K082712

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

JAN - 2 2009

Submitter's Name:	Theken Spine, LLC
Establishment Registration #:	1530901
Address:	1800 Triplett Blvd. Akron, Ohio 44306
Telephone Number:	330-475-8600
Fax Number:	330-773-7697
Contact Person:	Dale Davison
Date Prepared:	9/12/2008

B. Device Information

Trade Name:	Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices
Common Name:	Intervertebral body fusion device
Classification:	**MAX** 888.3080 (Class II) – Intervertebral body fusion device **MQP** 888.3060 (Class II) – Spinal intervertebral body fixation orthosis
Predicate Devices:	Theken Surgical REVEAL VBR System, K050058 Theken Spine Vu ePOD System, K071031 Theken Spine Vu aPOD System, K080822
Device Description:	The Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices are comprised of PEEK OPTIMA-LT cages with fenestrations and radii on all sides and toothed ridges. The toothed ridges of the concave cages engage with the superior and inferior end plates of the neighboring vertebral bodies to resist rotation and migration. The Vu ePOD is a straight shaped cage while the Vu LPOD has a curved shape. The Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices may be used individually or in a pair depending on the surgical need.
Summary of Test Data:	Mechanical testing of the subject device consisted of static axial compression, static compression shear, dynamic axial compression, dynamic compression shear, subsidence and expulsion. Testing was conducted in accordance with ASTM F-2077 and ASTM F-2267. The construct performed as designed and met or exceeded all product specifications.
Intended Use:	When used as an intervertebral body fusion device the Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices are indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is indicated for use with autograft only. The Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices are intended for use with supplemental fixation such as the Coral Spinal System or the BodyForm Thoracolumbar Fixation System. Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

When used as a vertebral body replacement (VBR) the Vu ePOD and Vu LPOD VBR System is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or otherwise unstable vertebral body due to tumor or trauma (ie. fracture).

The Vu ePOD and Vu LPOD VBR System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The device is indicated for use with autograft or allograft only.

The Vu ePOD and LPOD VBR System is intended for use with supplemental internal spinal fixation such as the BodyForm Thoracolumbar Fixation System or the Coral Spinal System.

C. Substantial Equivalence

The technological characteristics of the Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices are similar to the predicate device REVEAL Vertebral Body Replacement (K050058), the Theken Spine Vu ePOD System (K071031) and the Theken Spine Vu aPOD System (K080822).

The subject device similarities include:

- The same indications for use as the Vu aPOD
- The same basic design as the Vu ePOD and Vu LPOD
- The same operating principle
- The same materials
- Used in conjunction with supplemental fixation
- The same manufacturing environment
- The same sterilization process
- The same packaging configurations

Theken Spine believes that sufficient evidence exists to reasonably conclude that the Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices are substantially equivalent to the predicate device REVEAL Vertebral Body Replacement (K050058), the Theken Spine Vu ePOD System (K071031) and the Theken Spine Vu aPOD System (K080822). This is based on the design concept, the use of established, known materials, feature comparisons, mechanical testing, indications for use, pre-production quality assurance planning and engineering analysis. All implants represent a basic design concept in terms of safety and effectiveness, and differ only in minor details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Theken Spine, LLC
% Mr. Dale Davison
1800 Triplett Blvd
Akron, OH 44306

JAN - 2 2009

Re: K082712
Trade/Device Name: Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: II
Product Code: MAX, MQP
Dated: December 30, 2008
Received: December 31, 2008

Dear Mr. Davison:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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): **K082712**

Device Name: Theken Spine Vu ePOD and Vu LPOD System

Indications for Use:

When used as an intervertebral body fusion device, the Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices are indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is indicated for use with autograft only. The Vu ePOD and Vu LPOD Intervertebral Body Fusion Devices are intended for use with supplemental fixation such as the Coral Spinal System or the BodyForm Thoracolumbar Fixation System.
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

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

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