Biomet Inc.
Kari Hovorka
Regulatory Affairs Specialist
56 East Bell Drive, PO Box 587
WARSAW, IN 46581

April 15, 2020

Re: K193373
Trade/Device Name: Comprehensive® Reverse Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: March 17, 2020
Received: March 18, 2020

Dear Kari Hovorka:

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 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)*
K193373

Device Name
Comprehensive® Reverse Shoulder

Indications for Use *(Describe)*
(IFU 01-50-0903 Biomet® Comprehensive® Reverse Shoulder Products)

Biomet 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.

(IFU 01-50-0890 Biomet® Comprehensive® Reverse Shoulder Screws)

Biomet 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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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 Comprehensive Reverse Shoulder 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: Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Primary Contact Person: Kari Hovorka
Regulatory Affairs Specialist
Telephone: (877.652.0830)

Secondary Contact Person: Jared Cooper
Regulatory Affairs Manager
Telephone: (574- 372-1941)

Date: December 2, 2019

Subject Device:

Trade Name: Comprehensive® Reverse Shoulder
Common Name: Shoulder Prosthesis, Reverse Configuration
Classification Name:
Shoulder joint metal/polymer semi-constrained cemented prosthesis

- PHX – Shoulder Prosthesis, Reverse Configuration (21 CFR 888.3660)
- KWS – Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented (21 CFR 888.3660)

Predicate Device(s):

Predicates	510(k) Number
Comprehensive Reverse Shoulder	K080642 - **Primary**
Comprehensive Reverse Shoulder – Humeral Trays	K113069
Comprehensive Reverse Shoulder – E1 (Poly) Humeral Bearings	K113121
Comprehensive Reverse Shoulder – Mini Baseplate	K120121
Comprehensive Reverse Shoulder – Titanium Glenospheres	K131353

Comprehensive Reverse Shoulder – Screws	K132239
Comprehensive Vault Reconstruction System (VRS)	K152754

Purpose and Device Description:

The purpose of this submission is:

- To provide a cumulative assessment of design changes made to the system since original clearance;
  - The subject Glenosphere devices introduce a modified inner surface finish and a pilot hole modification;
  - The subject Humeral Tray and the Humeral Bearing devices introduced dimensional modifications;
- To document previously cleared (K152754) compatibility between the Comprehensive® Reverse Shoulder and the Trabecular Metal™ Reverse Shoulder;
- To update labeling in order to bring the Instructions for Use up to current practices;
- To insure that the all of the instrumentation/accessories for use with this system are appropriately associated with a 510(k).

Device Description:
The Comprehensive® Reverse Shoulder (CRS) is a total shoulder replacement system in a reverse configuration. The CRS was designed to provide a complete, seamless system based on the Comprehensive Shoulder platform by avoiding the need to remove a well-fixed humeral stem associated with a prior anatomical shoulder arthroplasty for conversion to reverse shoulder arthroplasty. This is made possible because the CRS can utilize any of the existing Comprehensive stems, including primary, revision, or fracture stems in cemented or uncemented applications. The CRS performs its function by replacing the damaged or diseased articular surfaces of the native shoulder with artificial surfaces with the intent to improve shoulder function and/or reduce shoulder pain.

Intended Use and Indications for Use:

These devices are intended for shoulder joint arthroplasty.

(*IFU 01-50-0903 Biomet® Comprehensive® Reverse Shoulder Products)*
Biomet 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.

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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 predicate
- **Indications for Use:** Similar to predicate; the subject devices have similar indications as compared to the predicate devices. The modifications to the indications does not alter the safety or efficacy of the subject devices. The change is not a result of safety or performance issues nor is the intent to significantly improve safety to efficacy. No new risks result from the change in indications wording.
- **Materials:** Identical to predicate.
- **Design Features:** Similar to predicate; the design changes made to the subject Comprehensive Reverse Shoulder device include addition of a 30-grit blast finish process to the inner surface of the glenosphere components, diameter reduction of the pilot hole of glenosphere components, refinement of tolerance band of the fillet between the taper and base of the tray, and narrowing of the interior notch width of the humeral bearings.
- **Sterilization:** Similar to predicate; ArComXL Humeral Bearings devices were cleared to be sterilized with either EtO or Gas Plasma sterilization in K080642. Subject ArComXL Humeral Bearings devices are provided sterile by Gas Plasma, with no changes to the sterilization parameters as cleared in K080642. The remaining subject components have identical sterilization parameters to predicate devices.

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

Non-Clinical Tests:

- Fatigue Strength Testing was completed to demonstrate that the modifications do not adversely impact the fatigue strength of the Comprehensive trays and humeral constructs under a clinically motivated unconstrained fixture conditions. The test method noted in the previous testing submitted with K113069, Comprehensive Reverse Humeral Tray Medium Fatigue Strength Determination, and the test report presented in this submission are sufficiently different such that the test results cannot be directly compared. Fatigue testing was performed in the Zimmer Fatigue and Fracture Mechanics Laboratory (Warsaw, IN) to demonstrate that the Humeral bearing

and tray construct could withstand a fatigue load of 566N for 5 million cycles. Zimmer Biomet established a laboratory fatigue test method and requirement for shoulder implant
system based on extensive literature review as described in the test report.

- Range of Motion analysis provides verification of the Range of Motion (ROM) conformance to ASTM Fl378-12.

Clinical Tests:

- None provided

Substantial Equivalence Conclusion:

The subject Comprehensive Reverse Shoulder has the same intended use and similar indications for use as the subject devices. The subject devices have similar technological characteristics to the predicates, and the information provided herein demonstrates that:

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