510(k) Summary
(21 CFR Part 807.92)

JUN 28 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:	15 March 2007

B. Device Information

Trade Name:	x•POD Adjustable Vertebral Body Replacement
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-Reveal VBR System (K050058) Osteotech, Inc. – VBR (K003155) Osteotech, Inc. – VBR (K012254) Synthes (USA) – Synex Spacer System
Material Composition:	Titanium Alloy (Ti6Al4V) per ASTM F136 and ISO 5832-3
Device Description:	The x•POD Adjustable Vertebral Body Replacement is comprised of a cylindrical titanium (Ti-6Al-4V) mechanism with rectangular endplates. The system has fenestrations axially and laterally to maximize bone graft placement. The implants are manufactured in a variety of geometric combinations to better fit each patient's pathology. The anatomically designed endplates are designed to minimize expulsion and rotation of the implant postoperatively. The x•POD Adjustable Vertebral Body Replacement is manufactured from titanium alloy (Ti-6Al-4V) per ASTM F136 and ISO 5832-3 standards. The x•POD Adjustable Vertebral Body Replacement construct is used individually and is always implanted with the construct oriented vertically.

Intended Use:	The x•POD Adjustable 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 (e.g., fracture). The x•POD Adjustable 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. It is recommended that bone graft material be packed in the interior openings of the device prior to implantation. The x•POD Adjustable Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems, such as the BodyForm Thoracolumbar Fixation System (K983622, SE 12/98) or Coral Pedicle Screw System (K041592, SE 9/04).

C. Substantial Equivalence

The technological characteristics of the x•POD Adjustable Vertebral Body Replacement are similar to the following predicate devices:

REVEAL VBR System manufactured by Theken Spine, LLC (K050058, SE 05/17/05).
VBR™ manufactured by Osteotech, Inc (K003155, SE 01/04/2001).
VBR™ manufactured by Osteotech, Inc (K012254, SE 11/16/2001).
Synex Spacer System manufactured by Synthes (USA) (K003836, SE 05/29/2001).

Establishment of equivalence is based on similarities of intended use, design, and physical characteristics. All implants are used to treat the same conditions, have the same precautions and contraindications for use, and have the same potential for complications. Based on the design concept, the use of established materials, mechanical testing, indications for use, pre-production quality assurance planning and engineering analysis, Theken Spine believes that the x•POD Adjustable Vertebral Body Replacement 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

Theken Spine
% Mr. Dale Davison
Vice President of Engineering
283 East Waterloo Road
Akron, Ohio 44319

JUN 28 2007

Re: K070786
Trade/Device Name: x•POD Adjustable Vertebral Body Replacement
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: May 21, 2007
Received: May 22, 2007

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.

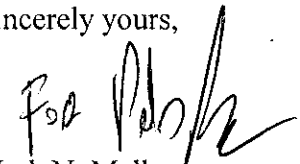
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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,



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):___K070786

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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)

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

510(k) Number K070786