August 24, 2026

Biomet Orthopedics, Inc.
Ainsley Carne
Senior Specialist, Regulatory Affairs
56 E. Bell Dr.
Warsaw, Indiana 46582

Re: K253515
Trade/Device Name: Zimmer Biomet OSS™ Orthopedic Salvage System OsseoTi® Sleeves and Augments
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, LPH, KRO
Dated: July 24, 2026
Received: July 24, 2026

Dear Ainsley Carne:

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,

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

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.	K253515

Please provide the device trade name(s).

Zimmer Biomet OSS™ Orthopedic Salvage System OsseoTi® Sleeves and Augments

Please provide your Indications for Use below.

OSS System Indications:

• Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.
• Correction of varus, valgus, or posttraumatic deformity.
• Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
• Ligament deficiencies.
• Tumor resections.
• Treatment of non-unions, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
• Revision of previously failed total joint arthroplasty.
• Trauma.

These devices are to be used with bone cement unless composed of OsseoTi® titanium alloy or a proximal femur is indicated for use (USA).

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

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

510(k) #: K253515

510(k) Summary

Prepared on: 2026-08-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biomet Orthopedics
Applicant Address	56 East Bell Drive Warsaw IN 46582 United States
Applicant Contact Telephone	574-527-6823
Applicant Contact	Mrs. Ainsley Carne
Applicant Contact Email	ainsley.carne@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Zimmer Biomet OSS™ Orthopedic Salvage System OsseoTi® Sleeves and Augments
Common Name	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
Classification Name	Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulation Number	888.3350
Product Code(s)	JDI, LPH, KRO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K141331	Biomet Orthopedic Salvage System (OSS™) Product Line Extension	JDI
K142814	Biomet Orthopedic Salvage System, Proximal Femoral and Hybrid Tibial Components	JDI

Device Description Summary

21 CFR 807.92(a)(4)

The proposed modifications to the subject components are manufacturing process changes, specifically 1) Transfer of additive manufacturing from an external vendor to West Campus, 2) Transfer of end-of-line processes from North Campus to West Campus, 3) Updates to packaging configuration as part of cost savings, and one design change 4) Reduction in OsseoTi thickness from between 2-4mm to 1.5mm.

1) Transfer of additive manufacturing
2) Transfer of end-of-line processes
3) Packaging configuration updates
4) OsseoTi thickness reduction

The Zimmer Biomet Orthopedic Salvage System (OSS™) offers a variety of component options for treatment of patients that require proximal femoral, distal femoral, total femur, or proximal tibial replacements, as well as resurfacing components for the proximal tibia and distal femur. The OSS System offers the surgeon treatments for patients presenting bone loss and deformity associated with bone tumors resection, trauma, and difficult revision arthroplasty. The OSS OsseoTi Sleeves and Augments offer a variety of component options for the treatment of patients that require proximal tibial replacements and resurfacing components for the proximal tibia and distal femur. These components are available in various designs and sizes intended to address a range of patient anatomies.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

OSS System Indications:

• Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.
• Correction of varus, valgus, or posttraumatic deformity.
• Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
• Ligament deficiencies.
• Tumor resections.
• Treatment of non-unions, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
• Revision of previously failed total joint arthroplasty.
• Trauma.

These devices are to be used with bone cement unless composed of OsseoTi® titanium alloy or a proximal femur is indicated for use (USA).

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Indications for Use are identical between the Subject and Predicate components.

Technological Comparison 21 CFR 807.92(a)(6)

The subject, predicate, and reference components are all sleeves and augments. The design features are all identical apart from the OsseoTi thickness (previously 2-4mm, now 1.5mm). The manufacturing process is similar to the predicate/reference, save for the transfer of lower level processing in-house and an upper level processing transfer from North Campus to West Campus.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

OsseoTi Lattice Characterization for Renishaw RENAM 500Q 60-Micron Layer Height Direct Metal Laser Sintering Process (ASTM F1147, ASTM F1044, ASTM F1978, ASTM F1854, ASTM F1160, ASTM F3001)

OSS OsseoTi Augment – Proximal Femoral Connection Loading (ISO 7206-4)

Manufacturing Validations of OSS OsseoTi (ASTM F3001, ASTM F1854, ASTM E8/E8M, ASTM E539, ASTM E1409, ASTM E1447, ASTM E1941, ASTM E2371)

Elma 5-Stage Central Cleaning Validations (ISO 10993-5)

Dry Heat Biological Upgrade Validations

Clinical testing not applicable.

The proposed device has the same intended use as the predicate(s). The proposed device has similar technological characteristics to the predicate(s), and the information provided herein demonstrates that:
• any differences do not raise new questions of safety and effectiveness; and
• the proposed device is at least as safe and effective as the legally marketed predicate device(s).