October 28, 2020

Biomet Manufacturing Corp.
Patricia Beres
Regulatory Affairs Principal
56 East Bell Drive
Warsaw, Indiana 46580
USA

Re: K193038
Trade/Device Name: Comprehensive Shoulder System
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-sonstrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, KWT, KWS, HSD
Dated: October 20, 2020
Received: October 21, 2020

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)*
K193038

Device Name
Comprehensive Shoulder System

Indications for Use *(Describe)*

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 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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Comprehensive Shoulder System 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.
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Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact Person:
Patricia Sandborn Beres
Regulatory Affairs Principal
Telephone: (574-267-6639 ext. 1278)
Fax: fax (574-372-1683)

Date:
October 8, 2020

Subject Device:
Trade Name: Comprehensive Shoulder System
Common Name: Shoulder replacement prosthesis

Classification Name:
- MBF - Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3670)
- HSD – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690)
- 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)

Predicate Device(s):

Primary Predicate	**510(k) Number**
Comprehensive Primary Shoulder	K060692
Reference Predicates	**510(k) Number**
Comprehensive Humeral Fracture Positioning Sleeves	K033506
Versa-Dial Humeral Head Prostheses	K040610
Comprehensive Modular Hybrid Glenoid	K060694
Versa-Dial Humeral Heads	K060716
Titanium Versa-Dial Humeral Heads	K140390
Comprehensive Porous Coated Fracture Stem	K140652

Purpose and Device

Comprehensive Shoulder System consists of partial and total shoulder replacement components use in cemented and uncemented applications. The devices are modular components consisting of humeral stems, modular heads and glenoid components.

The components of the Comprehensive Anatomic Shoulder System contained in this submission have all previously been cleared. The purpose of this submission is:

- To update the indications to meet global regulatory requirements;
- To document changes made to the system since original clearance;
- To insure that all of the instrumentation/accessories for use with this system are appropriately associated with a 510(k)

Intended Use and
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 implant in a revision procedure.

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Summary of Technological Characteristics:

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

- **Intended Use:** Similar to predicate
- **Indications for Use:** Identical to predicate
- **Materials:** Identical to predicate; alternate for humeral stems and humeral heads
- **Design Features:** Identical to predicate
- **Sterilization:** Identical to predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Fatigue testing of Titanium Alloy Forged Humeral Stems, Titanium Alloy Wrought Humeral Stems and Cobalt Alloy Humeral Stems was conducted. Five samples of each type were subjected to a fatigue load of 400N or greater for 5 million cycles in reverse configuration at a worst case orientation. All samples withstood the applied fatigue without fracture of the stem.
  - Porous coating characterization
  - Biocompatibility
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

The proposed Comprehensive Shoulder System has the same intended use and indications for use as the predicate devices. The proposed 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 proposed devices are at least as safe and effective as the legally marketed predicate devices.