March 27, 2019

Zimmer, Inc.
Dalene Binkley
Regulatory Affairs Project Manager
345 East Main Street
Warsaw, Indiana 46580

Re: K181611
Trade/Device Name: Comprehensive Reverse 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, KWS, PAO, KWT
Dated: August 23, 2018
Received: August 24, 2018

Dear Dalene Binkley:

This letter corrects our substantially equivalent letter of September 24, 2018.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K181611

Device Name
Comprehensive Reverse Shoulder System

Indications for Use *(Describe)*

Comprehensive 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 Comprehensive 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.

Titanium glenospheres are intended for patients with Cobalt Alloy material sensitivity. The wear of these devices has not been tested but, based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A Cobalt Alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

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 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Comprehensive Reverse 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 August 12, 2005.

Sponsor:

Zimmer, Inc.
345 East Main Street
Warsaw, IN 46580
Establishment Registration Number: 1822565

Contact Person:

Dalene Binkley
Regulatory Affairs Project Manager
Telephone: 574-372-6789
Fax: 574-372-1683

Date:

June 18, 2018

Subject Device:

Trade Name: Comprehensive Reverse Shoulder System

Common Name: Shoulder Prosthesis, Reverse Configuration

Classification Name:

- PHX– Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
- KWS – Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
- PAO – Shoulder joint metal/polymer (+additive) semi-constrained cemented prosthesis (21 CFR 888.3360)
- KWT – Shoulder joint, metal/polymer, non-constrained, cemented prosthesis (21 CFR 888.3650)

Predicate Device(s):

K113069 (Primary)	Comprehensive Reverse Humeral Shoulder Tray	Biomet Manufacturing Corp
K131353	Comprehensive Reverse Shoulder – Titanium Glenosphere	Biomet Manufacturing Corp
K133378	Trabecular Metal Reverse Shoulder System, Vivacit-E® Vitamin E Highly Crosslinked Polyethylene Liners	Zimmer, Inc.

Reference Devices:

K080642	Comprehensive Reverse System	Biomet Manufacturing Corp
K013991	Prolong Highly Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Components	Zimmer, Inc.

Purpose and Device Description:

The purpose of this submission is to include newly designed trays, liners and a glenosphere into the Comprehensive Reverse Shoulder System.

The devices are a line extension of the Comprehensive Reverse Shoulder System and consists of new 36mm and 40mm tray and liner locking mechanism designs as well as a new 40mm glenosphere. The highly cross-linked ultrahigh molecular weight (HXPE) polyethylene liners are offered either in *Prolong*® (Standard) or *Vivacit-E* (Vitamin E). The tray taper geometry as well as the material (Ti-6AL-4V and Co-28Cr-6Mo) and thickness offerings are identical (standard, +5mm, +10mm) to the predicate. The trays will still be offered with a centric (standard) taper as well as two other offset tapers (+3 and +6) to provide more offerings to the surgeon.

Intended Use and Indications for Use:

Comprehensive 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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Summary of Technological Characteristics:

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

- **Intended Use:** Identical to primary predicate
- **Indications for Use:** Identical to primary predicate
- **Materials:** The polyethylene liners (*Prolong* and *Vivacit-E*), Co-Cr-Mo and Titanium trays and glenospheres are identical to those predicates currently marketed.
- **Design Features:** The design features of the subject device are similar to those predicates currently marketed. The design differences have not identified any issues that would impact the safety and efficacy of the devices.
- **Sterilization:** Identical assurance level and validation methods to the primary predicate.

Summary of Performance Data (Nonclinical and/or Clinical)

Non-clinical testing demonstrated that the proposed devices meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

- **Non-Clinical Tests:**
  - Assembly Force
  - Locking Mechanism Fatigue
  - Tray Fatigue
  - Tray and Liner Fatigue
  - Liner Torque-Out
  - Taper Strength
  - Finite Element Analysis (FEA)

- Range of Motion (ROM)
- Wear Rationale
- MRI Conditional

- **Clinical Tests:** Clinical data and conclusions were not needed for this device.

Substantial Equivalence Conclusion

The proposed devices are line extensions to the predicate devices. They share the same indications for use/intended use, utilize the same materials and manufacturing processes, and have similar technical features as their predicates. No new issues of safety and efficacy have been raised.