K051756

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JUL 2 8 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Trabecular Metal Femoral Cone Augments

Submitter Name And Address:	Zimmer Trabecular Metal Technology, Inc. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818-1800
Fax Number:	(973) 829-0825
Date Prepared:	June 30, 2005
Device Trade Name:	Trabecular Metal Femoral Cone Augments
Device Common Name:	Knee System Augments
Classification Number and Name:	21 CFR § 888.3560 Prosthesis, Knee

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Device Description:

The Trabecular Metal Femoral Cone Augments are to be used in conjunction with Zimmer Inc.'s LCCK and Rotating Hinge Knee femoral components. The subject devices are used to address distal femoral cavitary defects encountered when implanting either of these two systems. The design of the augment interface inversely corresponds to the design of an LCCK or Rotating Hinge Knee femoral component. The augment has a rectangular, tapered shape. The opposing sides of the rectangle are longer than the center allowing the sides of the augment to fit into the condyles of the femoral component and the center of the augment to fit over the "box" of the femoral component. The center of the augment is hollow to allow passage of the stem through the center of the cone and into the femoral canal. The augments are fixed to the femoral component with bone cement. The Trabecular Metal Femoral Cone Augments are for cemented use along the bone in the USA, and for cementless or cemented use along the bone outside the USA.

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510(k) Summary (Continued)

Indications for Use:

The Trabecular Metal Femoral Cone Augments are indicated for use in the reconstruction of bony defects in knee reconstruction due to severe degeneration, trauma, or other pathology of the knee joint, and in the revision or salvage of failed, previously reconstructed knee procedures and implants. The Trabecular Metal Tibial Cone Augments are for cemented use only in the USA, and for cementless or cemented use outside the USA.

Device Technological Characteristics and Comparison to Predicate Device:

A comparison of device technological characteristics and properties demonstrates that the device is substantial equivalent to the cited predicate devices.

Performance Data:

Testing of the subject devices were not performed. Previous testing of Trabecular Metal and Trabecular Metal devices support a determination of substantial equivalence.

Conclusion:

The Trabecular Metal Femoral Cone Augments are substantially equivalent to the predicate devices (K040630) identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2005

Ms. Marci Halevi
Manager of Regulatory Affairs
Zimmer Trabecular Metal Technology, Inc.
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K051756
Trade/Device Name: Trabecular Metal Femoral Cone Augments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: June 28, 2005
Received: June 29, 2005

Dear Ms. Halevi:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051756
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Indications for Use

510(k) Number (if known): _____

Device Name: _____

Indications for Use:

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Prescription Use _____ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Milham

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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(Posted November 13, 2003)