Zimmer, Inc
Caleb Barylski
Regulatory Affairs Specialist
P.O. Box 708
Warsaw, Indiana 46581-0708

May 31, 2019

Re: K182678
Trade/Device Name: Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology MR Labeling
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LWJ, LZO, MEH
Dated: April 25, 2019
Received: April 29, 2019

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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*

K182678

Device Name

Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology MR Labeling

Indications for Use *(Describe)*

• Total hip replacement for patients with:

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

• Hemi-hip replacement for patients with:

fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

• The femoral stem is for cementless use only.

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 subject Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology MR Labeling 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:

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

Date:

08-Nov-2018

Subject Device:

Trade Name: Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology MR Labeling
Common Name: Hip Prosthesis

Classification Name:

- LPH - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)
- LWJ - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (21 CFR 888.3360)
- LZO - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (21 CFR 888.3353)
- MEH - Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate (21 CFR 888.3353)

Predicate Device(s):

Zimmer, Inc.

K063251	Zimmer M/L Taper Hip Prosthesis With Modular Neck Technology
K071856	Zimmer M/L Taper Hip Prosthesis With Kinectiv Technology System, Model(S) 7848 Series(Modular Necks), 7713 Series
K081007	Zimmer M/L Taper Hip Prosthesis With Kinectiv Technology System

Summary of Technological Characteristics:

The purpose of this submission is to update the Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology Instructions for Use to include MR Conditional labeling within the precaution section. The device package label will also be updated to include the MR Conditional symbol. The addition of MR labeling to the subject devices does not impact indications, materials, design features or dimensions, packaging or sterilization. The subject devices are intended for use in hip arthroplasty. Specific indications for use are below.

Indications for Use:

Zimmer M/L Taper Hip Prosthesis with Kinectiv Technology

- Total hip replacement for patients with:

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

- Hemi-hip replacement for patients with:

fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

- The femoral stem is for cementless use only.

Summary of Performance Data

- **Non-Clinical Tests:**
  Zimmer has performed non-clinical Magnetic Resonance Imaging (MRI) studies on implants which are determined to be MR Conditional in accordance to ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Tests included the following:
  - RF-induced heating (ASTM F2182-11a)
  - Image Artifact (ASTM F2119-07)
  - Magnetic Displacement (ASTM 2052-14)

- **Clinical Tests:**
  Clinical data was not provided for the subject devices.

- **Marketing History and Clinical Publications**
  A summary of the marketing history and clinical publications related to the subject devices is included.

Substantial Equivalence Conclusion

Non-clinical tests provided in this Traditional 510(k) establish the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment. The subject devices are substantially equivalent to the legally marketed predicated devices.