December 10, 2020

Zimmer, Inc.
Yoriko Kobayashi
Sr. Specialist, Regulatory Affairs
1800 W. Center Street
Warsaw, Indiana 46580

Re: K192798
Trade/Device Name: Zimmer® Segmental System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, JDI, LZO, LPH, KWY, LWJ, KWZ, KWL
Dated: November 10, 2020
Received: November 12, 2020

Dear Yoriko Kobayashi:

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,

Ting Song
Assistant Director, Knee Arthroplasty Devices
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)*
K192798

Device Name
Zimmer Segmental System

Indications for Use *(Describe)*
This device is indicated for:
– Moderate to severe knee instability
– Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the proximal and/or distal femur and/or proximal tibia
– Valgus, varus or flexion deformities
– The salvage of previously failed surgical attempts
• A total femoral replacement construct consisting of Segmental proximal femoral, Segmental System segments and Segmental System distal femoral components may be used without cement.
• Variable Stiffness stem extensions require the use of either a smooth or Trabecular Metal stem collar, which must be cemented to the stem. Following cementing to the stem, the smooth collar must be cemented against the bone. The remainder of the stem must be used uncemented.
• Fluted stem extensions require the use of either a smooth or Trabecular Metal stem collar, which must be cemented to the stem. Following cementing to the stem extension, the smooth collar must be cemented against the bone. The remainder of the stem must also be cemented against the bone.
• The Trabecular Metal collar may be used cemented or uncemented against the bone.
• All other constructs are for cemented 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.

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 Segmental System 510(k) premarket notification.

Sponsor:

Zimmer, Inc.
1800 W. Center Street
Warsaw, IN 46580
Establishment Registration Number: 1822565

Contact Person:

Yoriko Kobayashi
Sr. Specialist, Regulatory Affairs
Telephone: 574-372-4222
Fax: 574-372-4710

Date:

November 10, 2020

Subject Device:

Trade Name: Zimmer® Segmental System
Common Name: Knee Prosthesis,
Hip Prosthesis

Classification Name:

- KRO –Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer (21 CFR 888.3510)
- JDI – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350)
- LZO – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (21 CFR 888.3353)
- LPH – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)
- KWY – Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented (21 CFR 888.3390)
- LWJ – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (21 CFR 888.3360)
- KWZ – Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer (21 CFR 888.3310)
- KWL – Prosthesis, Hip, Hemi-, Femoral, Metal (21 CFR 888.3360)

Predicate Device(s):

Zimmer Segmental System	K070978 K081860 K101296 K110940 K150028 K183136

Purpose and Device Description:

The purpose of this submission is an addition of the MR conditional information to the labeling for the predicate devices, and changes in packaging, device design and etching. The subject devices are intended for use in limb salvage arthroplasty. Specific indications for use are below.

Intended Use and Indications for Use:

This device is indicated for:
– Moderate to severe knee instability
– Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the proximal and/or distal femur and/or proximal tibia
– Valgus, varus or flexion deformities
– The salvage of previously failed surgical attempts

• A total femoral replacement construct consisting of Segmental proximal femoral, Segmental System segments and Segmental System distal femoral components may be used without cement.
• Variable Stiffness stem extensions require the use of either a smooth or Trabecular Metal stem collar, which must be cemented to the stem. Following cementing to the stem, the smooth collar must be cemented against the bone. The remainder of the stem must be used uncemented.
• Fluted stem extensions require the use of either a smooth or Trabecular Metal stem collar, which must be cemented to the stem. Following cementing to the stem extension, the smooth collar must be cemented against the bone. The remainder of the stem must also be cemented against the bone.

• The Trabecular Metal collar may be used cemented or uncemented against the bone.
• All other constructs are for cemented use only.

Summary of Technological Characteristics:

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

- **Intended Use:** Identical to predicate
- **Indications for Use**: Identical to predicate
- **Material:** Identical to predicate
- **Design Features:** Similar to predicate
- **Sterilization:** Identical to predicate

Summary of Performance Data (Nonclinical and/or Clinical)

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 2052-15)
  - Magnetically Induced Torque (ASTM F2213-17)
- Finite Element Analysis (FEA) for implant stress
- Fatigue strength testing per internal test method
- Packaging testing (ISO 11607-1)
- Biocompatibility (ISO 10993)
- Bacterial Endotoxin Test (BET) per ANSI/AAMI ST 72:2011as part of cleaning validation demonstrating implants meet the limit of ≤20 Endotoxin units (EU)/Device per USP41-NF36 Chapter <161> Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

Clinical Tests:

Clinical data was not provided for the subject devices.

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, as well as any differences do not raise new questions of safety and effectiveness. The subject devices are substantially equivalent to the legally marketed predicated devices.