



September 24, 2026

Zimmer, Inc.
Alexandria Irwin
Regulatory Affairs Sr Specialist
1800 W. Center St.
Warsaw, Indiana 46580

Re: K262955

Trade/Device Name: OsseoFit Stemless Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: August 24, 2026
Received: August 24, 2026

Dear Alexandria Irwin:

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,

Joseph P. Russell -S

for: Farzana Sharmin, PhD

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.

K262955

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Please provide the device trade name(s).

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OsseoFit Stemless Shoulder System

Please provide your Indications for Use below.

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Implant Indications:

Anatomic Total Shoulder Applications:

- Osteoarthritis
- The patient must be anatomically and structurally suited, as evident by scapula and proximal humerus closure, to receive the implants.

OsseoFit® Stemless Shoulder humeral components have a porous surface and are indicated for uncemented biological fixation applications

Compatible Glenoid components are intended to be implanted with bone cement. The porous posts may be inserted without bone cement.

Compatible Convertible Glenoid Baseplate components are intended for cementless applications with the addition of screw fixation.

Please select the types of uses.

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

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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)

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Zimmer, Inc.
Applicant Address	1800 W Center St Warsaw IN 46580 United States
Applicant Contact Telephone	2604049023
Applicant Contact	Mrs. Alexandria Irwin
Applicant Contact Email	alexandria.irwin@zimmerbiomet.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	OsseoFit Stemless Shoulder System
Common Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Name	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-Constrained
Regulation Number	888.3660
Product Code(s)	PKC

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241873	OsseoFit Stemless Shoulder System	PKC

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The OsseoFit Stemless Shoulder System consists of a stemless humeral implant and humeral head adapter for anatomic total shoulder applications. The OsseoFit Stemless Shoulder System includes an anatomical (left/right specific), asymmetric humeral anchor with OsseoTi porous technology to allow biological fixation and is intended for cementless use with the Identity Shoulder System Humeral Heads. The Identity heads can be used with a compatible Alliance Glenoid Implant or Comprehensive Convertible Baseplate liner.

The OsseoFit Stemless Shoulder System was previously cleared under K241873 with device-specific Monoblock Broaches. This Special 510(k) is being submitted to add new device-specific surgical instruments intended to facilitate implantation of the OsseoFit humeral anchor. Specifically, the subject submission adds Universal (also known as modular) broaches, which are provided as non-sterile, reusable instruments.

The OsseoFit Universal Broaches are a 2-piece construction, consisting of a Proximal Broach Body and a Distal Broach Body, which allow for intra-operative flexibility between Inlay and Onlay configurations. The Proximal Broach Body is offered in Left or Right configurations. The Distal Broach Body is offered in Sizes 1-5 in Left and Right configurations. When the Proximal and Distal Broach Body are assembled together, they replicate the previously cleared Monoblock Broaches

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Anatomic Total Shoulder Applications:

- Osteoarthritis
- The patient must be anatomically and structurally suited, as evident by scapula and proximal humerus closure, to receive the implants.

OsseoFit® Stemless Shoulder humeral components have a porous surface and are indicated for uncemented biological fixation applications

Compatible Glenoid components are intended to be implanted with bone cement. The porous posts may be inserted without bone cement.

Compatible Convertible Glenoid Baseplate components are intended for cementless applications with the addition of screw fixation.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

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

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject devices have similar technological characteristics as the predicate device. The proposed and predicate devices are utilized in the identical anatomical site during bone preparation and are terminally sterilized by the healthcare facility in the same manner.

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

- Intended Use: Identical to predicate
- Indications for Use: Identical to predicate
- Materials: Identical to predicate
- Design Features: Similar to predicate. The OsseoFit Universal Broaches are a 2-piece construction, consisting of a Proximal Broach Body and a Distal Broach Body. The Proximal Broach Body is offered in Left or Right configurations. The Distal Broach Body is offered in Sizes 1-5 in Left and Right configurations. When the Proximal and Distal Broach Body are assembled together, they replicate the Predicate Device Monoblock Broach geometry.
- Packaging: Identical to predicate
- Sterilization: Identical to predicate

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-Clinical Tests/Justifications:

- Physical testing was performed utilizing the subject Universal Broaches and applicable accessory instrumentation. The subject Universal Broaches successfully met the acceptance criteria to withstand the loads experienced during use and to be capable of being extracted from the joint space after use.

Animal and Clinical Tests:

- None provided

Based on non-clinical evaluations and a comparison of device technology, the subject device is substantially equivalent to the predicate device.