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

November 25, 2015

Zimmer, Incorporated
Mr. Mark D. Warner
Sr. Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K152494
Trade/Device Name: Zimmer® NexGen® Complete Knee Solution Tibial and Femoral Augments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, KRO
Dated: August 31, 2015
Received: September 2, 2015

Dear Mr. Warner:

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 Parts 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,

Mark N. Melkerson -S

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)*
K152494

Device Name
Zimmer® NexGen® Complete Knee Solution Tibial and Femoral Augments

Indications for Use *(Describe)*

For NexGen Augments used with NexGen Knee Systems – Cruciate Retaining (CR), Cruciate Retaining Augmentable (CRA), Posterior Stabilized (PS), Legacy Posterior Stabilized (LPS), and Legacy Constrained Condylar Knee (LCCK):
This device is indicated for patients with severe knee pain and disability due to:
– Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
– Collagen disorders, and/or avascular necrosis of the femoral condyle.
– Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
– Moderate valgus, varus, or flexion deformities.
– The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.
• CR and LPS porous coated femoral and tibial baseplate components may be used cemented or uncemented biological fixation). The CR Hydroxyapatite/tricalcium phosphate [HA/TCP] coated femoral or tibial baseplate components may only be used uncemented. All other femoral, tibial baseplate and all-polyethylene patella components are indicated for cemented use only.
• NexGen Augments that may be used with cemented CR, CRA, PS, LPS, and LCCK femoral and tibial baseplate components are indicated for cemented use only.

For NexGen Augments used with NexGen Rotating Hinge Knee System:
This device is indicated for patients with:
– 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 femoral condyle.
– Valgus, varus, or flexion deformities.
– The salvage of previously failed surgical attempts.
This device is intended 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.

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P.O. Box 708
Warsaw, IN 46581-0708
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510(k) Summary

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:

Mark Warner
Sr. Specialist, Regulatory Affairs
Telephone: (574) 372-4150
Fax: (574) 372-4605

Date:

August 31, 2015

Trade Name:

Zimmer® *NexGen*® Complete Knee Solution Tibial and Femoral Augments

Common Name:

Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/Metal/Polymer

Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer

Classification Names and References:

Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3560, JWH

Knee joint femorotibial metal/polymer constrained cemented prosthesis, 21 CFR 888.3510, KRO

Classification Panel:

Orthopedics/87

Predicate Device(s):

NexGen Complete Knee Solution Cruciate Retaining (Augmentable) and Legacy Constrained Condylar Knee, manufactured by Zimmer, Inc. (K946150)

NexGen Complete Knee Solution Rotating Hinge Knee, manufactured by Zimmer, Inc. (K013385)

Purpose and Device Description:

The *NexGen* augments are used with the following *NexGen* Knee Systems:

NexGen Rotating Hinge Knee
NexGen Complete Knee Solution:

- Cruciate Retaining Augmentable (CRA)
- Legacy Constrained Condylar (LCCK)
- Cruciate Retaining (CR)
- Posterior Stabilized (PS)
- Legacy Posterior Stabilized (LPS)

This submission includes tibial and femoral augments of various shapes and sizes. Augments are attached via bone cement or screw to tibial baseplate and femoral components indicated for cemented use only. Use of these augments is optional.

Intended Use:

For NexGen augments used with NexGen Knee Systems – Cruciate Retaining (CR), Cruciate Retaining augmentable (CRA), Posterior Stabilized (PS), Legacy Posterior Stabilized (LPS), and Legacy Constrained Condylar Knee (LCCK):

This device is indicated for patients with severe knee pain and disability due to:

– Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
– Collagen disorders, and/or avascular necrosis of the femoral condyle.
– Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
– Moderate valgus, varus, or flexion deformities.
– The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

CR and LPS porous coated femoral and tibial baseplate components may be used cemented or uncemented biological fixation). The CR Hydroxyapatite/tricalcium phosphate [HA/TCP] coated femoral or tibial baseplate components may only be used uncemented. All other femoral, tibial baseplate and all-polyethylene patella components are indicated for cemented use only.

NexGen augments that may be used with cemented CR, CRA, PS, LPS, and LCCK femoral and tibial baseplate components are indicated for cemented use only.

For NexGen augments used with NexGen Rotating Hinge Knee System:

This device is indicated for patients with:
– 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 femoral condyle.
– Valgus, varus, or flexion deformities.
– The salvage of previously failed surgical attempts.
This device is intended for cemented use only.

Comparison to Predicate Device:

NexGen tibial and femoral augments were initially cleared in K946150, K013385. The subject devices include additional shapes and sizes of the predicate devices. They have the same intended use, function, and fundamental technology as the predicate devices. The difference between the subject and predicate devices do not raise new issues of safety and effectiveness.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Shelf Life Testing:
Accelerated aging testing conducted demonstrated that the subject *NexGen* augments have a shelf life of 10 years.

Performance Testing:
Non-clinical testing demonstrated that the subject *NexGen* augments have adequate attachment strength to resist joint reaction forces generated during weight-bearing activities and that PMMA coated titanium substrate to bone cement demonstrated an increased maximum shear load compared to uncoated titanium.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.