Biomet Manufacturing Corp.
Patricia Beres
Regulatory Affairs Principal
56 East Bell Drive
Warsaw, Indiana 46582

November 4, 2021

Re: K211729
Trade/Device Name: Comprehensive® Convertible Glenoid - Vivacit-E Liner
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT, PAO, MBF
Dated: October 5, 2021
Received: October 7, 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 Jiping Chen, PhD
Acting Division 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)*
K211729

Device Name
Comprehensive® Convertible Glenoid – Vivacit-E Liner

Indications for Use *(Describe)*

Anatomic Applications

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

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.

Comprehensive Convertible Glenoid Baseplate components are intended for cementless applications 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 application. 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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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
patty.beres@zimmerbiomet.com
(574) 267-6639

Date:

November 1, 2021

Subject Device:

Trade Name: Comprehensive® Convertible Glenoid – Vivacit-E Liner
Common Name: Shoulder prosthesis

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)
- KWT - Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650)
- PAO - Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
- MBF - Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3670)

Predicate Device(s):

Device	Manufacturer	510(k) Number
Primary Predicate		
Comprehensive Convertible Glenoid	Biomet Manufacturing Corp.	K130390
Reference Predicates for Testing		
Bio-Modular Shoulder System	Biomet Manufacturing Corp.	K992119, K030710, K093803
Reference Predicates for Materials, Sterilization and Packaging		

Persona Revision Knee System	Zimmer Inc.	K191625

Device Description:

The proposed device is an orthopaedic total joint intended to replace the damaged or diseased natural shoulder joint in shoulder arthroplasty to provide pain relief and restore function. It is modular in design, consisting of a baseplate held to the bone with bone screws and a modular liner. The device is designed to be implanted as the glenoid component of an anatomic total shoulder with the option to convert to a reverse shoulder configuration without removal of the metal components.

The current submission is to expand the product offering by the addition of a liner manufactured from Vivacit-E Vitamin E Highly Crosslinked Polyethylene (VEHXPE).

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ZIMMER BIOMET

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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:** Identical to reference predicate
- **Design Features:** Identical to primary predicate with the exception of removal of cosmetic tabs
- **Sterilization:** The predicate Convertible Glenoid E1 Liners were Gamma sterilized whereas the subject Convertible Glenoid Vivacit-E Liners are EtO sterilized similar to the reference predicate device.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Dissociation Testing
  - Shear Testing
  - Insertion Testing
  - Biocompatibility Assessment
  - Packaging Assessment
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

Based on the information contained within this submission, it is concluded that the Comprehensive Convertible Glenoid – Vivacit-E Liner is substantially equivalent to the identified predicate and reference devices. The subject device has similar technological characteristics to the previously cleared devices, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is as safe and effective as the legally marketed predicate devices.