December 11, 2024

Zimmer, Inc.
Alexandria Irwin
Regulatory Affairs Sr Specialist
1800 W. Center Street
Warsaw, Indiana 46850

Re: K241873
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: November 5, 2024
Received: November 5, 2024

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 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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2024.12.11 16:43:06 -05'00'

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

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)*

K241873

Device Name

OsseoFit Stemless Shoulder System

Indications for Use *(Describe)*

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.

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.

510(k) #: K241873

510(k) Summary

Prepared on: 2024-12-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer, Inc.
Applicant Address	1800 W. Center Street Warsaw IN 46850 United States
Applicant Contact Telephone	1 574-373-0167
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	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem with No Diaphyseal Incursion, Semi-Constrained
Classification Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
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
K171858	Sidus Stem-Free Shoulder	PKC
K182516	Comprehensive Nano Stemless Shoulder	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 humeral implant is an anatomical (left/right specific), asymmetric humeral anchor with six fins whose location, length, and height vary. The OsseoFit humeral implants are available in Onlay and Inlay variants. The Onlay implants sit on top of the prepared bone while the Inlay implants have a dished superior portion with a shorter fin length to allow the implant to sit within the bone. The OsseoFit Humeral Implant also includes anterior suture holes for soft tissue attachment.

The humeral implants are manufactured through additive manufacturing which includes areas of OsseoTi porous technology to allow biological fixation.

The OsseoFit Stemless Shoulder System is intended for cementless applications and is designed to be used with a compatible Identity Shoulder System (K213856) humeral head. The Identity Humeral Head is assembled to the OsseoFit Humeral Head Adapter via a locking taper by a disposable impactor that is packaged together with the head adapter. The Identity heads can be used with a compatible Alliance Glenoid Implant (K191814 and K193180) or Comprehensive Convertible Baseplate liner (K211729).

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 use as the predicate device(s) and has the similar indications for use as the predicate(s). The OsseoFit Stemless Shoulder System narrowed the indications to Osteoarthritis.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has similar technological characteristics as the designated predicates. The rationale for substantial equivalence is based on consideration of the following characteristics:

• Intended Use: Identical to predicates
• Indications for Use: Similar to predicates
• Materials: Similar to predicates
• Design Features: Similar to predicates
• Packaging: Similar to predicates
• Sterilization: Identical to predicates

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

Non-Clinical Tests
• Analysis of Potential Cortical Perforation
• Construct Fatigue Testing
• Corrosion Fatigue Testing
• Initial Fixation Evaluation in physiological loading condition: Micromotion testing
• Initial Fixation Characterization: Pull out testing
• Initial Fixation Characterization: Lever out testing
• Initial Fixation Characterization: Torque out testing
• Static Tensile and Torsional Modular Junction Testing
• Range of Motion Analysis
• Magnetic Resonance Imaging (MRI) Environment Compatibility Evaluation
• Porous coating/metal characterization
• Additive Manufacturing Process Validation Report
• Mechanical and chemical characterization of Additive Manufacturing
• Cleaning Validation

Clinical Tests
None Provided

Conclusion
Non-clinical testing demonstrated that the new device is substantially equivalent to the predicate device.