July 31, 2025

Zimmer Biomet
Sean Gleason
Regulatory Affairs Manager
1800 W Center Street
Warsaw, Indiana 46580

Re: K243571
Trade/Device Name: Trabecular Metal Acetabular Revision System, Acetabular Liners and Constrained Liners
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, KWZ
Dated: July 1, 2025
Received: July 1, 2025

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 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,

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.

Submission Number *(if known)*

K243571

Device Name

Trabecular Metal Acetabular Revision System, Acetabular Liners and Constrained Liners

Indications for Use *(Describe)*

Acetabular Liners:
The Trabecular Metal™ Revision Shell Liner is indicated for cemented use in the Trabecular Metal Revision Shell for initial placement or as an in situ replacement polyethylene bearing surface for joint instability,wear and/or damage.

Constrained Liners:
The Trabecular Metal Acetabular Revision System Cemented Constrained Liner is intended to be cemented into a Trabecular Metal Acetabular Revision System shell; the shell is intended for cementless fixation into the acetabulum. The Trabecular Metal Acetabular Revision System Cemented Constrained Liner is indicated for use as a component of a total hip prosthesis in complex primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

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."

510(k) Summary

Applicant:

Zimmer, Inc.
1800 W. Center Street
Warsaw, IN 46580, USA
Establishment Registration Number: 1822565

Contact Person:

Sean Gleason
Regulatory Affairs Manager
Telephone: 220-219-8092
Email: sean.gleason@zimmerbiomet.com

Date:

July 31, 2025

Subject Device:

Trade Name: Trabecular Metal Acetabular Revision System, Acetabular Liners and Constrained Liners
510(k) Number: K243571
Common Name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
Classification Name & Product Code:
JDI: Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)
KWZ: Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)

Predicate Device(s):

Primary Predicate 510(k): K051516
Predicate Trade Name: Trabecular Metal Revision Shell Liners
Product Code: JDI

Additional Predicate 510(k): K072121
Predicate Trade Name: Trabecular Metal Acetabular Revision System Cemented Constrained Liner
Product Code: KWZ

Device Description Summary:

The Trabecular Metal Acetabular Revision System (TMARS) Acetabular Liner and Cemented Constrained Liner are polyethylene/ metal acetabular liners, which, when used with a Trabecular Metal Acetabular Revision System Shell, forms the acetabular component of a total hip prosthesis. The acetabular liner constructs are manufactured from Longevity highly cross-linked ultra-high molecular weight polyethylene (UHMWPE). The cemented constrained liners are manufactured from Longevity highly cross-linked UHMWPE and contain a titanium alloy constraining ring. All devices in the scope of this 510(k) are sterile, single-use items.

Intended Use/ Indications for Use:

Acetabular Liners:
The Trabecular Metal™ Revision Shell Liner is indicated for cemented use in the Trabecular Metal Revision Shell for initial placement or as an in situ replacement polyethylene bearing surface for joint instability, wear and/or damage.

Constrained Liners:
The Trabecular Metal Acetabular Revision System Cemented Constrained Liner is intended to be cemented into a Trabecular Metal Acetabular Revision System shell; the shell is intended for cementless fixation into the acetabulum. The Trabecular Metal Acetabular Revision System Cemented Constrained Liner is indicated for use as a component of a total hip prosthesis in complex primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

Indications for Use Comparison:

The subject device has the same intended use and indications for use as the predicates.

Technological Comparison:

The technological characteristics of the subject device and predicate device are similar. The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Identical to the predicate device
- **Indications for Use:** Identical to the predicate device
- **Raw Materials:** Identical to the predicate device
- **Design Features:** Identical to the predicate device
- **Packaging:** Identical to the predicate device
- **Sterilization:** Different sterilization method, however sterility assurance level is identical to the predicate

Non-Clinical and/or Clinical Tests Summary & Conclusions:

The following non-clinical testing and assessments were performed to support substantial equivalence:

- Lever Out (TMARS Constrained Liner)
- Liner and Shell Torque-Out (TMARS Liner and Constrained Liner)
- Dynamic Impingement (TMARS Liner and Constrained Liner)
- Liner Push-Out (TMARS Liner and Constrained Liner)
- Liner-Head Pull Out (TMARS Constrained Liner)
- Polyethylene Liner Wear (TMARS Liner and Constrained Liner)
- Range of Motion (TMARS Liner and Constrained Liner)

No clinical testing was conducted.

Biocompatibility testing on the TMARS Liners and Constrained Liners was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed with no unexpected results.

The TMARS Liners and Constrained Liners conform to the material properties of ASTM F648. The material properties of the subject device are comparable to the predicate devices.

All non-clinical testing and assessments demonstrated that the new device is substantially equivalent to the predicate device.

Substantial Equivalence Conclusion:

Based on the information provided in this submission, the Trabecular Acetabular Revision System, Acetabular Liners and Constrained Liners is substantially equivalent to the identified predicate device.