FEB 2 0 2004

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

Submitter's Name:	Theken Surgical
Address:	283 E. Waterloo Akron, Ohio 44319
Telephone Number:	330-773-7677 x221
Fax Number:	330-773-7697
Contact Person:	Tony Perry
Date Prepared:	12/12/2003

B. Device Information

Trade Name:	Theken CPOD / LPOD Vertebral Body Replacement System (CPOD / LPOD VBR)
Common Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 878.3060)
Device Classification:	Class II (per 21 CFR 878.3060) Panel: Orthopedic, Product Code: MQP, Panel Code: 87
Predicate Device:	SIGNUS Medical LLC Tetris™ Spinal Implant (K022793)
Comparative Device:	DePuy AcroMed, Inc. Stackable Cage™ System (K990148) Synthes Spine Company, L.P. Synthes Synex™ Spacer System (K003836) Osteotech Inc., VBR™ (K003155)
Material Composition:	Titanium Ti-6Al-4V (ELI) per ASTM F-136.
Subject Device Description:	The Theken CPOD / LPOD VBR is comprised of Titanium rounded rectangular and rectangular frames with fenestrations and radii on all sides and toothed spikes which are used in combination with Titanium spacer components. The frames and spacer can be locked together into a variety of geometric configurations to fit each individual patient's pathology. The toothed spikes of the rounded rectangular and rectangular frames engage with the superior and inferior end plates of the neighboring vertebral bodies to resist rotation and migration. A single construct is sufficient to be used at all spinal levels and pathologies.
Intended Use:	The Theken CPOD / LPOD VBR 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 Theken CPOD / LPOD VBR is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absences 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 CPOD / LPOD VBR System is designed to be constructed using two cage components in conjunction with an appropriate single spacer component. This combination of components creates an implantable construct. The use of a single cage as an implant has not been tested or approved. The Theken CPOD / LPOD VBR is intended to be used with supplemental internal spinal fixation systems, such as the Theken BodyForm Thoracolumbar Fixation System (K983622) or the DePuy Acromed ISOLA System (K980485).

C. Substantial Equivalence

The technological characteristics of the Theken CPOD / LPOD VBR are similar to the following predicate devices:

1) Tetris™ Spinal Implant (K022793), manufactured by SIGNUS Medical LLC and cleared by the FDA on April 8, 2003.
2) Stackable Cage™ System (K990148), manufactured by DePuy AcroMed, Inc. and cleared by the FDA on September 3, 1999.
3) Synthes Synex™ Spacer System (K003836), manufactured by Synthes Spine Company, L.P. and cleared by the FDA on May 29, 2001.

Establishment of equivalence is based on similarities of intended use, design, and physical characteristics. All implants are used to treat the same conditions, have essentially the same precautions and contradictions 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. Based on the design concept, the use of established well known materials, feature comparisons, mechanical testing, indications for use, pre-production quality assurance planning and engineering analysis (adherence to GLP), Theken Surgical believes that sufficient evidence exists to reasonably conclude that the CPOD / LPOD VBR is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Mr. Tony Perry
Thekēn Surgical
283 East Waterloo Road
Akron, Ohio 44319

Re: K032064
Trade Name: Theken Surgical CPOD and LPOD Vertebral Body Replacement Devices
Regulation Number: 21 CFR 888.3060
Regulation Name: Vertebral Body Replacement Device
Regulatory Class: II
Product Code: MQP
Dated: December 2, 2003
Received: December 9, 2003

Dear Mr. Perry:

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 (301) 594-4659. 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
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): K032064

Device Name: Theken Surgical CPOD/LPOD VBR

Indications For Use:

The CPOD/LPOD is indicated for use in the thoracolumbar spine (i.e. T1 to L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (e.g. fracture).

The CPOD/LPOD 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 CPOD/LPOD is intended to be used with supplemental, internal spinal fixation systems such as the Theken Body Form Thoracolumbar Fixation System (K983622) or the DePuy Acromed ISOLA System (K980485).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K032064