September 17, 2020

Zimmer Inc
Caleb Barylski
Specialist, Regulatory Affairs
1800 W Center Street
Warsaw, Indiana 46580

Re: K191735
Trade/Device Name: CPT Hip System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI

Dear Caleb Barylski:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 20, 2020. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Vesa Vuniqi, OHT6: Office of Orthopedic Devices, 1-301-796-5773, vesa.vuniqi@fda.hhs.gov.

Sincerely,

Vesa Vuniqi -S

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

Zimmer Inc
Caleb Barylski
Specialist, Regulatory Affairs
1800 W Center Street
Warsaw, Indiana 46580

March 20, 2020

Re: K191735
Trade/Device Name: CPT Hip System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: February 20, 2020
Received: February 21, 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,

Daniel S. Ramsey -S
2020.03.20 09:44:18 -04'00'

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)*

K191735

Device Name
CPT Hip System

Indications for Use *(Describe)*

The CPT Hip System is indicated for cemented use in:
– Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.
– Patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis.
– Patients suffering from disability due to previous fusion.
– Patients with previously failed endoprostheses and/or total hip components in the affected extremity.
– Patients with acute femoral neck fractures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 CPT Hip System 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.
1800 W. Center Street
Warsaw, IN 46580
Establishment Registration Number: 1822565

Contact Person:

Caleb Barylski
Specialist, Regulatory Affairs
Telephone: (574-371-0250)

Date:

19-Mar-2020

Subject Device:

Trade Name: CPT Hip System
Common Name: Hip Prosthesis

Classification Name:

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

Predicate Device(s):

K960658	COLLARLESS POLISHED TAPER HIP PROSTHESIS	Zimmer, Inc.
K030265	CPT 12/14 HIP PROSTHESES, MODEL 00-8114-040/050-00	Zimmer, Inc.

Purpose and Device Description:

The CPT (Collarless Polished Taper) Hip System is designed for cement fixation into the intramedullary canal for pathological or degenerative conditions involving the femur that merit total hip arthroplasty.

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 CPT Hip System is indicated for cemented use in:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis.
- Patients suffering from disability due to previous fusion.
- Patients with previously failed endoprostheses and/or total hip components in the affected extremity.
- Patients with acute femoral neck fractures.

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:** Substantially equivalent to predicates
- **Materials:** Identical to predicates
- **Design Features:** Substantially equivalent to predicates
- **Sterilization:** Identical to predicates

Summary of Performance Data (Nonclinical and/or Clinical):

Non-Clinical Tests:

- 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 in distal fatigue per ISO 7206-4
- Range of Motion analysis per ISO 21535 and internal requirements
- Fretting/Corrosion testing per ASTM F1875
- Anatomic fatigue testing and accelerated corrosion fatigue testing per internal requirements

- Load to failure, insertion force, and stem subsidence testing for distal stem centralizers

- **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.