August 11, 2025

Zimmer Inc.
Alexandria Irwin
Regulatory Affairs Principal
1800 W. Center Street
Warsaw, Indiana 46580

Re: K251098
Trade/Device Name: Identity Revision Humeral Stems
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, KWT, KWS, HSD, PHX
Dated: July 7, 2025
Received: July 7, 2025

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: 2025.08.11 13:12:55 -04'00'

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)*

K251098

Device Name

Identity Revision Humeral Stems

Indications for Use *(Describe)*

Hemiarthoplasty/Conventional Total Application:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
• Rheumatoid arthritis.
• Correction of functional deformity.
• Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
• Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.
Optional use in revision: in some medical conditions (e.g. revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.

Reverse Application:
Identity Revision Humeral Stem products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Identity Revision Humeral Stem is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component or reverse components for total shoulder arthroplasty (conventional or reverse applications). The humeral components may be used cemented or uncemented (biological 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.

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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510(k) #: K251098

510(k) Summary

Prepared on: 2025-08-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer Inc.
Applicant Address	1800 W. Center Street Warsaw IN 46580 United States
Applicant Contact Telephone	574-373-0167
Applicant Contact	Ms. Alexandria Irwin
Applicant Contact Email	Alexandria.Irwin@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Identity Revision Humeral Stems
Common Name	Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
Classification Name	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Uncemented
Regulation Number	888.3670, 888.3650, 888.3660, 888.3690
Product Code(s)	MBF, KWT, KWS, HSD, PHX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213856	Identity Shoulder System	MBF, KWT, K
K193038	Comprehensive Shoulder System	MBF, KWT, K

Device Description Summary

21 CFR 807.92(a)(4)

The Identity Revision Humeral Stems are comprised of titanium alloy. The diameters of the stems range in 1mm increments from 4mm to 18mm in a revision length of 133-134mm. The stem is designed with a distal portion that is cylindrical in shape with a rounded tip and a proximal portion that is flared, eight-sided shape. The devices have a machine finish distally and a plasma-spray titanium porous coating proximally. To support placement and bone reconstruction in fracture cases, the Identity Revision Humeral Stems feature proximal suture holes as well as etch lines for location of the stem with respect to the native humeral head. The humeral stems employ an oval reverse taper which allows the attachment of either an Identity Humeral Stem Adapter for hemi- and anatomic total shoulder applications or an Identity Humeral Tray for reverse shoulder applications.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Hemiarthoplasty/Conventional Total Application:
- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Correction of functional deformity.
- Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
- Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Optional use in revision: in some medical conditions (e.g. revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.

Reverse Application:
Identity Revision Humeral Stem products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Identity Revision Humeral Stem is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.
The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component or reverse components for total shoulder arthroplasty (conventional or reverse applications). The humeral components may be used cemented or uncemented (biological fixation).

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

The indications for use are identical to the primary predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The rationale for substantial equivalence is based on consideration of the following characteristics:
• Intended Use: Identical to predicate device
• Materials: Identical to predicate and reference devices
• Stem Diameter, Length and Suture Holes: Similar or identical features to the predicate devices. The diameter and length of the subject device are within range of the predicate devices. Fatigue testing was conducted to demonstrate that the overall design performance will not be affected by these differences.
• Porous Region: The subject device has an extended porous region compared to the primary predicate, however, it is within range of the reference predicate. Fatigue testing was conducted to demonstrate that performance will not be affected by these differences.
• Packaging: The subject device has Identical packaging compared to the reference device, however the thermoformed retainer varies in design to fit the stem lengths
• Sterilization: Identical to predicate device

Based on the above information, the proposed device has similar and/or identical technological characteristics to the predicate and reference devices, and the information provided herein demonstrates that:
• any differences do not raise new questions of safety and effectiveness; and
• the proposed device is as safe and effective as the legally marketed predicate device

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

Non-Clinical Tests/Justifications:
• Fatigue Testing
• Range of Motion Analysis
• Magnetic Resonance Imaging (MRI)

No animal or clinical testing provided

Conclusion
Testing and evaluations performed demonstrate that the subject device is substantially equivalent to the identified predicate device.