February 24, 2020

Zimmer Inc.
Patricia Beres
Regulatory Affairs Principal
P.O. Box 708
WARSAW, IN 46581-0708

Re: K193180
Trade/Device Name: Alliance Augmented Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT
Dated: January 23, 2020
Received: January 24, 2020

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 (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,

Michael C. 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)*
K193180

Device Name
Alliance Augmented Glenoid

Indications for Use *(Describe)*

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
5. Difficult clinical management problems, 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.

The Alliance Monoblock glenoid components are indicated for cemented application only. The Alliance Modular Glenoid components are intended to be implanted with bone cement. The TM and porous posts 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.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the ALLIANCE AUGMENTED GLENOID 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 August 12, 2005.

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person:

Patricia Sandborn Beres
Regulatory Affairs Principal
Telephone: (574-267-6639 extension 1278)
Email: patty.beres@zimmerbiomet.com

Date:

November 15, 2019

Subject Device:

Trade Name: Alliance Augmented Glenoid
Common Name: Anatomic Glenoid Prosthesis

Classification Name:

- KWS – Prosthesis Shoulder, Semi-Constrained, Metal/Polymer Cemented (21 CFR 888.3660)
- KWT – Prosthesis, Shoulder, Non-Constrained, Metal/Polymer (21 CFR 888.3650)

Predicate Device(s):

Predicates	Device	Manufacturer	510(k) Number
Primary Predicate	Alliance Glenoid	Zimmer, Inc.	K191814
Reference Predicate	Aequalis Perform+	Tornier	K150583

Purpose and Device Description:

The Alliance Glenoid system is a series of glenoid components which includes previously cleared (K191814) monoblock glenoids with 2 or 3 pegs and modular glenoids with 3 or 4 pegs. In addition to the predicate neutral (flat) modular 4-pegged design, an augmented configuration for correction of glenoid bone defects is being added to the product line. All glenoid types are available in various sizes. The posts of the modular

glenoids are made of either a Tivanium® substrate with Trabecular Metal (TM) sleeve or the Tivanium® substrate with Porous Plasma Spray (PPS) coating.

The Alliance Glenoids are intended to be used with existing humeral stem and head components to complete a total shoulder replacement construct.

Intended Use and Indications for Use:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
5. Difficult clinical management problems, 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.

The Alliance Monoblock Glenoid components are indicated for cemented application only. The Alliance Modular Glenoid components are intended to be implanted with bone cement. The TM and porous posts may be inserted without bone cement.

Summary of Technological Characteristics:

The following items are identical between the proposed and predicate devices:

- Indications for use
- Articulating Geometry
- Sizing (Size 2-5)
- Modular Post attachment
- Polyethylene peripheral peg design and splay
- Material (UHMWPE and Ti-6Al-4V)
- Sterilization method (gamma radiation, SAL 10-6)
- Instrument Materials

This submission proposed the following design change:

- Addition of a 12.5-degree augment wedge to the under surface of the component.
- Addition of associated implant specific instruments

- Updated packaging/sterilization references

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Glenoid Loosening (Rocking Horse) (ASTM F2028)
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

The proposed Alliance Augmented Glenoid 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 at least as safe and effective as the legally marketed predicate device