Biomet Inc.
Rhonda Myer
Project Manager & Regulatory Affairs
Zimmer Biomet
1800 West Center Street
Warsaw, Indiana 46580

September 25, 2020

Re: K193546

Trade/Device Name: Distal Centralizers
Regulation Number: 888.3360
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: JDG
Dated: August 24, 2020
Received: August 26, 2020

Dear Rhonda Myer:

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 Vesa Vuniqi
Acting 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)*

K193546

Device Name
Distal Centralizers

Indications for Use *(Describe)*

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

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.

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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 Distal Centralizer 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 September 13, 2019.

Sponsor:
Biomet Inc.
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Warsaw, IN 46581
Establishment Registration Number: 1825034

Primary Contact Person:
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Secondary Contact Person:
Jason Heckaman
Regulatory Affairs Associate Director
Telephone: (574) 373-3364

Date:
September 25, 2020

Subject Device:
Trade Name: Distal Centralizers
Common Name: Prosthesis, Hip, Femoral Component, Cemented, Metal
Classification Name: JDG – prosthesis, hip, femoral component, cemented, metal (21 CFR 888.3360)

Predicate Device(s):

Device	510(k) Number
Integral Co-Cr Femoral Components; Including PMMA Distal Centralizers	K942479

Purpose and Device Description:
The purpose of this submission is to move the subject devices from Branson bioburden reduction process into a bioburden reduction process using REVOX technology. Additionally, this submission is intended to ensure modifications made since the last clearance have been reviewed by the FDA.

The subject devices, Distal Centralizers, are cylindrical components designed to slide onto the distal end of a cemented femoral stem prior to insertion into the femoral canal.

Indications for Use:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
5. Revision of previously failed total hip arthroplasty

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:** Similar 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. Additionally, the results of the Geometric Evaluation Analyses demonstrate the subject devices met the established acceptance criterion. Collectively, these reports demonstrate the modifications being submitted at this time, since the last clearance, will perform as intended and is substantially equivalent to the predicate device(s) referenced in the submission.

Clinical Tests:
None provided

Substantial Equivalence Conclusion:

The proposed Distal Centralizers have the identical 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.