December 10, 2021

Zimmer, Inc.
Katherine Choi
Regulatory Affairs Specialist
1800 W. Center Street
Warsaw, Indiana 46580

Re: K210842
Trade/Device Name: VerSys Cemented Revision/Calcar
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: November 10, 2021
Received: November 12, 2021

Dear Katherine Choi:

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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210842

Device Name

VerSys Cemented Revision/Calcar

Indications for Use *(Describe)*

VerSys Cemented Revision/Calcar is indicated for total hip arthroplasty in patients:

Whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief and when there is progressive disability.

Type of Use *(Select one or both, as applicable)*

[X] 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

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

Contact Person

Name: Kat Choi
Title: Regulatory Affairs Specialist
Phone: 260-602-2359
Email: Katherine.Choi@zimmerbiomet.com

Date Prepared

10-Nov-2021

Subject Device

Trade Name: VerSys Cemented Revision/Calcar (CRC) Hip System
Common Name: Hip Prosthesis

Classification Name:

- 21 CFR 888.3350 - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented

Product Code:

- JDI – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350)

Predicate Device

510(k) Number	Device Name	Manufacturer
K913649	Modular Calcar Replacement Hip System	Zimmer, Inc.

Reference Devices

510(k) Number	Device Name	Manufacturer
K030265, K191735	CPT Hip System	Zimmer, Inc.
K921224	BiMetric Hip System	Biomet Orthopedics

Device Description

Device Identification: VerSys Cemented Revision/Calcar (CRC) Hip System

Device Characteristics: The VerSys CRC Hip System includes femoral stems and build-up blocks that are permanent hip implants and provided sterile via gamma irradiation.

Description: The VerSys CRC Hip System include femoral stems in a variety of body sizes and lengths and build-up blocks in heights of 10mm, 20mm, and 30mm. The block is attached to the femoral stem by inserting two Tivanium® Ti-6Al-4V alloy screws into the holes provided. Only one build-up block can be attached to a femoral stem. The modular connection of the femoral stem is a Morse-type 12/14

taper designed to mate with the corresponding bore of a femoral head.

Materials: The femoral stems are manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F799. The build-up blocks and associated screws are manufactured from Tivanium® Ti-6Al-4V alloy conforming to ASTM F136. The materials for the stems and build-up blocks are categorized as "implant/device – tissue/bone" with a contact duration of "permanent > 30 days."

Indications for Use

The VerSys CRC Hip System is indicated for total hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief and when there is progressive disability.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics compared to the predicate device(s):

- **Intended Use:** Identical
- **Indications for Use:** Identical
- **Materials:** Identical
- **Design Features:** Similar
- **Sterilization:** Identical

Summary of Performance Data to Support Substantial Equivalence (Nonclinical and/or Clinical)

Non-Clinical Tests:

- Performance testing to determine equivalence to legally marketed devices
- Proximal fatigue testing per internal requirements
- Distal fatigue testing per internal requirements
- Finite Element Analysis for worst-case proximal fatigue Strength per ISO 7206-6.
- Finite Element Analysis for worst-case distal fatigue Strength per ISO 7206-4.
- Fretting/Corrosion of the stem/build-up block junction using setup contained within ISO 7206-6

Clinical Tests:

- Clinical test data is not provided for the subject device.

Substantial Equivalence Conclusion

Based on the information contained within this submission, it is concluded that the VerSys CRC Hip System is substantially equivalent to the identified predicate device.