February 7, 2022

Biomet, Inc.
Gregory Foster
Sr. Specialist Regulatory Specialist
56 East Bell Drive
PO Box 587
Warsaw, Indiana 4658

Re: K212431
Trade/Device Name: Biomet Answer/Impact/Integral Distal Centralizer/Centering Sleeve
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: JDG, LZO
Dated: November 11, 2021
Received: November 12, 2021

Dear Gregory Foster:

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,

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212431

Device Name
Biomet Answer/Impact/Integral Distal Centralizer/Centering Sleeve

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

Sponsor:

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

Contact Person:

Gregory Foster
Sr. Regulatory Specialist
Telephone: (574) 371-0519
Fax: (574) 377-3718
Gregory.foster@zimmerbiomet.com

Date:

07-Feb-2022

Subject Device:

Trade Name: Biomet Answer/Impact/Integral Distal Centralizer/Centering Sleeve.

Common Name: Prosthesis, Hip, Femoral Component, Cemented, Metal

Classification Name:

21 CFR 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

- JDG– Prosthesis, Hip, Femoral Component, Cemented, Metal
- LZO - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented

Predicate Device(s):

K193546	Distal Centralizers	Biomet, Inc.

Device Description:

The subject devices, Biomet Answer/Impact/Integral Distal Centralizer/Centering Sleeves, are cylindrical components designed to slide onto the distal end of a cemented femoral stem prior to insertion into the femoral canal.

This submission proposes a new bioburden reduction manufacturing process that includes a new contact material for the Biomet Answer/Impact/Integral Distal Centralizer/Centering Sleeve.

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 the predicate
- **Indications for Use:** Identical to the predicate
- **Materials:** Identical to the predicate
- **Design Features:** Identical to the predicate
- **Sterilization:** Identical to the predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - A biocompatibility assessment was performed in accordance with ISO 10993-1. The data provided by the testing confirmed the biocompatibility of the candidate manufacturing process flow for the Biomet Answer/Impact/Integral Distal Centralizer/Centering Sleeve in long-term contact with patient bone and tissues.
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

Based on the information contained within this submission, it is concluded that the Biomet Answer/Impact/Integral Distal Centralizer/Centering Sleeve are substantially equivalent to the identified predicate device.