DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2015

Zimmer, Incorporated
Ms. Yoriko Kobayashi
Regulatory Affairs Specialist
P.O. Box 708
Warsaw, Indiana 46581

Re: K150028
Trade/Device Name: Zimmer Segmental System XT Components
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: January 6, 2015
Received: January 7, 2015

Dear Ms. 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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150028

Device Name

Zimmer Segmental System XT Components

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 the 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.

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708 Telephone: (574) 372-4803 Fax: (574) 372-4605
Contact Person:	Yoriko Kobayashi Specialist, Regulatory Affairs Zimmer K.K Telephone: +81-364-026-748 Fax: (574) 372-4605
Date:	January 06, 2015
Trade Name:	*Zimmer*® Segmental System XT Components
Product Code / Device:	KRO – Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer,
Regulation Number / Description:	21 CFR § 888.3510 – Knee joint femorotibial metal/polymer constrained cemented prosthesis
Predicate Device:	Zimmer Segmental System, manufactured by Zimmer, Inc., K070978, cleared July 3, 2007
Device Description / Intended Use:	The *Zimmer* Segmental System is intended to replace the proximal femur, mid-shaft femur, distal femur, proximal tibia and/or total knee in cases that require extensive resection and restoration. The Segmental System provides for cross compatibility between selected components from the *MOST Options*® System and *NexGen*® Rotating Hinge Knee System. A total mid-calf to hip replacement can be achieved using the Segmental System. The cleared distal femoral and the proposed distal femoral components are designed to be compatible with standard NexGen patella components.

The proposed Segmental System XT components are identical to corresponding existing predicate Segmental System components for use in the distal femur, except for an extended boss on the polyethylene insert component and a corresponding pocket in the distal femoral component.

Indications for Use:

The Segmental System 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 the *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.

Comparison to Predicate Device:

The proposed Segmental System components are similar or identical in intended use, materials, sterility, and performance characteristics to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (lab) component fatigue performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.