510(k) Summary

NOV 18 2011

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Kathleen Rutherford Associate Director, Regulatory Affairs Telephone: (973) 576-0139 Fax: (973) 884-8792
Date:	July 8, 2011
Trade Name:	Vista®-S Device
Common Name:	Intervertebral body fusion device & Spinal Vertebral Body Replacement
Classification Name:	Intervertebral fusion device, 21 CFR § 888.3080, Spinal vertebral body replacement device, 21 CFR § 888.3060
Device Panel/Product Code:	Orthopedic ODP & MQP

Device Description:

The Vista®-S Device is a box-shaped device for interbody fusion and vertebral body replacement fabricated from polyetheretherketone (PEEK). The Vista®-S Device is currently cleared to accommodate the replacement of a vertebral body in the thoracic and lumbar region of the spine. Use of this device is expanded to include use as a cervical interbody fusion device at one level from C2-T1. The device is available in a variety of cross sections and heights to accommodate variations in the individual pathology and anatomic condition of the patient. The superior and inferior surfaces of the device contain a pattern of teeth to provide for initial stability. Radiopaque markers are press fit into the device to aid in determining the location of the implant postoperatively.

Indications for Use:

The Vista®-S Device is intended for use in skeletally mature patients with degenerative disc disease (DDD) with/without radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Vista®-S Device is intended for use with supplemental spinal fixation systems and with autogenous bone graft. The Vista®-S Device is implanted via an anterior approach.

The Vista®-S Device is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) for partial replacement of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Vista®-S Device is intended for use with supplemental internal spinal fixation systems. The Vista®-S Device may be used with bone graft.

Device Technological Characteristics and Comparison to Predicate Device(s):

The Vista®-S Device was shown to be substantially equivalent to legally marketed predicate devices. The predicate devices include this Vista®-S Device as a VBR (K070382), C-Thru by EBI (K092336), NUBIC by SIGNUS (K082848), TM-S Fusion Device by Zimmer TMT (K103033), and Vista®-P Device by Zimmer TMT (K061155).

The Vista®-S Device has the identical material as previously cleared predicate devices. The intended use and indications for use of the subject device are similar to those of its predicate devices. The sizes, design features and overall geometry of the device in the current submission are similar to the cleared predicate devices.

There are no significant differences between the Vista®-S Device and the predicate devices currently being marketed that would adversely affect the use of the product. Any differences in technological characteristics do not raise new issues of safety or efficacy. The subject system is similar to its predicate devices with respect to intended use/indications for use, material, technological characteristics and basic principles of operation.

Performance Data:

Mechanical testing was performed on the Vista®-S Device as recommended by the FDA *Class II Special Controls Guidance Document: Intervertebral Fusion Device*. The results of testing and analyses conducted demonstrate that the proposed system adequately meets the predetermined requirements established for its mechanical performance.

Substantial Equivalence:

The Vista®-S Device is substantially equivalent to its predicate devices with respect to intended use/indications for use, materials, technological characteristics and basic principles of operation as demonstrated by the supporting performance testing data.

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

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Zimmer Trabecular Metal Technology, Inc.
% Ms. Kathleen Rutherford
Associate Director, Regulatory Affairs
10 Pomeroy Road
Parsippany, New Jersey 07054

Re: K111983
Trade/Device Name: Vista®-S Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: October 28, 2011
Received: October 31, 2011

Dear Ms. Rutherford:

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): K111983

Device Name: Vista®-S Device

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K111983