April 27, 2026

Zimmer, Inc.
Ana Montoya
Regulatory Affairs Specialist
1800 W Center St.
Warsaw, Indiana 46580

Re: K260182
Trade/Device Name: Avenir® Müller Stem; 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, KWL, KWY, KWZ, LWJ, MEH
Dated: January 21, 2026
Received: January 21, 2026

Dear Ana Montoya:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

LIMIN SUN -S

Limin Sun, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260182

Device Name
Avenir® Müller Stem

Indications for Use *(Describe)*
The Avenir Müller Uncemented Hip Stems are intended for cementless use in total or hemi hip arthroplasty and are indicated for the following conditions:
• Noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g. rheumatoid arthritis.
• Acute traumatic fracture of the femoral head or neck.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260182

Device Name
Avenir Complete™ Hip System

Indications for Use *(Describe)*
The Avenir Complete Hip System is intended for cementless use in in total or hemi hip arthroplasty and is indicated in 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

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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ZIMMER BIOMET

510(k)Summary Prepared on: 2026-04-24

Contact Details

Applicant Name: Zimmer, Inc
Applicant Adress: 1800 W Center Street Warsaw IN 46580 United States
Applicant Contact Telephone: +57 3193346263
Applicant Contact: Ms. Ana Montoya
Applicant Contact Email: ana.montoya@zimmerbiomet.com

Device Name: Avenir® Müller Stem
Avenir Complete™ Hip System
Common Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Classification Name: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
Regulation Number: 888.3353
Product Code(s): LZO, KWL, KWY, KWZ, LWJ, MEH

Legally Marketed Predicate Devices

The predicate devices for subject device of this submission are listed in Table 1

Table 1. Predicate Devices for Avenir Müller® Stem and Avenir Complete™ Hip System.

	Device Name	Manufacturer	510(k) Number
Primary Predicate	Avenir® Müller Stem	Zimmer Switzerland Manufacturing GmbH	K193030
Additional Predicate	Avenir Complete™ Hip System	Zimmer, Inc.	K182048
Additional Predicate	Avenir Complete™ Hip System - Size 0 Coxa Vara Stems	Zimmer, Inc.	K192189
Reference Device(s)	Avenir® Müller Stem (MR Labeling)	Zimmer Switzerland Manufacturing GmbH	K200112

Device Description Summary

Reason for Submission

This submission requests the addition of a second production line (Line B) at supplier Medicoat S.A.S (formerly Zimmer Etupes, France) for cleaning, porous coating (Commercially Pure-Titanium), hydroxyapatite (HA) coating, and packaging of the subject Avenir Müller® Stem and Avenir Complete™ Hip System.

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510(k)Summary

The Avenir Stems are intended for use in total or hemi hip arthroplasty. These stems are designed for cementless implantation into the proximal femur to replace the damaged or diseased natural joint. The stems are manufactured from a titanium alloy Ti-6Al-4V (Protasul-64WF).They have a wedge-shaped design with a 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. The Avenir Stems are provided sterile and are for single use only. System specific instrumentation is available to prepare the femur for implantation of the Avenir femoral stems.

Intended Use/Indications for Use

Avenir® Müller Stem:

The Avenir Müller Uncemented Hip Stems are intended for cementless use in total or hemi hip arthroplasty and are indicated for the following conditions:

- Noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g. rheumatoid arthritis.
- Acute traumatic fracture of the femoral head or neck.

Avenir Complete™ Hip System:

The Avenir Complete Hip System is intended for cementless use in in total or hemi hip arthroplasty and is indicated in 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

Indications for Use Comparison

The subject devices have the same intended use and indications for use as the predicate devices.

Technological Comparison

The subject device has similar technological characteristics as the identified predicate devices. The rationale for substantial equivalence is based on consideration of the following characteristics:

- Materials: Identical to predicate devices.
- Design Features: Identical to predicate devices.
- Sterilization: Identical to predicate devices.
- Air Plasma Spray Coating: Similar to primary predicate device.

Any minor differences are addressed via predicate device and / or performance testing, and do not raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

- Distal Fatigue testing of Avenir® Müller Stem and Avenir Complete™ Hip System per ISO 7206-

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510(k)Summary

4; and
- Coating Characterization of the dual CP-Ti/HA) coating
- No clinical testing was required to support substantial equivalence.

Conclusion

The subject Avenir Müller Stem and Avenir Complete Hip System have the same intended use and indications for use as the predicate devices. The differences in technological characteristics between the subject and the predicate devices do not raise new questions of safety and effectiveness. The performance testing and information provided demonstrate that the subject devices are substantially equivalent to the predicate devices.