hip arthroplasty. It is a wedge-shaped, collarless design and features a three dimensional proximal-to-distal taper. The stem and neck are a single unit and the stem features proximal ribs on the anterior and posterior surfaces which are designed to increase stability. Except for the polished neck area, the surface of the stem is coated with Ti-6Al-4V titanium alloy plasma spray and oversprayed by a hydroxyapatite coating. The stem is available as both a lateralized and standard version.

The Avenir® Cemented Hip Stem is a stainless steel alloy femoral stem designed to replace the proximal femur in total or hemi-hip arthroplasty. It is a wedge-shaped, collarless design and features a three dimensional proximal-to-distal taper. The stem and neck are a single unit. The stem is highly polished and available as both a lateralized and standard version.

Intended Use

Avenir® Müller Stem is intended for:

- Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
- Failed previous hip surgery (not THA) where pain, deformity, or dysfunction persists.
- Optional use in revision: in some medical conditions (e.g., early revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.
- Acute traumatic fracture of the femoral head or neck.
- Avascular necrosis of the femoral head.

Avenir® Müller Stems are for cementless use only.

The Avenir® Cemented Hip Stem is intended for total or hemi hip arthroplasty with cemented applications for rehabilitating hips damaged as a result of:

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

Comparison to Predicate Device:

The intended use of the modified devices, as described in its labeling, has not changed as a result of the modifications proposed in the

present submission. Zimmer GmbH proposes modification of the indications for use thereby limiting the indications within those of the previously cleared devices. Modification of the packaging configuration for the subject implant devices is proposed. The new packaging configuration and the methods to support the package integrity have been previously described in K182048 (Avenir Complete Hip System). The proposed changes do not alter the fundamental scientific technology shared by both the subject devices and predicate device. Zimmer GmbH is furthermore seeking clearance for certain system-specific Class II instruments - these instruments that have previously considered Class I exempt and correction of classification to Class II is proposed within present submission.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Packaging configuration change:

Packaging performance testing was performed to verify that packaging configuration maintains integrity of the sterile barrier system up to the point of use and provides adequate protection to the product through the hazards of sterilization, handling, distribution and storage according to ISO 11607-1:2006 and ISO 11607-2:2006. Packaging Configuration testing was conducted by representative worst-case products.

Correction of instrument classification from Class I to Class II:

Amendment of Design Controls with verification of mechanical integrity and resistance.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion:

The subject devices have the same intended use and similar indications for use as the predicate device. The subject devices use the same operating principle, incorporate the same basic design and labelling and are manufactured and sterilized using the same materials and processes as the predicate device.

Except for the modifications described in this submission the subject devices are identical to the predicate 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 subject devices are at least as safe and effective as the legally marketed predicate device.