Zimmer, Inc
Carol Vierling
Regulatory Affairs Project Manager
P.O Box 708
Warsaw, Indiana 46581-0708

April 2, 2019

Re: K181171
Trade/Device Name: Zimmer Biomet Ceramic Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, KWY, KWZ
Dated: February 28, 2019
Received: March 4, 2019

Dear Carol Vierling:

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
2019.04.02 16:43:05 -04'00'

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)*
K181171

Device Name
Zimmer Biomet™ Ceramic Heads

Indications for Use *(Describe)*

The Zimmer Biomet™ Ceramic Heads are indicated for the following conditions: (1) a severely painful and/or disabled hip joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia, (2) avascular necrosis of the femoral head, (3) acute traumatic fracture of the femoral head or neck, (4) failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement, (5) certain cases of ankylosis, (6) nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

When used with constrained acetabular liners, the Zimmer Biomet™ Ceramic Heads are intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

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.

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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 Zimmer Biomet™ Ceramic Heads 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:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person:

Carol Vierling
Regulatory Affairs Project Manager
Telephone: (706-476-2938)

Date:

March 27, 2019

Subject Device:

Trade Name: Zimmer Biomet™ Ceramic Heads
Common Name: Ceramic Femoral Head Prosthesis

Classification Name:

- KWY—Hip joint femoral (hemi-hip), metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)
- KWZ—Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
- LZO– Hip joint/metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)

Primary Predicate:	K151307	ICONACY™ I-Hip™	ICONACY Orthopedic Implants, LLC
Additional Predicates:	K071535	BIOLOX® *delta* Ceramic Femoral Head	Zimmer, Inc.
	K131684	BIOLOX® *delta* Ceramic Heads	Biomet UK Ltd.

Reference Device:	K141653	BIOLOX® *delta* Option Ceramic Heads	Biomet UK Ltd.

Purpose and Device Description:

This traditional 510(k) premarket notification is being submitted to obtain clearance for the Zimmer Biomet™ Ceramic Heads. The heads are made from an alumina matrix composite.

The Zimmer Biomet Ceramic Heads are supplied with a 12/14 bore or Type 1 bore and are offered in a variety of head diameters and neck configurations. They are intended for mating with a variety of Titanium Alloy and Cobalt-Chromium Alloy femoral stems equipped with tapered necks.

Intended Use and Indications for Use:

The Zimmer Biomet™ Ceramic Heads are indicated for the following conditions: (1) a severely painful and/or disabled hip joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia, (2) avascular necrosis of the femoral head, (3) acute traumatic fracture of the femoral head or neck, (4) failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement, (5) certain cases of ankylosis, (6) nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

When used with constrained acetabular liners, the Zimmer Biomet™ Ceramic Heads are intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

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:** Similar to the predicate
- **Materials:** Identical to the predicate
- **Design Features:** Both the subject and predicate devices mate with a variety of femoral stems equipped with tapered necks. The variety of head diameters and neck configurations is similar although the subject device is available in a larger range of sizes.
- **Sterilization:** Identical

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Static Compression
  - Axial fatigue and Post-Fatigue Compression
  - Axial Pull-Off
  - Resistance to Wear and Head Retention were considered.
  - Range of Motion

- **Clinical Tests:**
  - Clinical data was not deemed necessary for the subject device.

Substantial Equivalence Conclusion

The subject device has the same intended use and similar indication for use as the predicate devices. The subject device is made of the identical material using a similar manufacturing process as the primary predicate device. In addition, the subject device has similar technological characteristics to the predicates and reference device. The performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate devices.