Michael McBurney
Regulatory Affairs Associate
56 East Bell Drive
Warsaw, Indiana 46581

January 22, 2019

Re: K183553
Trade/Device Name: Compress and Mini Compress Anti-Rotation Spindles
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder Joint Metal/Polymer/Metal Nonconstrained Or Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBF, JDC, KWS, KWT, JDI, KRO, KWY, KWZ, LPH, LZO, MEH
Dated: December 18, 2018
Received: December 20, 2018

Dear Michael McBurney:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Daniel S. Ramsey -S
2019.01.22 17:35:50 -05'00'

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)*

K183553

Device Name

Compress Segmental Femoral Replacement System

Indications for Use *(Describe)*

1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.

2. Tumor resections.

3. Revision of previously failed total joint arthroplasty.

4. Trauma.

The Compress Segmental Femoral Replacement System components are intended for uncemented use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K183553

Device Name

Compress Segmental Humeral Replacement System

Indications for Use *(Describe)*

1. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty.
4. Trauma.

The Compress Segmental Humeral Replacement System components are intended for uncemented use.

The Discovery® Elbow and Nexel® Elbow components when used in conjunction with the Compress Segmental Humeral Replacement System are restricted to the Compress Segmental Humeral Replacement System indications and are intended to be inserted with bone cement.
When components of the Compress Segmental Humeral Replacement System are used with Biomet's Discovery® Elbow System, the user should refer to the package insert contained with the Discovery® components for additional information (01-50-0901). Compatibility is limited to Biomet manufactured Discovery® Elbow components.
When components of the Compress Segmental Humeral Replacement System are used with the Zimmer Nexel® Elbow System, the user should refer to the package insert contained with the Nexel® components for additional information (87-6204-077-88).
When components of the Compress Segmental Humeral Replacement System are used with Biomet's Comprehensive® Segmental Revision System, the user should refer to the package insert contained with the Comprehensive Segmental Revision System components for additional information (01-50-0911).
The Modular Hybrid® Glenoid when used in conjunction with the Compress Segmental Humeral Replacement System is restricted to the Compress Segmental Humeral Replacement System indications and is intended to be used with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the subject 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: 1825034

Contact Person:

Michael McBurney
Regulatory Affairs Associate
Telephone: (574-373-2564)

Date:

January 18, 2019

Subject Device:

Trade Name: Compress and Mini Compress Anti-Rotation Spindles

Common Name: Limb salvage arthroplasty

Classification Name:

- MBF – prosthesis, shoulder, semi-constrained, metal/polymer, uncemented (21 CFR 888.3670)
- JDC – prosthesis, elbow, constrained, cemented (21 CFR 888.3150)
- KWS – prosthesis, shoulder, semi-constrained, metal/polymer cemented (21 CFR 888.3660)
- KWT – prosthesis, shoulder, non-constrained, metal/polymer cemented (21 CFR 888.3650)
- JDI – prosthesis, hip, semi-constrained, metal/polymer, cemented (21 CFR 888.3350)
- KRO – prosthesis, knee, femorotibial, constrained, cemented, metal/polymer (21 CFR 888.3510)
- KWY – prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented (21 CFR 888.3390)
- KWZ – prosthesis, hip, constrained, cemented or uncemented, metal/polymer (21 CFR 888.3310)

- LPH – prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (21 CFR 888.3358)
- LZO – prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (21 CFR 888.3353)
- MEH – prosthesis, hip, semi-constrained, uncemented, metal / polymer, non-porous, calcium phosphate (21 CFR 888.3353)

Predicate Device(s):

Primary Predicate Device:

K101475 Compress Anti-Rotation Spindles (Biomet, Inc.)

Additional Predicates:

K112905 Compress Segmental Humeral Replacement System (Biomet, Inc.)

K123297 Compress Segmental Humeral Replacement System (Biomet, Inc.)

Description:

The Compress and Mini Compress Anti-Rotation Spindles are components of the Compress Segmental Femoral Replacement System and Compress Segmental Humeral Replacement System. The Anti-Rotation Spindles attach to an anchor plug and a proximal/distal femoral/humeral component to serve as a method of fixing a segmental joint replacement to a patient's host bone. The Anti-Rotation Spindles contain several conical washers which allow a compressive load to be applied at the prosthetic implant-bone interface at the time of device insertion. The Anti-Rotation Spindles also include a series of holes around the spindle collar to allow placement of pins to prevent rotation of the component. The purpose of this submission is the update of the surgical techniques associated with the Compress and Mini Compress Anti-Rotation Spindles to revise the recommended pin selection range for use with the Anti-Rotation Spindles.

Summary of Technological Characteristics:

The updates to the surgical techniques do not impact indications, materials, design features or dimensions, packaging or sterilization. The subject devices are

intended for use in limb salvage arthroplasty. The indications for use are as follows:

- **Indications for Use – Compress Segmental Femoral Replacement System:**
  1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
  2. Tumor resections.
  3. Revision of previously failed total joint arthroplasty.
  4. Trauma.

  The Compress Segmental Femoral Replacement System components are intended for uncemented use.

- **Indications for Use – Compress Segmental Humeral Replacement System:**
  1. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
  2. Tumor resections.
  3. Revision of previously failed total joint arthroplasty.
  4. Trauma.

  The Compress Segmental Humeral Replacement System components are intended for uncemented use.

  The Discovery® Elbow and Nexel® Elbow components when used in conjunction with the Compress Segmental Humeral Replacement System are restricted to the Compress Segmental Humeral Replacement System indications and are intended to be inserted with bone cement.

  When components of the Compress Segmental Humeral Replacement System are used with Biomet's Discovery® Elbow System, the user should refer to the package insert contained with the Discovery® components for additional information (01-50-0901). Compatibility is limited to Biomet manufactured Discovery® Elbow components.

  When components of the Compress Segmental Humeral Replacement System are used with the Zimmer Nexel® Elbow System, the user should refer to the package insert contained with the Nexel®

components for additional information (87-6204-077-88).

When components of the Compress Segmental Humeral Replacement System are used with Biomet's Comprehensive® Segmental Revision System, the user should refer to the package insert contained with the Comprehensive® Segmental Revision System components for additional information (01-50-0911). The Modular Hybrid® Glenoid when used in conjunction with the Compress Segmental Humeral Replacement System is restricted to the Compress Segmental Humeral Replacement System indications and is intended to be used with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Geometric evaluation was conducted, demonstrating the necessity for revisions to the subject surgical techniques to clarify the Anti-Rotation Pin usage.

- **Clinical Tests:**
  Clinical data was not provided for the subject devices.

Substantial Equivalence Conclusion

The subject surgical technique modifications are implemented per the results of the geometric evaluation. The subject devices are substantially equivalent to the legally marketed predicate devices.