JUL 07 2014

510(k) Summary

Submitter: Zimmer Trabecular Metal Technology, Inc.
10 Pomeroy Road
Parsippany, New Jersey 07054

Contact Person: Judith Rosen
Sr. Regulatory Affairs Specialist
Telephone: 973-576-0032 ext. 28138
Fax: (973) 884-8792
Email: judith.rosen@zimmer.com

Date: May 29, 2014

Trade Name: Vista®-S Device

Common Name: Intervertebral body fusion device

Classification Name: Intervertebral fusion device, 21 CFR § 888.3080,

Device Panel/Product Code: Orthopedic / ODP

Device Description:

The purpose of this submission is a line extension to the Vista®-S Device adding additional height and footprint options. The Vista®-S Device is a box-shaped device for interbody fusion fabricated from polyetheretherketone (PEEK). 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.

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 an IBF and VBR (K111983 and K070382), TM-S Fusion Device by Zimmer (K111119 and K103033), and Alphatec Spine Novel XS (K081730).

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 the same as 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 device is similar to its predicate devices with respect to intended use/indications for use, material, technological characteristics and basic principles of operation.

Performance Data:

Finite Element Analysis (FEA) testing was conducted and included in this submission. The FEA model simulated testing conditions described in *ASTM F2077-03 Test Methods for Intervertebral Body Fusion Devices* and satisfy the testing requirements as recommended by the FDA *Class II Special Controls Guidance Document: Intervertebral Fusion Device*. The FEA tests that were performed are as follows:

- Axial Compression
- Torsion
- Compression Shear

An engineering rationale along with the FEA testing determined that the proposed line extension to the Vista-S device does not represent a new worst case for testing and are therefore considered substantially equivalent to the predicates referenced.

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 Center – WO66-G609
Silver Spring, MD 20993-0002

July 7, 2014

Zimmer Trabecular Metal Technology, Incorporated
Ms. Judith Rosen
Senior Regulatory Affairs Specialist
10 Pomeroy Road
Parsippany, New Jersey 07054

Re: K133784
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
Dated: May 29, 2014
Received: May 30, 2014

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133784

Device Name
Vista®-S Device

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."