Biomet Inc.
% Aishwarya Pandey
Regulatory Affairs Specialist
Biomet INC
56 East Bell Drive
Warsaw, Indiana 46581

December 10, 2021

Re: K212435
Trade/Device Name: Comprehensive Humeral Fracture Positioning Sleeves
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT
Dated: November 8, 2021
Received: November 12, 2021

Dear Aishwarya Pandey:

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, Ph.D., M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212435

Device Name
Comprehensive Humeral Fracture Positioning Sleeve

Indications for Use *(Describe)*
INDICATIONS
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
5. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Optional use in revision: in some medical conditions (e.g. revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.
Humeral components with a MacroBond® Surface Coating are indicated for either cemented or uncemented press-fit applications.
Humeral components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.
The Comprehensive® Modular Hybrid® Glenoid is intended to be implanted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.
The Comprehensive Humeral Positioning Sleeves are for cemented use only and are intended for use with the Comprehensive Fracture Stem.
The Versa-Dial Humeral Head Prosthesis is intended for use only with the Comprehensive Shoulder Stems (Fracture, Primary and Revision), and the glenoid components of the Comprehensive Shoulder System.
The Titanium Versa-Dial Humeral Head Prosthesis is indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

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.

510(k) Summary

Sponsor:

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

Contact Person:

Aishwarya Pandey
Regulatory Affairs Specialist
Telephone: +1 574 373 3740
Fax: (574-372-1683)

Date:

02-August-2021

Subject Device:

Trade Name: Comprehensive Humeral Fracture Positioning Sleeves
Common Name: Centering sleeve
Classification Name:

- KWS: Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
- KWT: Shoulder joint metal/polymer non-constrained cemented prosthesis. (21CFR888.3650)

Predicate Device(s):

K193038	Comprehensive Shoulder System	Biomet, INC.
K033506	Comprehensive Humeral Fracture Positioning Sleeves	Biomet, INC.

Reference Device(s):

K193546	Distal Centralizer	Biomet, INC.

Device Description: The Comprehensive Humeral Fracture Positioning Sleeves is composed of Polymethylmethacrylate (PMMA) and is used in conjunction with the Comprehensive Humeral Fracture System. The device is a sleeve that fits over the distal tapered end of the Comprehensive Humeral Fracture Stem and stops at a point below the fins of the stem.

The purpose of this submission is to move the Comprehensive Humeral Fracture Positioning Sleeve devices from Branson bioburden reduction process into a bioburden reduction process using REVOX technology.

Indications for Use:

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

Optional use in revision: in some medical conditions (e.g. revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.
Humeral components with a MacroBond® Surface Coating are indicated for either cemented or uncemented press-fit applications.

Humeral components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

The Comprehensive® Modular Hybrid® Glenoid is intended to be implanted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

The Comprehensive Humeral Positioning Sleeves are for cemented use only and are intended for use with the Comprehensive Fracture Stem.

The Versa-Dial Humeral Head Prosthesis is intended for use only with the Comprehensive Shoulder Stems (Fracture, Primary and Revision), and the glenoid components of the Comprehensive Shoulder System.

The Titanium Versa-Dial Humeral Head Prosthesis is indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

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:** Identical to predicate
- **Design Features:** Identical to predicate
- **Sterilization:** Identical to predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  Testing was completed to demonstrate that the change in bioburden reduction process using REVOX technology does not have any impact on sterilization, shelf life, or biocompatibility of the device.
  Clinical Tests:
  None provided

Substantial Equivalence Conclusion

Based on the information contained within this submission, it is concluded that the Comprehensive Humeral Positioning Sleeves is substantially equivalent to the identified predicate and reference devices.