K101363

DEC 16 2010

510(k) Summary

Manufacturer: Theken Spine, LLC
1800 Triplett Blvd
Akron, OH 44306

Device Trade Name: Theken Spine Vu c•POD Intervertebral Body Fusion Device

Contact: Glenn Stiegman
Vice President, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Office: 202.552.5800
Fax: 202.552.5798

Date Prepared: November 24, 2010

Classification: §888.3080, Intervertebral body fusion device

Class: II

Product Code: ODP

Indications For Use:
The Vu c·POD Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C2-C3 to C7-T1. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. The Vu c·POD implants are to be used with autogenous bone graft and implanted via an open, anterior approach. The cervical device is to be used in patients who have had six weeks of nonoperative treatment. The Vu c·POD Intervertebral Body Fusion Device is intended for use with supplemental internal fixation systems, such as the Theken Manta Ray or the Theken Tether systems.

Device Description:
The Vu c·POD Intervertebral Body Fusion Device consists of cervical spinal interbody fusion devices as well as instrumentation designed specifically for the implantation of these devices. The Vu c·POD spacers are manufactured from PEEK OPTIMA LT1 polymer per ASTM F2026. Radiographic markers present with the Vu aPOD spacers are comprised of tantalum per ASTM F560. The Vu c·POD Intervertebral Body Fusion Device is for single level anterior spinal use from the C2-C3 to C7-T1 disc levels.

K101363

Predicate Device(s):
The Vu c·POD Intervertebral Body Fusion Device was shown to be substantially equivalent to previously cleared devices, including the US Spine Phantom PLUS Cage System (K082801), Interbody Innovations Zeus Cervical Cage (K081614), LDR Spine MC+ (K080588), LDR Spine ROI-C Cervical Cage (K091088), Synthes Spine Zero-P Cervical Cage (K072981), and SpineArt Tryptik® Cervical Cage (K091873).

Summary of Technological Characteristics:
The Vu c·POD Intervertebral Body Fusion Device, in comparison to relevant predicate devices, has been shown to have the same indications for use, design, material of manufacture, and function.

Performance Standards:
Preclinical testing has been performed per ASTM F2077 (static axial compression, static compression-shear, static torsion, dynamic axial compression, dynamic compression-shear, expulsion) and ASTM F2267 (static subsidence) indicating that the Vu c·POD Intervertebral Body Fusion Device is substantially equivalent to predicate devices.

Conclusion:
Sufficient information, including extensive testing, has been presented to demonstrate the Vu c·POD Intervertebral Body Fusion Device is substantially equivalent to predicate devices with the same indications, intended use, and technological features.

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

Theken Spine, LLC
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Glenn Stiegman
Vice President, Regulatory Affairs
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

DEC 16 2010

Re: K101363
Trade/Device Name: Vu c·POD Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: December 02, 2010
Received: December 03, 2010

Dear Mr. Stiegman:

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

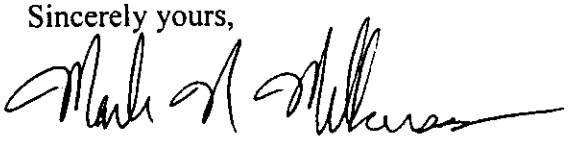
or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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

DEC 16 2010

Indications for Use

510(k) Number (if known): K101363

Device Name: **Integra Spine Vu c•POD Intervertebral Body Fusion Device**

The Vu c·POD Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease (DDD) at one level from C2-C3 to C7-T1. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. The Vu c·POD implants are to be used with autogenous bone graft and implanted via an open, anterior approach. The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Vu c·POD Intervertebral Body Fusion Device is intended for use with supplemental internal fixation systems, such as the Integra Spine Manta Ray or the Integra Spine Tether systems.

Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 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 K101363