



April 13, 2026

Zimmer, Inc.
Alexandria Irwin
Regulatory Affairs Senior Specialist
1800 W. Center St.
Warsaw, Indiana 46850

Re: K253592

Trade/Device Name: Zimmer Biomet Reverse Shoulder Prosthesis (Alliance Humeral Bearings, Identity Humeral Trays, Comprehensive Reverse Humeral Trays, Comprehensive Reverse 32mm Glenospheres and Adapter)

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: November 17, 2025

Received: March 12, 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,

A large, light blue watermark of the letters 'FDA' is visible in the background behind the signature.

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.

K253592

?

Please provide the device trade name(s).

?

Zimmer Biomet Reverse Shoulder Prosthesis(Alliance Humeral Bearings, Identity Humeral Trays, Comprehensive Reverse Humeral Trays, Comprehensive Reverse 32mm Glenospheres and Adapter)

Please provide your Indications for Use below.

?

Zimmer Biomet Reverse Shoulder 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 Zimmer Biomet Reverse Shoulder 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 titanium Glenosphere components are indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium Glenospheres is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

The humeral components are indicated for either cemented or uncemented (biological fixation).

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

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)

?

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	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	Zimmer Biomet Reverse Shoulder Prosthesis(Alliance Humeral Bearings, Identity Humeral Trays, Comprehensive Reverse Humeral Trays, Comprehensive Reverse 32mm Glenospheres and Adapter)
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	21 CFR 888.3670
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
K240876	Identity Shoulder System	MBF
K193373	Comprehensive Reverse Shoulder	PHX
K181611	Comprehensive Reverse(Mini) Shoulder System	PHX
K121543	Zimmer Trabecular Metal Reverse Shoulder System	KWT
K233481	Altivate Reverse Glenoid	PHX
K200209	Persona Personalized Knee System	JWH

Device Description Summary

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

This submission is seeking approval of Alliance Humeral Bearings, Identity Humeral Trays, Comprehensive Reverse Humeral Trays, Comprehensive Reverse 32mm Glenospheres and Adapter to provide compatibility with the Identity Shoulder System and/or the Comprehensive Reverse System. This submission is a collection of components designed with the intention of providing the modularity and adaptability necessary to facilitate individual anatomical adjustment and restoration of the glenohumeral joint during reverse shoulder arthroplasty. Modular joints provide intraoperative flexibility for accurate and reproducible reconstruction of the glenohumeral joint to restore limb kinematics. The modularity of the humeral components also allows convertibility from an anatomical total shoulder arthroplasty to a reverse shoulder arthroplasty with retention of the well-fixed humeral stem in case of failure of the prosthesis or the rotator cuff.

Intended Use/Indications for Use

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

Zimmer Biomet Reverse Shoulder 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 Zimmer Biomet Reverse Shoulder 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 titanium Glenosphere components are indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium Glenospheres is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

The humeral components are indicated for either cemented or uncemented (biological fixation).

Compatible 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 indications for use are similar 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 devices
- Indications for Use: Similar to predicate devices
- Materials: Identical to predicate devices
 - Alliance Humeral Bearings: Identical to primary predicate
 - Identity Trays: Identical to primary predicate
 - Comprehensive Reverse Trays: Identical to predicate device.
 - Comprehensive Glenospheres: Co-Cr-Mo Glenospheres: Identical to predicate device: No surface treatment processing applies to the cobalt chrome variant. Ti-6Al-4V Glenospheres: Similar to predicate device. The Ti-6Al-4V glenospheres include a surface hardening treatment process identical to reference device K200209.
 - Comprehensive Taper Adapter: Identical to predicate device
- Manufacturing Process: Similar to predicate devices
 - Alliance Humeral Bearings: Machined from Vitamin E-stabilized highly crosslinked polyethylene; marked, cleaned, and packaged; sterilized via ethylene oxide. Similar to primary predicate polyethylene bearings.
 - Identity Trays: Machined from wrought titanium alloy; marked, cleaned and packaged; sterilized via gamma irradiation. Similar to primary predicate humeral trays.
 - Comprehensive Reverse Trays: Machined from wrought titanium alloy; marked, cleaned and packaged; sterilized via gamma irradiation. Similar to predicate device humeral trays.
 - Comprehensive Glenospheres: Machined from wrought titanium or cobalt chrome alloy with polished surfaces; titanium variants include surface hardening comparable to predicate devices; cleaned, packaged, and sterilized via gamma irradiation. Similar to predicate device glenospheres.
 - Comprehensive Taper Adapter: Machined from wrought titanium alloy; marked, cleaned and packaged; sterilized via gamma irradiation. Similar to predicate device taper adapters.
- Design Features: Similar to predicate devices
 - Alliance Humeral Bearings: Polyethylene components that articulate with glenospheres and engage with humeral trays through a locking mechanism. Offered in multiple configurations to support joint stability and motion. Design and function are similar to primary predicate humeral bearing components.
 - Identity Trays: Metallic components that interface with the humeral stem and support modular bearing attachment through a locking mechanism. Offered in multiple configurations to accommodate patient anatomy. Design and function are similar to primary predicate humeral trays.
 - Comprehensive Reverse Trays: Metallic components that interface with the humeral stem and support modular bearing attachment through a locking mechanism. Offered in multiple configurations to accommodate patient anatomy. Design and function are similar to predicate device humeral trays.

o Comprehensive Glenspheres: Metallic spherical components that articulate with humeral bearings and connect to the baseplate via a modular taper adapter. Offered in multiple configurations to support joint stability and motion. Design and function are similar to predicate device glensphere components.

o Comprehensive Taper Adapter: Metallic component that provides a modular connection between the glensphere and baseplate through dual taper interfaces. Design and function are similar to predicate device taper adapter components.

• Packaging: Similar to predicate devices

o Alliance Humeral Bearings: Similar to primary predicate, both packaged in double sterile tray with protective packaging.

o Identity Trays: Identical to primary predicate, however primary predicate includes a physical IFU, while subject device has an eIFU.

o Comprehensive Reverse Trays: Similar to predicate device, both packaged in double sterile configuration with protective packaging.

o Comprehensive Glenspheres: Similar to predicate device, both packaged in double sterile tray with protective packaging.

o Comprehensive Taper Adapter: Similar to predicate device, both packaged in double sterile configuration with protective packaging.

• Sterilization Method: Identical to predicate device

o Alliance Humeral Bearings: Sterilized via ethylene oxide. Method is identical to primary predicate crosslinked polyethylene bearing component

o Identity Trays: Sterilized via gamma irradiation. Method is identical to the primary predicate humeral tray components.

o Comprehensive Reverse Trays: Sterilized via gamma irradiation. Method is identical to predicate device humeral tray components.

o Comprehensive Glenspheres: Sterilized via gamma irradiation. Method is identical to predicate device glensphere components.

o Comprehensive Taper Adapter: Sterilized via gamma irradiation. Method is identical to predicate device taper adapter components.

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

Non-Clinical Tests/Justifications:

Non-clinical testing and engineering evaluations were conducted to assess mechanical performance and functional integrity of the subject device under worst case conditions relative to predicate devices.

• Finite Element Analysis (FEA): Used to identify worst case configurations and loading conditions.

• Fatigue Strength Evaluation: Conducted to assess durability of components and constructs under cyclic loading

• Accelerated Corrosion Fatigue (ACF) Testing: Performed to evaluate fretting and corrosion of modular junctions as well as construct strength.

• Micromotion & Moment Analysis: Conducted to evaluate construct strength, modular junction demand and initial fixation behavior under physiological loading conditions.

• Lever Out Resistance (ASM F1820): evaluated locking mechanism resistance to disengagement.

• Static Axial and Torsional Strength (ASTM F2009, ASTM F1820): Evaluated strength of modular connections under axial and torsional loading.

• Wear Assessment (ASTM F1378): Evaluated articulating geometries, materials, and surface characteristics to confirm no new worst case condition.

• Range of Motion Analysis (ASTM F1378): Evaluated system-level range of motion and potential impingement.

• Magnetic Resonance Imaging (MRI, ASTM F2052, F2213, F2119): Conducted to establish MR-conditional use.

• rTSA Humeral Construct Performance Requirement: rTSA performance requirements were defined using predicate device strength and supported by biomechanical literature.

The subject devices have the same intended use and similar indications for use as the predicate device. The subject devices have similar technological characteristics to the predicates.

Non-clinical testing demonstrates that the subject device meets design requirements and performs as intended under worst case conditions. Results confirm that the subject device is equivalent to or bounded by predicate device performance, including fatigue strength, modular connection integrity, resistance to fretting and corrosion and construct level initial fixation under physiological loading conditions. No new risk or failure modes were identified.

No animal or clinical testing was required.

The subject device demonstrates safety and effectiveness equivalent to the legally marketed predicate device. and the information provided herein demonstrates that:

• any differences do not raise different questions of safety and effectiveness; and

• the subject devices are as safe and effective as the legally marketed predicate device.