February 4, 2026

Zimmer, Inc.
Serena Guiducci
Regulatory Affairs Project Manager
1800 W. Center Street
Warsaw, Indiana 46580

Re: K252623
Trade/Device Name: G7® Revision Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, KWZ, LZO, OQG, OQH, OQI, PBI
Dated: January 5, 2026
Received: January 5, 2026

Dear Serena Guiducci:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

RYAN TROMBETTA -S

For: 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)*
K252623

Device Name
G7® TM Acetabular System

Indications for Use *(Describe)*
The G7® TM Acetabular System is intended for total hip arthroplasty in skeletally mature patients for the following indications:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
• Revision procedures where other treatment or devices have failed

Porous acetabular shells and femoral stems are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

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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"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."

K252623
510(k) SUMMARY
Zimmer, Inc., G7® TM Acetabular System

Date Prepared	February 3, 2026
Sponsor	Zimmer, Inc. 1800 W. Center Street Warsaw, IN 46580 Establishment Registration Number: 1822565
510(k) Contact	Serena Guiducci Regulatory Affairs Project Manager serena.guiducci@zimmerbiomet.com Telephone: +447813565276
Trade Name	G7® TM Acetabular System
Common Name	Hip Joint Prosthesis
Product Code-Device Regulation Number	LPH - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358) KWZ - Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310) LZO - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) OQG - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358) OQH - Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350) OQI - Hip Joint Metal/ceramic/polymer Semi-constrained Cemented Or Nonporous Uncemented Prosthesis (21 CFR 888.3353) PBI - Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
Predicate Device	K140669 Zimmer, Inc. G7® OsseoTi Acetabular Shells
Reference Device	K091508/K101229/K103662/K151448/K200823 Biomet Orthopedics, Continuum® Multi-Hole Acetabular Shell
Device Description	The G7® TM Acetabular System consists of a Trabecular Metal® coated acetabular shell, available in multi screw hole patterns, and Rim Fix™ screws. The G7® TM Acetabular System is intended for use without bone cement in total hip arthroplasties. This system provides surgeons with multiple acetabular implant options to address a range of patient anatomies. The G7® TM acetabular shells are made from Tivanium® (Ti-6Al-4V ELI Alloy) as per ASTM F136-13 with a porous Tantalum pad (Trabecular Metal®) per ASTM F560-22 that is diffusion bonded to the exterior of the shell. The subject shells are designed to be compatible with the existing G7® acetabular liners and other accessories and instruments provided in the G7® Acetabular System platform. The Rim Fix™ screws are self-tapping screws made from the same material of the shell, Tivanium® (Ti-6Al-4V Alloy) per ASTM F136-13. The subject screws are designed for use in the perimeter of the G7® TM acetabular shell rim to provide additional inferior fixation. The subject implants are provided sterile and are for single-use only.

	Existing instrumentation is used to prepare the bone and facilitate insertion of the subject shells and screws. The new instrumentation is used to facilitate the implantation of the subject screws.
Indications for Use Statement	The G7® TM Acetabular System is intended for total hip arthroplasty in skeletally mature patients for the following indications: • Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis • Rheumatoid arthritis • Correction of functional deformity • Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques • Revision procedures where other treatment or devices have failed Porous acetabular shells and femoral stems are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

Technological Comparison
The subject and predicate devices share the same intended use, indications for use, and sterilization, and have similar materials and design. The differences in technological characteristics do not introduce new questions of safety and effectiveness.

Non-Clinical Performance tests
• Acetabular Shell Unsupported Fatigue Testing (ASTM F3090-24)
• Fretting Corrosion Testing (ASTM F1875-98)
• Range of Motion (ROM) (ISO 21535:2023)
• Dual Mobility Liner Disassembly Testing (ASTM F1820-22)
• Wear Testing (ISO 14242-1:2014)
• MRI Safety Testing (ASTM F2182-2019e2, ASTM F2052-21, ASTM 2213-17, ASTM F2119-24, ASTM F2503-23e1)
• Shell Deformation Testing (ISO 7206-12:2016)
• Polyethylene Liner Disassembly rationale
• Freedom Constrained Liner Disassembly rationale
• Impingement Performance rationale
• Augment Fatigue Performance rationale
• Screw Insertion and Removal Torque and Pull-Out and Pull-Through Testing (ASTM F543-23:2023)
• Screw Micromotion Testing (ASTM F1839-08:2021, ASTM F3090-24:2024)
• Trabecular Metal (TM) Coating Characterization

Conclusion
The subject G7® TM Acetabular System has the same intended use/indications for use and the same or similar technological characteristics compared to the legally marketed predicate devices. The information included in this submission demonstrates that the subject G7® TM Acetabular System is substantially equivalent to the legally marketed predicate devices.