Zimmer, Inc.
Jason Heckaman
Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

January 30, 2019

Re: K183136
Trade/Device Name: Zimmer Segmental System Proximal Femoral Component
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: January 3, 2019
Received: January 4, 2019

Dear Jason Heckaman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
2019.01.30 11:27:29 -05'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K183136

Device Name
Zimmer Segmental System Proximal Femoral Component

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 MOST Options or 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 Proximal Femoral Component 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:

Jason Heckaman
Regulatory Affairs Manager
Telephone: 574-373-3364
Fax: 574-372-4710

Date:

January 3, 2019

Subject Device:

Trade Name: Zimmer Segmental System Proximal Femoral Component

Classification Name:

- LZO – Prosthesis, Hip, Semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (21 CFR 888.3353)

Predicate Device(s):

Primary: K110940 – Zimmer Segmental System Trabecular Metal Proximal Tibial Component, Trabecular Metal Proximal Femoral Component and additional Segment with Male/Female Taper components (Zimmer, Inc.)

Secondary: K101296 – Zimmer Segmental System Proximal Femoral Component and Small Diameter Stem Extensions (Zimmer, Inc.)

Purpose and Device Description:

The Zimmer Segmental System Proximal Femoral Component is an implantable device, designed to replace the proximal portion of the natural femur. It is manufactured from Tivanium Ti-6Al-4V alloy. The subject device contains suture holes located on the medial and lateral sides for soft tissue attachment, a proximal

male taper permitting use with various femoral head components, and a distal female taper that allows for attachment with compatible Zimmer Segmental System components.

The subject modifications are changes to the manufacturing process for the Zimmer Segmental System Proximal Femoral Component.

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 MOST Options or 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 rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Identical to predicate device
- **Indications for Use:** Similar to predicate device
- **Materials:** Identical to predicate device
- **Design Features:** Identical to predicate device
- **Sterilization:** Identical to predicate device
- **Manufacturing Process:** Similar to predicate device.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Cleaning validation, including analysis of bacterial endotoxin, organic contaminants, inorganic contaminants and cytoxicity.
- **Clinical Tests:**
  - Clinical data was not deemed necessary for the subject device.

Substantial Equivalence Conclusion

The proposed Zimmer Segmental System Proximal Femoral Component has the same intended use and similar indications for use as the predicate device. There are no changes to the device design, materials, labeling, packaging, shelf life or sterilization. The proposed device has similar technological characteristics to the predicate, and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness;
- and the proposed device is at least as safe and effective as the legally marketed predicate device.