Zimmer, Inc. July 16, 2020
Caleb Barylski
Specialist, Regulatory Affairs
1800 W. Center Street
Warsaw, Indiana 46580

Re: K191449
Trade/Device Name: ZCA All-Poly Acetabular Cups
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: July 15, 2020
Received: July 16, 2020

Dear Caleb Barylski:

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)*

K191449

Device Name

ZCA All-Poly Acetabular Cups

Indications for Use *(Describe)*

The acetabular cup is indicated for cemented use in skeletally mature individuals undergoing primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

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 ZCA All-Poly Acetabular Cups 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:

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

Contact Person:

Caleb Barylski
Regulatory Affairs Specialist
Telephone: (574-371-0250)
Email: Caleb.Barylski@zimmerbiomet.com

Date:

July 14, 2020

Subject Device:

Trade Name: ZCA All-Poly Acetabular Cups
Common Name: Hip Prosthesis

Classification Name:

- JDI– prosthesis, hip, semi-constrained, metal/polymer, cemented (21 CFR 888.3350)

Predicate Device(s):

K901240	NON-METAL BACKED ACETABULAR CUP FOR CEMENTED	MEDTEK (purchased by Zimmer, Inc.)
K030153	ZCA All-Poly Acetabular Cup, Snap-In, Model 8005-946/958-32	Zimmer, Inc.

Purpose and Device Description:

ZCA is an acetabular cup prosthesis intended for use in total hip arthroplasty. It is manufactured from conventional Ultra-High Molecular-Weight Polyethylene (UHMWPE).

The current submission is a retrospective 510(k) for devices that are currently marketed in the U.S. Through a review of the changes to the device system based on the current FDA Guidance document "Deciding When to Submit a 510(k) for

a Change to an Existing Device" (October 25, 2017), Zimmer Inc. has decided to submit a 510(k) for the cumulative changes.

Intended Use and Indications for Use:

The acetabular cup is indicated for cemented use in skeletally mature individuals undergoing primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Summary of Technological Characteristics:

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

- **Intended Use:** Identical to predicates
- **Indications for Use:** Similar to predicates
- **Materials:** Substantially equivalent to predicates
- **Design Features:** Substantially equivalent to predicates
- **Sterilization:** Identical to predicates

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - **Performance Evaluation –** Performance testing was completed on the line extension to determine equivalence to legally marketed devices.
  - **Shelf Life –** Accelerated and real time aging testing conducted shows the sterile devices included in this submission have a shelf life of eight years.
  - **Compatibility –** Functional Relationship Analysis, wear performance, range of motion, and lever-out pull-through strength evaluation conducted shows the implants in this submission are compatible with femoral heads.
- **Clinical Tests:**
  - Clinical test data is not provided for the subject device.

Substantial Equivalence Conclusion

The data presented in this submission show that the changes do not affect the safety and/or effectiveness of the subject devices and that the subject devices will perform

in a substantially equivalent manner to the legally marketed predicate devices.