June 16, 2026

Zimmer, Inc.
Sean Gleason
Regulatory Affairs Manager
1800 W. Center St.
Warsaw, Indiana 46580

Re: K260831
Trade/Device Name: Z1 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, KWZ, KWY, LWJ
Dated: May 18, 2026
Received: May 18, 2026

Dear Sean Gleason:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260831

Device Name
Z1 Hip System

Indications for Use *(Describe)*
Z1 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.

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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K260831
510(k) SUMMARY
Zimmer, Inc., Z1 Hip System

Date Prepared	June 15, 2026
Sponsor	Zimmer, Inc. 1800 W. Center Street Warsaw, IN 46580 Establishment Registration Number: 1822565
510(k) Contact	Sean Gleason Regulatory Affairs Manager Sean.gleason@zimmerbiomet.com Telephone: (220) 219-8092
Trade Name	Z1 Hip System
Common Name	Hip Joint Prosthesis
Product Code-Device Regulation Number	LZO - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) MEH – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) KWZ – Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310) KWY – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390) LWJ – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360)
Predicate Device	Primary Predicate: K251906, Z1 Hip System Additional Predicate: K233476, Z1 Hip System
Device Description	The Z1 Hip System consists of femoral hip stems intended for use in total or hemi hip arthroplasty. The stem is designed for cementless implantation in 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 either a forged titanium alloy Ti-6Al-4V or wrought titanium alloy Ti-6Al-4V bar stock and have a wedge-shaped design with a proximal-to-distal taper. Apart from the highly polished neck region and the taper, the entire surface of the stem is grit-blasted, proximally sprayed with a Ti-6Al-4V titanium alloy plasma coating (TPS), and followed by as hydroxyapatite (HA) overcoat. 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 Z1 Hip Stems are provided sterile and are for single use only. System-specific instrumentation is available to prepare the femur for implantation of the Z1 Hip System femoral stems. The stems are compatible with previously cleared Zimmer Biomet modular femoral heads, taper adapters, and/or acetabular components. The purpose of this Premarket Notification (510(k)) is to introduce an additional HA and TPS coating suppliers and an additional gamma sterilization supplier for the Z1 stems manufactured from wrought bar stock.

Indications for Use Statement	Z1 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.
Indications for Use Comparison	The indications for use of the subject device and predicate device are identical.
Technological Comparison	The technological characteristics of the subject device and predicate device are identical in design specification.
Non-Clinical and/or Clinical Tests Summary	The following nonclinical tests and engineering rationales were provided to support the determination of substantial equivalence between the subject devices and the predicate devices: - Distal stem fatigue testing per ISO 7206-4 - Dual coating characterization - Range of Motion (ROM) per ISO 21535 - Corrosion performance rationale - Femoral head disassembly performance rationale
Conclusion	Based on the information provided in this submission, the Z1 Hip System is substantially equivalent to the identified predicate devices.