K070754

510(k) Summary

AUG 3 1 2007

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Jennifer P. Harakal Senior Specialist, Regulatory Affairs Telephone: (973) 576-0133 Fax: (973) 884-8795
Date:	March 16, 2007
Trade Name:	Trabecular Metal™ Vertebral Body Replacement System
Common Name:	Vertebral Body Replacement Device
Classification Name and Reference:	Spinal Intervertebral Body Fixation Orthosis 21 CFR § 888.3060, MQP

DEVICE DESCRIPTION

The Trabecular Metal Vertebral Body Replacement (VBR) System is designed to be used as a replacement for a diseased or damaged vertebral body and the adjacent disc when spinal surgery is indicated. The Trabecular Metal VBR System is wholly comprised of Trabecular Metal Porous Tantalum (tantalum deposited on a vitreous carbon skeleton) and is available in a variety of configurations to accommodate the anatomical requirements of different patients.

INDICATIONS FOR USE

The Trabecular Metal Vertebral Body Replacement System is comprised of vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Trabecular Metal Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The Trabecular Metal Vertebral Body Replacement may be used with bone graft.

DEVICE TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE(S)

Zimmer Trabecular Metal Technology, Inc. has submitted documentation demonstrating the substantial equivalence of the proposed System to its predicate devices. The subject

System is similar to its predicate devices with respect to intended use/indications for use, materials, and basic principles of operation.

PERFORMANCE DATA

The results of testing and analyses conducted demonstrate that the worst cases of the proposed System adequately meet the predetermined requirements established for its mechanical performance.

SUBSTANTIAL EQUIVALENCE

The Trabecular Metal™ Vertebral Body Replacement System is substantially equivalent to its predicate devices with respect to intended use/indications for use, technological characteristics and basic principles of operation. As demonstrated by supporting performance data, these technological differences do not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2007

Zimmer Trabecular Metal Technology
% Ms. Jennifer P. Harakal
Senior Regulatory Affairs Specialist
10 Pomeroy Road
Parsippany, NJ 07054

Re: K070754
Trade/Device Name: Trabecular Metal™ Vertebral Body Replacement System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: July 18, 2007
Received: July 19, 2007

Dear Ms. Harakal:

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.

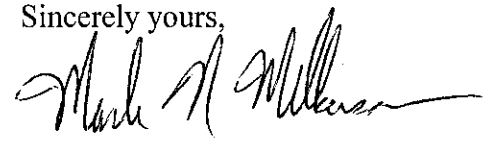
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K070754

Device Name: Trabecular Metal™ Vertebral Body Replacement System

Indications for Use:

The Trabecular Metal Vertebral Body Replacement System is comprised of vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Trabecular Metal Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The Trabecular Metal Vertebral Body Replacement may be used with bone graft.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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