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510(k) Summary

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Judith Rosen Senior Regulatory Affairs Specialist Telephone: (973) 576-0032 ext 28138 Fax: (973) 884-8792
Date:	November 30, 2010
Trade Name:	Trabecular Metal™ Femoral Cone Augments
Common Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented and uncemented
Classification Name:	"Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis"; and "Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis"
Reference:	21 CFR § 888.3560, JWH and 21 CFR § 888.3565, MBH

DEVICE DESCRIPTION

The NexGen® Trabecular Metal™ Femoral Cone Augments are manufactured wholly of Trabecular Metal™, porous tantalum. The existing, commercially available NexGen® Trabecular Metal™ Femoral Cone Augments have a tapered elliptical cross-section. The periphery of the distal end is larger than that of the proximal end. The cone is not fully enclosed at its top most proximal section (giving the impression of U-Shape through slot). A similar pattern is also present in the modified femoral cones, with the exception that these cones are fully enclosed at its top most proximal section.

Both the modified femoral cones augments and the existing, commercially available femoral cone augments are to be used in conjunction with Zimmer's NexGen® Complete Knee Systems – both the Legacy® Constrained Condylar Knee (LCCK) Stemmed Femoral Implant and the femoral component of Zimmer's Rotating Hinge Knee (RHK) System. When used with the RHK System, the Trabecular Metal™ Femoral Cone Augments are for cemented use only. Fixation of all of the cone augments to the femoral implant is accomplished by cementing the internal portion of the augment to the superior side (non-articulating side) of the femoral component. Apposition of the cone to bone inside the medullary canal is with or without cement when used with the LCCK femoral implant and with cement for the RHK femoral implant.

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The existing, commercially available augments come in three sizes; small, medium and large and three height options. The proposed additional femoral cones will come in the same three sizes: small, medium and large and two height options.

INDICATIONS FOR USE

Trabecular Metal Femoral 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 Femoral Cone Augments are for cemented use only. When used with the NexGen Complete Knee Solution – Legacy Constrained Condylar Knee System, the Trabecular Metal Femoral Cone Augments are for cementless or cemented use.

DEVICE TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICES

The NexGen® Trabecular Metal™ Femoral Cone Augments were shown to be substantially equivalent to legally marketed predicate devices. The predicate devices are Zimmer's Trabecular Metal™ Femoral Cone Augments (K040630, K051756, K053340), Zimmer's NexGen® Trabecular Metal™ Tibial Cone Augments (K031962, K053340), Zimmer's NexGen® Complete Knee Solution - Trabecular Metal™ Augments (K024161, K040487), Zimmer's (formerly Implex) Continuum Knee System Trabecular Metal™ (formerly Hedrocel®) Tibial Spacers (K982302), and Zimmer's (formerly Implex) Continuum Knee System Trabecular Metal™ (formerly Hedrocel®) Revision Femoral Spacers (K0980781).

The NexGen® Trabecular Metal™ Femoral Cone Augments have the same material as previously cleared predicate devices. The intended use and indications for use of the subject devices are identical to that of the predicate. This submission is for an extension of the product line; sizes, cross sectional dimensions, design features and overall geometry of the device in the current submission are similar to the predicate device.

There are no significant differences between the proposed NexGen® Trabecular Metal™ Femoral Cone Augments and the predicate currently being marketed that would adversely affect the use of the product. Any differences in technological characteristics do not raise new issues of safety and efficacy.

PERFORMANCE DATA

Performance testing of Trabecular Metal™ material is included in a master file, on file at the FDA, which includes static compression, static tension, static shear, axial compression fatigue and rotational beam fatigue. Young's modulus of elasticity of Trabecular Metal has been measured in tension and compression. The results of testing and analysis define the properties of Trabecular Metal™, porous tantalum.

Mechanical testing was performed on Trabecular Metal predicate devices which include fatigue testing, wear testing, and assembly torque testing. The results of testing and analyses conducted indicate that predicates of the Trabecular Metal™ Femoral Cone Augments should maintain assembly integrity when assembled using the surgical technique instructions.

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A comparative Finite Element Analysis (FEA) study was performed to evaluate the strength of the proposed femoral cone designs across different normal gait activities (walking, stair ascent/decent and deep flexion). The results of testing and analyses conducted demonstrate that the proposed implant adequately meets the predetermined requirements established for its mechanical performance, supporting substantial equivalence to the predicate.

CONCLUSION

The NexGen® Trabecular Metal™ Femoral Cone Augments product line extension is the same as the predicate device with respect to intended use/indications for use, technological characteristics and basic principles of operation. This product line extension does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Zimmer Trabecular Metal Technology, Inc.
% Ms. Judith Rosen
10 Pomeroy Road
Parsippany, New Jersey 07054

FEB 15 2011

Re: K103517
Trade/Device Name: Trabecular Metal Femoral Cone Augments
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: November 30, 2010
Received: November 30, 2010

Dear Ms. Rosen:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103517

Device Name: Trabecular Metal Femoral Cone Augment

Indications for Use:

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Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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for M. Mckasson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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