K071031

510(k) Summary
(21 CFR Part 807.92)

JUL 30 2007

A. Submitter Information

Submitter's Name:	Theken Spine, LLC
Address:	283 E. Waterloo Akron, Ohio 44319
Telephone Number:	330-773-7677 x221
Fax Number:	330-773-7697
Contact Person:	Dale Davison
Date Prepared:	4/9/07

B. Device Information

Trade Name:	Vu e•POD Vertebral Body Replacement (VBR) System
Common Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 888.3060)
Device Classification:	Class II (per 21 CFR 888.3060) Panel: Orthopedic, Product Code: MQP, Panel Code: 87
Predicate Device:	Theken Surgical, LLC CPOD/LPOD VBR System (K032064) Theken Surgical, LLC REVEAL VBR System (K050058)
Material Composition:	Polyetheretherketone (PEEK-OPTIMA LT) per ASTM F-2026 Tantalum per ASTM F-560 Titanium 6Al-4V ELI per ASTM F-136
Subject Device Description:	The Vu e•POD Vertebral Body Replacement is comprised of PEEK concave cages with fenestrations and radii on all sides and toothed spikes used in combination with a titanium spacer component. The cages and spacer can be locked together into a variety of geometric configurations to fit each individual patient's pathology. The toothed spikes of the concave cages engage with the superior and inferior end plates of the neighboring vertebral bodies to resist rotation and migration. The Vu e•POD Vertebral Body Replacement may be used individually or in a pair depending on the surgical need, however, the device is always implanted with the construct oriented vertically.
Intended Use:	The Vu e•POD Vertebral Body Replacement is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g., fracture). The Vu e•POD Vertebral Body Replacement 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. Bone graft material is recommended to be packed into the interior openings of the device prior to implantation. The Theken Vu e•POD Vertebral Body Replacement is intended to be used with supplemental internal spinal fixation systems, such as the Theken Surgical, LLC, BodyForm Thoracolumbar Fixation

System (K983622, Approved 12/98) or the Theken Surgical, LLC, Coral Spinal System (K041592, Approved 9/04).

C. Substantial Equivalence

The technological characteristics of the Vu e•POD Vertebral Body Replacement are similar to the predicate device CPOD / LPOD Vertebral Body Replacement System (K032064), manufactured by Theken Surgical, LLC and cleared by the FDA on February 20, 2004 and REVEAL Vertebral Body Replacement (K050058), Manufactured by Theken Surgical, LLC and clear by the FDA on May 17, 2005

The subject device similarities include:

- The same indications for use
- The same basic design
- The same operating principle
- The same materials
- Implanted using the same surgical techniques and equipment type
- Used in conjunction with the same 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 e•POD Vertebral Body Replacement is substantially equivalent to the predicate device REVEAL Vertebral Body Replacement (K050058), manufactured by Theken Surgical, LLC and cleared by the FDA on May 17, 2005. 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 are used to treat the same conditions, have the same precautions and contraindications for use, and have equivalent potential for complications for the risk of use. In addition they all 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
283 East Waterloo Road
Akron, Ohio 44319

JUL 30 2007

Re: K071031
Trade/Device Name: Vu e•POD Vetebral Body Replacement
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: April 10, 2007
Received: April 11, 2007

Dear Mr. Dale 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 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 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,

Barbara Buchup

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): K071031

Device Name: Vu e•POD Vetebral Body Replacement

Indications For Use:

The Vu e•POD Vertebral Body Replacement 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 e•POD Vertebral Body Replacement 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. Bone graft material is recommended for packing in the interior opening of the device prior to implantation.

The Vu e•POD Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems, such as the Theken Surgical, LLC, BodyForm Thoracolumbar Fixation System (K983622, Approved 12/98) or the Theken Surgical, LLC, Coral Spinal System (K041592, Approved 9/04).

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)

Barbara Buehler

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

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