January 3, 2018

Biomet Manufacturing Corp
Patricia Sandborn Beres
Regulatory Affairs Specialist
56 E. Bell Drive
Warsaw, Indiana 46582

Re: K172502
Trade/Device Name: Comprehensive Augmented Glenoid Components, Comprehensive Standard Baseplate, Comprehensive Mini Baseplate
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, PAO, KWS, KWT, MBF
Dated: December 1, 2017
Received: December 4, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

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)*

K172502

Device Name
Comprehensive Reverse Shoulder Standard and Mini Baseplates
Comprehensive Augmented Glenoid Baseplates

Indications for Use *(Describe)*

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.

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.

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ZIMMER BIOMET

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 Glenoid Components 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:

Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1835034

Contact Person:

Patricia Sandborn Beres
Regulatory Affairs Principal
Telephone: (574-267-6639)
Fax: fax (574-371-1683)

Date:

January 3, 2018

Subject Device:

Trade Name: Comprehensive Augmented Glenoid Components, Comprehensive Standard Baseplate, Comprehensive Mini Baseplate
Common Name: Shoulder Replacement Prosthesis
Classification Name:

- PHX– Shoulder Prosthesis, Reverse Configuration (21 CFR888.3660)
- PAO- prosthesis, shoulder, semi-constrained, metal/polymer + additive, cemented (21 CFR 888.3660)
- KWS - prosthesis, shoulder, semi-constrained, metal/polymer cemented (21 CFR 888.3660)
- KWT - prosthesis, shoulder, non-constrained, metal/polymer cemented (21 CFR 888.3650)
- MBF - prosthesis, shoulder, semi-constrained, metal/polymer, uncemented (21 CFR 888.3670)

Predicate Device(s):

Device	Manufacturer	510(k) Number
Comprehensive Reverse Shoulder –Mini Baseplate	Biomet, Inc.	K120121
Comprehensive Reverse Shoulder	Biomet, Inc.	K080642
Equinoxe Reverse Total Shoulder System	Exactech, Inc.	K110708
Comprehensive Reverse Shoulder – Titanium Glenosphere	Biomet, Inc	K131353

Purpose and Device Description:

This submission is for manufacturing of an alternate version of exiting Comprehensive Standard and Mini Baseplates\ components with the porous plasma spray (PPS) coating applied by an outside vendor and the addition of Zimmer's Calcicoat coating. There is no change to the design to these existing products.

The new Comprehensive Reverse Augmented Baseplate has an augmented backside while retaining the existing Comprehensive Reverse baseplate geometry. The device will be available with three augment sizes, Small, Medium and Large. The new variant will be manufactured with PPS coating applied by a vendor and Zimmer Calcicoat coating.

Intended Use and Indications for Use:

Reverse Applications:

The Comprehensive Reverse Shoulder is 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.

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:** Identical to predicate
- **Materials:** Substrate and porous coating is the same as the predicate; *Calcicoat*® coating has been previously cleared for orthopedic products
- **Design Features:** Identical or similar to predicates
- **Sterilization:** Identical assurance level and validation methods to predicate (new vendor)

Summary of Performance Data:

- **Non-Clinical Tests:**
  - PPS and HA/TCP Coating Pore Size and Porosity
  - Glenoid Loosening/Disassociation Test Method
  - Shear testing justification
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion:

The proposed Comprehensive Glenoid Baseplates have the same intended use and indications for use as the predicate devices. The proposed devices have 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 devices are at least as safe and effective as the legally marketed predicate devices.