



July 2, 2025

Zimmer Inc.  
Deanna Strombeck  
Regulatory Affairs Specialist  
1800 W. Center Street  
Warsaw, Indiana 46580

Re: K250848

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, KWS, HSD, KWT, PKC, PHX

Dated: May 20, 2025

Received: May 30, 2025

Dear Deanna Strombeck:

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](mailto: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: 2025.07.02 15:07:29  
-04'00'

Farzana Sharmin, Ph.D.  
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

Submission Number (if known)

K250848

Device Name

Identity Shoulder System

Indications for Use (Describe)

### Hemiarthroplasty/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 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.**

## Indications for Use

510(k) Number (if known)  
K250848

Device Name  
Identity Shoulder System

### Indications for Use (Describe)

#### Comprehensive Nano Stemless Shoulder System

1. Primary total shoulder arthroplasty.
2. Non-inflammatory degenerative joint disease including

Comprehensive Nano Stemless Shoulder humeral components have a porous coated surface coating and are indicated for uncemented biological fixation applications.

The Comprehensive Modular Hybrid Glenoid is intended to be implanted with bone cement. The porous titanium peg may be inserted without bone cement.

### 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) Summary

In accordance with content and format of a 510(k) summary (21 CFR §807.92) and the Safe Medical Devices Act of 1990, the following information is provided for the Identity Shoulder System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on September 13, 2019.

**Sponsor:** Zimmer Inc.  
P.O. Box 708  
1800 W. Center Street  
Warsaw, IN 46580  
Establishment Registration Number: 1822565

**Contact Person:** Deanna Strombeck  
Regulatory Affairs Specialist  
Telephone: (574) 377-8133  
Deanna.strombeck@zimmerbiomet.com

**Date:** March 20, 2025

**Subject Device:** **Trade Name:** Comprehensive Humeral Head Adapter  
**Common Name:** Shoulder Head Adapter  
**Classification Name:**

- MBF –Prosthesis, –Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3670)
- KWT - Shoulder joint metal/polymer nonconstrained cemented prosthesis (21 CFR 888.3650)
- KWS - Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
- HSD - Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690)
- PHX - Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
- PKC - Prosthesis, Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)

**Predicate Device(s):** Primary Predicate Device  
K213856 Identity Shoulder System

Reference Predicate  
K182516 Comprehensive Nano Stemless Shoulder  
K193038 Comprehensive Shoulder System

**Purpose and Device  
Description:**

K214001 Comprehensive Shoulder System,  
Comprehensive Reverse Shoulder System (MR labeling)

The Identity Shoulder System is previously cleared (K213856/K240876) as 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 is cleared for hemi-arthroplasty and conventional total shoulder replacement in both the anatomic and reverse configurations. The current submission is for the anatomic configuration.

The subject Comprehensive Humeral Head Adapter (CHHA) is a line extension to the Identity Shoulder System (K213856) cleared for the hemi-arthroplasty configuration and anatomic Total Shoulder Configuration.

The new CHHA (PN SAHHA002) allows additional compatibility with the previously cleared Identity Humeral Heads (K213856) and the Comprehensive humeral components, excluding fracture stems, as noted below:

- Comprehensive Humeral Stems (K193038); and
- Comprehensive Nano Stemless shoulder component (K182516).

**Intended Use and  
Indications for Use:**

**Comprehensive Humeral Head Adapter with Identity  
Shoulder System**

Hemiarthroplasty/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 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 not recommended for patients who lack suspected material sensitivity to cobalt alloy.

#### **Comprehensive Humeral Head Adapter with Nano Stemless Shoulder System**

1. Primary total shoulder arthroplasty.
2. Non-inflammatory degenerative joint disease including osteoarthritis.

Comprehensive Nano Stemless Shoulder humeral components have a porous coated surface coating and are indicated for uncemented biological fixation applications.

The Comprehensive Modular Hybrid Glenoid is intended to be implanted with bone cement. The porous titanium peg may be inserted without bone cement.

**Summary of Technological Characteristics:**

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

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

**Summary of Performance Data (Nonclinical and/or Clinical)**

**Non-Clinical Verifications:**

- Fatigue, Fretting Corrosion and Fixation Stability Verification
- ROM Verification
- Static Modular Junction Strength Verification
- MRI Verification
  
- **Clinical Tests:**
  - None provided

**Substantial Equivalence Conclusion**

The proposed CHHA created as a line extension in this 510(k) for the Identity Shoulder System has the same intended use and indications for use as the primary predicate device. The proposed device has similar technological characteristics to the predicates, and the information provided herein demonstrates that:

- any differences do not raise different questions of safety and effectiveness; and
- the proposed device is as safe and effective as the legally marketed predicate device.