510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter Name And Address:	Zimmer Trabecular Metal Technology, Inc. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Robert A Poggie, PhD
Phone Number:	(201) 818-1800 x122
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Date Prepared:	April 25, 2006
Device Trade Name:	*Vista*® *P* Vertebral Body Replacement System
Device Common Name:	Vertebral Body Replacement Device
Classification Number, Product Code, & Name:	21 CFR § 888.3060 MPQ; Spinal Vertebral Body Replacement Device

SEP 2 2 2006

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The *Vista*® *P* Vertebral Body Replacement System is designed to be used as a replacement for a single diseased or damaged vertebral body and the adjacent disc when spinal surgery through an anterior approach is indicated.

The *Vista*® *P* Vertebral Body Replacement (VBR) System is comprised wholly of unfilled PEEK Optima material. This VBR system accommodates replacement of a vertebral body in the thoracic and lumbar region of the spine. The device is available in a variety of cross sections and heights to properly tension the spine. The device must be implanted in pairs and cannot be used singly.

The superior and inferior surfaces of the device have a pattern of teeth to provide increased stability. Radiopaque markers are press fit into the device to identify the boundary of the device in intra and postoperative imaging.

Indications for Use:

The *Vista*® *P* 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 *Vista*® *P* Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The *Vista*® *P* Vertebral Body Replacement may be used with bone graft.

Device Technological Characteristics and Comparison to Predicate Device:

The device is similar in design, geometry and sizing to the predicate devices and possesses identical indications for use. The unfilled PEEK Optima LT-1 material has been used in cited predicates for the same intended and indications for use.

Performance Data:

The subject *Vista*® *P* devices were mechanically tested per established ASTM standards. The results of this performance testing demonstrated that the device will perform as intended and is equivalent to the cited predicate devices.

Conclusion:

The *Vista*® *P* Vertebral Body Replacement System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2006

Zimmer Trabecular Metal Technology, Incorporated
c/o Dr. Robert A. Poggie
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K061155
Trade Name: Vista-P Device
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: August 28, 2006
Received: August 29, 2006

Dear Dr. Poggie:

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/industry/support/index.html.

Sincerely yours,

Barbara Brehm MD
for

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 Statement

510k Number: **K061155: Zimmer Trabecular, Vista-P Device**

Indications For Use

The *Vista*® *P* Vertebral Body Replacement System is a vertebral body replacement device 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 *Vista*® *P* Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The *Vista*® *P* Vertebral Body Replacement may be used with bone graft.

Prescription Use X OR... Over-The-Counter Use _____
(Per 21 CFR 801.109)

(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

510(k) Number K061155