



September 23, 2026

Zimmer Biomet
Nicole Meredith
Regulatory Affairs Principal
1800 W. Center St.
Warsaw, Indiana 46580

Re: K261453

Trade/Device Name: G7® 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, JDI, LZO, OQG, OQH, OQI

Dated: September 11, 2026

Received: September 11, 2026

Dear Nicole Meredith:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261453

?

Please provide the device trade name(s).

?

G7® Acetabular System

Please provide your Indications for Use below.

?

- Noninflammatory 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use ([21 CFR 801 Subpart D](#))
☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
☐ Infants (29 days old to < 2 years old)
☐ Children (2 years old to < 12 years old)
☐ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

?



510(k) Summary

Sponsor: Zimmer Inc.
1800 W. Center St
Warsaw, IN 46580

Contact Person: Nicole J. Meredith
Regulatory Affairs Principal
Telephone: 419-509-0897
Email: nicole.meredith1@zimmerbiomet.com

Date Prepared: May 1, 2026

Subject Device: **Trade Name:** G7 Acetabular System

Common Name: Hip Prosthesis

Classification Name:

- LPH— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)
- JDI— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350)
- LZO—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353)
- OQG—Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (21 CFR 888.3358)
- OQH—Hip, semi-constrained, cemented, metal/polymer + additive, cemented (21 CFR 888.3350)
- OQI—Hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented (21CFR 888.3353)

Predicate Device: K190660 – G7 Acetabular System, Zimmer, Inc.

Reference Devices: K990135 – Trilogy Longevity, Zimmer, Inc.
K042989 – RingLoc RX90 Low Profile Acetabular System, Biomet, Inc.

Purpose and Device Description: The purpose of this subject 510(k) is to introduce three new acetabular liners within the G7 Acetabular System. These new liners are manufactured from Vivacit-E® VEHXPE and available in a neutral



configuration only; no new constrained liners are being proposed within this submission.

In addition, this 510(k) proposes updates to the MR conditional labeling content of the IFU for the G7 Acetabular System Longevity® and Vivacit-E® Liners, previously cleared under K190660 on December 5, 2019, which is the same IFU that will be used for the subject new G7 liners.

Intended Use and Indications for Use:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. 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.

Summary of Technological Characteristics:

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

- **Intended Use:** Identical to the predicate
- **Indications for Use:** Identical to the predicate
- **Materials:** Identical to the predicate
- **Design Features:** Similar to the predicate
- **Sterilization:** Identical to the predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
 - Push-Out Testing per ASTM F1820
 - Lever-Out Testing per ASTM F1820
 - Torque-Out Testing per ASTM F1820
 - Anatomic Fatigue Testing
 - Lever-Out Fatigue Testing per ASTM F1820



- Wear Testing / Assessments per ISO 21535 and ISO 14242 series
 - Rim Impingement Analysis per ASTM F2582
 - Range of Motion Assessment per ISO 21535
 - MR Compatibility per ASTM F2182, ASTM F2052, ASTM F2213, and ASTM F2119
- **Clinical Tests:**
 - Clinical data was not deemed necessary for the subject device.

Substantial Equivalence Conclusion

The subject device has the same intended use and indications for use as the predicate device. The subject device has similar technological characteristics to the predicate, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness; and
- the subject device is at least as safe and effective as the legally marketed predicate devices.