January 29, 2020

Zimmer GmbH
Dawn Balazs-Metz
Regulatory Affairs Senior Specialist
Sulzerallee 8
WINTERTHUR 8404 CH

Re: K193099
Trade/Device Name: Anatomical Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD, KWS, KWT, PAO
Dated: November 4, 2019
Received: November 7, 2019

Dear Dawn Balazs-Metz:

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

Michael Owens
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193099

Device Name
Anatomical Shoulder™ System

Indications for Use *(Describe)*

Hemi- or Total Arthroplasty Application of the Anatomical Shoulder Humeral Stems and Domelock System

The Anatomical Shoulder Humeral Stems and Domelock System are indicated for:

• Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis if bone stock is adequate.
• Avascular necrosis.
• Conditions consequent to earlier operations.
• Optional use in revision: in some medical conditions (e.g. early revision when adequate bone stock exits), the surgeon may opt to use primary implants in a revision procedure).

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used in a total shoulder application, the Anaverse Anatomical Shoulder Pegged Glenoids Cemented and the Biomet all-polyethylene Keeled Glenoid are intended for cemented use only. The Biomet Modular Hybrid Glenoid is intended to be implanted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

Reverse Application of the Anatomical Shoulder System and ASHCOM Shoulder System

• The Anatomical Shoulder Reverse System and the ASHCOM Shoulder system are indicated for primary, fracture or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.
• The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used with the Anatomical Shoulder Glenoid Fixation, it is intended for uncemented use and requires two screws for fixation.

Fracture Application of the Anatomical Shoulder Fracture System

The Anatomical Shoulder Fracture System is intended for use in prosthetic replacement of the proximal humerus and the glenoid articular surface of the scapula during total, hemi- and fracture shoulder arthroplasty in treatment of the following:

• Complex 3- and 4-part fractures of the proximal humerus with subluxation of the head fragment.
• Complex 3- and 4-part fractures of the proximal humerus with loosening of the spongiosa in the head fragment.
• Complex 3- and 4-part fractures of the proximal humerus with additional cross split of the head fragment.
• Fracture instability after osteosynthesis of 3- and 4-part fracture fragments of the proximal humerus.
• Posttraumatic necrosis of the humeral head.
• Posttraumatic arthrosis after humeral head fracture.

The Humeral Fracture Stems are intended for either cemented or uncemented use. When used in a total shoulder application, the Anaverse Anatomical Shoulder Pegged Glenoids Cemented are intended for cemented use only.

Anatomical Shoulder Combined System

Advanced destruction of the shoulder joint resulting from:

• Omarthrosis
• Rheumatoid arthritis

• Post-traumatic arthritis
• Avascular necrosis of the humeral head
• Cuff-tear arthropathy (Bigliani/Flatow Heads with heights of 27mm or greater)
• Conditions following earlier operations

The Anatomical Shoulder Combined System is intended for cemented or cementless use.

When used with the following humeral stems the Anatomical Shoulder Combined System is intended for cemented use.
• Anatomical Shoulder Standard Cemented Humeral Stem
• Anatomical Shoulder Long Stem

When used with the following humeral stem the Anatomical Shoulder Combined System is intended for cementless use:
• Anatomical Shoulder Standard Uncemented Stem.

When used with the following humeral stems the Anatomical Shoulder Combined System is intended for cemented or cementless use:
• Anatomical Shoulder Fracture Stem.
• Anatomical Shoulder Fracture Long Stem.

When used with the following glenoids the Anatomical Shoulder Combined System is intended for cemented use:
• Bigliani/Flatow Glenoid (pegged and keeled).
• Trabecular Metal™ Glenoid.

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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ZIMMER BIOMET

510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Dawn Balazs-Metz Senior Specialist, Regulatory Affairs Telephone: +41 58 854 81 37 Fax: +41 52 244 86 58
Date:	November 04, 2019
Trade Name:	Anatomical Shoulder™ System
Classification Product Code :	**PHX** – Shoulder Prosthesis, Reverse Configuration **HSD** – Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented **KWS** – Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented **KWT** – Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented **PAO** – Prosthesis, Shoulder, Semi-constrained, Metal/Polymer + Additive, Cemented
Device Classification Name:	Shoulder Prosthesis
Regulation Number / Description:	21 CFR § 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR § 888.3690 - Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis 21 CFR § 888.3650 - Shoulder joint metal/polymer non-constrained cemented prosthesis
Predicate Device:	ASHCOM™ Shoulder System, Anatomical Shoulder™ System, and Anatomical Shoulder™ Combined System, manufactured by Zimmer GmbH, K170711, cleared June 1, 2017.
Device Description:	**Anatomical Shoulder™ System** The Anatomical Shoulder System is intended for long-term implantation into the human shoulder joint in primary or revision (Reverse Shoulder Arthroplasty), total or hemi- shoulder arthroplasty. The system is intended to relieve pain and restore function in patients with adequate bone stock to support the prosthesis. The proposed Anatomical Shoulder System is comprised of the following families of products:

ZIMMER BIOMET

Anatomical Shoulder Humeral Stems (Cemented, Uncemented)

Anatomical Shoulder Reverse System (Cups, PE-inlays, Glenoid Fixation, Screws, Glenospheres)

Anatomical Shoulder Fracture System (Stems, Heads)

Anatomical Shoulder Combined system (Bigliani / Flatow® Adaptors)

Anaverse™ Anatomical Shoulder Pegged Glenoid

Anatomical Shoulder Domelock® System (Heads, Dome Centric, T-Domes)

Anatomical Shoulder ASHCOM® Shoulder System (ASHCOM Shoulder AC-Connector)

Indications for use:

Hemi- or Total Arthroplasty Application of the Anatomical Shoulder Humeral Stems and Domelock System

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- Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis if bone stock is adequate.
- Avascular necrosis.
- Conditions consequent to earlier operations.
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- Anatomical Shoulder Standard Uncemented Stem.

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- Anatomical Shoulder Fracture Stem.
- Anatomical Shoulder Fracture Long Stem.

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- Bigliani/Flatow Glenoid (pegged and keeled).
- Trabecular Metal™ Glenoid.

Comparison to Predicate Device:

The Anatomical Shoulder System is being merged. Through merging of the IFU redundant indications have been removed and three

existing indications have been reworded for more clarity surrounding revision cases. The removal and clarification of the indications for the subject device limits the use of the devices within the currently cleared indications. A clarification to the previously cleared MR verbiage for the proposed device harmonizes the information provided to the user across the Zimmer Biomet shoulder portfolio. The clarification to the MR verbiage does not change compatibility/ final scanning recommendations provided to the user.

Modification of the packaging configuration for the subject implant devices is proposed. The proposed changes do not alter the fundamental scientific technology shared by both the subject devices and predicate devices.

Zimmer GmbH is furthermore seeking clearance for certain system-specific Class II instruments - these instruments that have previously considered Class I exempt and correction of classification to Class II is proposed within present submission.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Results of non-clinical performance testing and analyses demonstrate that the Anatomical Shoulder System is safe and effective and substantially equivalent to the predicate devices. Performance analyses included:

MR compatibility evaluation on the Anatomical Shoulder™ System.

No new MRI performance testing or simulations were completed for the Anatomical Shoulder™ System implant devices. The reports were only reviewed with the aim ensure that appropriate labelling of the Zimmer Shoulder implant systems be implemented upon harmonization of the MR verbiage across the Zimmer Biomet portfolio.

Correction of instrument classification from Class I to Class II:

Mechanical integrity and resistance testing was performed for instrument groups of mechanically loaded devices.

Packaging configuration change:

Packaging performance testing was performed to verify that packaging configuration maintains integrity of the sterile barrier system up to the point of use and provides adequate protection to the product through the hazards of sterilization, handling, distribution and storage according to ISO 11607-1:2006 and ISO 11607-2:2006. Packaging Configuration testing was conducted by representative worst-case products.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion:

The subject devices have the same intended use and similar indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes as the predicate devices.

Except for the modifications described in this submission the subject

devices are identical to the predicate devices, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness as established with performance testing; and
- the subject devices are at least as safe and effective as the legally marketed predicate devices.