Biomet Manufacturing Corp. February 19, 2021
Patricia Beres
Regulatory Affairs Principal
56 E. Bell Drive
Warsaw, Indiana 46582

Re: K202232
Trade/Device Name: Comprehensive Vault Reconstruction System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: January 19, 2021
Received: January 21, 2021

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,

For Michael Owens
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)*
K202232

Device Name
Comprehensive Vault Reconstruction System

Indications for Use *(Describe)*
Biomet Comprehensive Vault Reconstruction System Components 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 Vault Reconstruction System Component 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 Comprehensive Vault Reconstruction System glenoid baseplate components are intended for cementless application with the addition of screw fixation in patients with unusual anatomy and/or extensive bone loss which precludes the use of a standard glenoid baseplate component.

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.

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.

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510(k) Summary

Sponsor:

Biomet Manufacturing Corp.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact Person:

Patricia Sandborn Beres
Regulatory Affairs Principal
Telephone: 574-373-3872
patty.beres@zimmerbiomet.com

Date:

February 18, 2021

Subject Device:

Trade Name: Comprehensive Vault Reconstruction System
Common Name: Reverse Shoulder Glenoid Components

Classification Name:

- PHX– Shoulder Prosthesis, Reverse Configuration 21 CFR 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis

Predicate Device(s):

K152754 (Primary)	Comprehensive Vault Reconstruction System (VRS)	Biomet Manufacturing Corp.
K172502 (Reference)	Comprehensive Augmented Glenoid Components,	Biomet Manufacturing Corp.
K190595 (Reference)	Signature™ ONE System	Biomet Manufacturing Corp.

Device Description:

The Comprehensive Vault Reconstruction System is a glenoid baseplate for reverse shoulder arthroplasty designed to match the natural geometry of an individual patient.

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The Comprehensive Vault Reconstruction System Component 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 Comprehensive Vault Reconstruction System glenoid baseplate components are intended for cementless application with the addition of screw fixation in patients with unusual anatomy and/or extensive bone loss which precludes the use of a standard glenoid baseplate component.

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Summary of Technological Characteristics:

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

- **Intended Use:** Identical
- **Indications for Use:** Identical
- **Materials:** Identical
- **Design Features:** Identical
- **Dimensional Envelope:** Identical
- **Accessories:** Modification
- **Software:** Updated versions and CT delivery method
- **Sterilization:** Identical

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Coating Characterization
  - Engineering Justification
  - Software Validation
- **Clinical Tests:**
  - None

Substantial Equivalence Conclusion

The proposed Comprehensive Vault Reconstruction System and associated instruments has the same intended use and indications for use as the predicate device. The modified implants and instruments have similar or identical technological characteristics to the predicate. The proposed changes to the software used for design of the devices does not raise new issues of safety or efficacy. Based on the information contained within this submission, it is concluded that the Comprehensive Vault Reconstruction System is substantially equivalent to the identified predicate device.