Zimmer Inc.
Patricia Sandborn Beres
Regulatory Affairs Principal
P.O Box 708
Warsaw, Indiana 46581-0708

September 15, 2022

Re: K213856
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
Dated: September 14, 2022
Received: September 15, 2022

Dear Patricia Sandborn 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Victoria Lilling, M.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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213856

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 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) 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
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person:

Patricia Sandborn Beres
Regulatory Affairs Principal
Telephone: (574)-376-5271
patty.beres@zimmerbiomet.com

Date:

September 13, 2022

Subject Device:

Trade Name: Identity Shoulder System
Common Name: Shoulder joint replacement device

Classification Name:

- MBF –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)

Predicate Device(s):

Primary Predicate Device

K193038	Comprehensive Shoulder System

Reference Devices

K193373	Comprehensive Reverse Shoulder
K181611	Comprehensive Reverse Shoulder System
K193099	Anatomical Shoulder System
K103404	Bigliani Flatow Shoulder
K840643	Harris Galante Porous Total Hip System

Purpose and Device Description:

The Identity Shoulder System 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 comprises 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 constructed is intended to be used with a compatible glenospheres/baseplate component.

Intended Use/ Indications for Use:

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.
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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.

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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; differences are mainly dimensional and have been shown to not raise different questions of safety and effectiveness.
- **Sterilization:** Identical to predicates

Summary of Performance Data (Nonclinical and/or Clinical)

Non-Clinical Tests/Justifications:

- FEA
- Axial Pull Off
- Torsional Disassociation
- Micro-Motion
- Fatigue
- Accelerated Corrosion
- Range of Motion
- MRI

- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

The proposed Identity Shoulder System has the same intended use and indications for use as the predicate device. The proposed device has similar technological characteristics to the predicate, 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.