Zimmer Inc.
Patricia Beres
Regulatory Affairs Principal
1800 West Center St.
Warsaw, Indiana 46580

June 12, 2024

Re: K240876
Trade/Device Name: Identity Shoulder System
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, PAO
Dated: May 2, 2024
Received: May 2, 2024

Dear Patricia Beres:

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.

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
Digitally signed by Joseph P. Russell -S
Date: 2024.06.12 15:56:26 -04'00'

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

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)*

K240876

Device Name

Identity Shoulder System

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:

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 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).

The Titanium Humeral Head and 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 humeral head or Glenospheres is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

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.

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510(k) #: K240876

510(k) Summary

Prepared on: 2024-05-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer Inc.
Applicant Address	1800 West Center St. Warsaw IN 46580 United States
Applicant Contact Telephone	754-376-5271
Applicant Contact	Ms. Patricia Beres
Applicant Contact Email	patty.beres@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Identity Shoulder System
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
Product Code(s)	MBF, KWT, KWS, HSD, PHX, PAO

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
K201315	PERFORM Humeral System – Stem	PAO
K220914	Tornier Perform Humeral System – Fracture	PHX
K181611	Comprehensive Reverse Shoulder System	PHX

Device Description Summary

21 CFR 807.92(a)(4)

The Identity Shoulder System cleared previously in K213856 is a comprehensive 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 shoulder arthroplasty.

The Identity Shoulder System in the anatomic configuration is comprised of several individual components such as Humeral Stem, Fixed Angle Humeral Stem Adapter, Humeral Head Adapter, and Humeral Head. This configuration can be used as a hemi-arthroplasty with the humeral head articulating against the natural glenoid bone or as an anatomic total shoulder replacement with a compatible glenoid component.

The components of the Identity Shoulder System may also be used in the reverse configuration. Individual components include a Humeral Stem, Humeral Tray and Humeral Bearing. This construct is intended to be used with a compatible glenosphere/baseplate component.

The current 510(k) is for additional sizes/styles of humeral trays and bearings for the reverse configuration.
Extra Extended trays in 3 heights in a neutral configuration are being added to provide additional lateralization. A uniform thickness

bearing is also being added in an effort to improve internal/external range of motion and reduce potential of scapular notching.

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:

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.

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Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject devices are identical to the primary predicate Identity Shoulder System.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device has similar technological characteristics as the primary predicate system.

The following items are identical to the predicate Identity Shoulder System, cleared in K213856.
• Component Materials, raw and contact
• MRI Conditional Status and MRI language
• Sterilization methods and validations
• Packaging materials, methods and validations
• Shelf Life validations
• Biocompatibility

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

• Materials: Identical to primary predicate device
• Design Features: Similar to predicate devices
• Packaging: Identical to predicate devices
• Sterilization: Identical to primary predicate device

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Tests/Justifications:
• Finite Element Analysis (FEA)
• Range of Motion Analysis

• Magnetic Resonance Imaging (MRI)

Clinical Tests
None provided

Conclusion
Non-clinical testing demonstrated that the new devices do not represent new worst-case configurations than the predicate, and the subject device is substantially equivalent to the predicate device identified.