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

September 3, 2014

Zimmer, Incorporated
Ms. Diana Taylor
Regulatory Affairs Senior Specialist
P.O. Box 708
Warsaw, Indiana 46580

Re: K141840
Trade/Device Name: *NexGen*® Complete Knee Solutions Trabecular Metal Cone Broach
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: July 07, 2014
Received: July 08, 2014

Dear Ms. Taylor:

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)*

K141840

Device Name
NexGen® Complete Knee Solutions Trabecular Metal Cone Broach

Indications for Use *(Describe)*

Trabecular Metal Tibial Cone Augments are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates total knee arthroplasty. When used with the NexGen Complete Knee Solution - Rotating Hinge Knee (RHK) System, the Trabecular Metal Tibial Cone Augments are for cemented use only. When used with the NexGen Complete Knee Solution - Legacy Constrained Condylar Knee System, the Trabecular Metal Tibial Cone Augments are for cementless or cemented use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
574 267-6131

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Diana Taylor Regulatory Affairs Telephone: (574) 267-6131 Fax: (574) 372-4605
Date:	July 7, 2014
Trade Name:	*NexGen*® Complete Knee Solutions Trabecular Metal Cone Broach
Common Name:	Broach
Classification:	Class II Accessory 21 CFR 21 888.3560 and 21 CFR 888. 3565
Product Code:	JWH and MBH
Classification Panel:	Orthopedics
Predicate Device(s):	Trabecular Metal Tibial Cone Augments manufactured by Trabecular Metal Technologies, K102896, 12/13/2010 NexGen Trabecular Metal Coupled Tibial Cones manufactured by Trabecular Metal Technologies, K120990, 06/29/2012.
Description:	The NexGen TM Cone Broach, a 2-piece instrument (Broach and Handle), are manufactured from 17-4 stainless steel and designed to provide a multi-functional instrument to streamline the surgical process used when implanting the Trabecular Metal Tibial Cone Implants. The broaches are used to prepare the tibial metaphysis; the broach have teeth that are necessary to cut through bone and form the tibial canal to the correct shape and depth for a Trabecular Metal Tibial Cone Implant. The broaches are manually impacted, using a sequentially larger broach until reaching the final size for the Implant.

Indications for Use:	Trabecular Metal Tibial Cone Augments are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates total knee arthroplasty. When used with the NexGen Complete Knee Solution - Rotating Hinge Knee (RHK) System, the Trabecular Metal Tibial Cone Augments are for cemented use only. When used with the NexGen Complete Knee Solution - Legacy Constrained Condylar Knee System, the Trabecular Metal Tibial Cone Augments are for cementless or cemented use.
Comparison to Predicate:	Both the NexGen TM Cone Broach and the predicate broach are non-sterile, reusable manual orthopedic instruments that perform the same function as the predicate, are manufactured from identical materials, design mimics the currently marketed cone implants in order to prepare the tibial canal for Trabecular Metal Cone Implants using the same principal of operation (manual, sequential impaction with a mallet). The addition of design specific Coupled broaches and Large broach sizes provides design specific instrumentation for the full line of Cone Implants. The Large broach replaces a challenging manual burring step. The additional functionality of the instrumentation allows the surgical procedure to be streamlined. The TM Cone Broach is as safe and effective as the predicate instrumentation used to implant the Coupled, Medium and Large Trabecular Metal Cone Implants.
Substantial Equivalence Conclusions	Zimmer considers this 2-piece broach equivalent to the predicate one-piece broach based on design, size range and performance.