July 1, 2026

Biomet, Inc.
Yoriko Kobayashi
Regulatory Affairs Principal
56 E Bell Dr.
Warsaw, Indiana 46581

Re: K253434
Trade/Device Name: OSS™ Orthopedic Salvage System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, KRO
Dated: June 2, 2026
Received: June 3, 2026

Dear Yoriko Kobayashi:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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.	K253434

Please provide the device trade name(s).

OSS™ Orthopedic Salvage System

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 (not licensed in Canada) or a proximal femur is indicated for use (USA).

Zimmer Biomet OSS Reduced size (RS) components offers a variety of component options for treatment in small adults and adolescents (12-21 years) that require proximal femoral, distal femoral, total femur, or proximal tibial replacement as well as, resurfacing components for the proximal tibia and distal femur (Solely indicated for the USA).

* Not applicable to Regenerex® Ultra Porous Construct titanium knee augment usage (not licensed in Canada), or any other knee component.

Compress System Indications:
The Compress Segmental Femoral Replacement System is indicated for:
• Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
• Tumor resections.
• Revision of previously failed total joint arthroplasty.
• Trauma.

The Compress Segmental Femoral Replacement System components are intended for uncemented use.

When components of the OSS System are used with Zimmer Biomet Compress Segmental Femoral Replacement System, the user should refer to the package insert of the Zimmer Biomet Compress Segmental Femoral Replacement System components for information.

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) #: K253434

510(k) Summary

Prepared on: 2026-06-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BIOMET, INC.
Applicant Address	56 E Bell Dr Warsaw IN 46581 United States
Applicant Contact Telephone	1-800-613-6131
Applicant Contact	Yoriko Kobayashi
Applicant Contact Email	yoriko.kobayashi@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OSS™ Orthopedic Salvage System
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, KRO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K123501	Orthopedic Salvage System (OSS)	JDI

Device Description Summary

21 CFR 807.92(a)(4)

The OSS™ Orthopedic Salvage System 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. Zimmer Biomet OSS Modular Arthrodesis System and specialty components hip soft tissue claws are also used with the Zimmer Biomet OSS Orthopedic Salvage System.

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. *
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(12-21 years) that require proximal femoral, distal femoral, total femur, or proximal tibial replacement as well as, resurfacing components for the proximal tibia and distal femur (Solely indicated for the USA).

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• Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
• Tumor resections.
• Revision of previously failed total joint arthroplasty.
• Trauma.

The Compress Segmental Femoral Replacement System components are intended for uncemented use.

When components of the OSS System are used with Zimmer Biomet Compress Segmental Femoral Replacement System, the user should refer to the package insert of the Zimmer Biomet Compress Segmental Femoral Replacement System components for information.

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

The indications for Use are same between the predicate and the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technical characteristics such as design, material, chemical composition, and principal of operation. The modification proposed in this notification is to the manufacturing process of the devices, and non-clinical tests demonstrates the proposed device is as safe and effective as the predicate devices.

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

Process validations are completed for the proposed manufacturing process changes to confirm that the proposed processes will produce parts meeting the existing product specifications. Device performance (fatugue strength), biological safety and cleaning of the devices have been evaluated and reviewed for potential impact due to the proposed changes. It concluded that there is no significant impact to safety and effectiveness of devices due to the changes.

Clinical testing not applicable.

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