K081414

510(k) Summary
(21 CFR Part 807.92)

JUN 17 2008

A. Submitter Information

Submitter's Name:	Theken Spine, LLC
Address:	1800 Triplett Blvd Akron, Ohio 44306
Telephone Number:	330-475-8600
Fax Number:	330-773-7697
Contact Person:	Dale Davison
Date Prepared:	5/19/2008

B. Device Information

Trade Name:	Coral™ Spinal System
Common Name:	Pedicle Screw Spinal System
Classification:	**MNI** 888.3070 – Pedicle Screw Spinal System **MNH** 888.3070 – Pedicle Screw Spinal System **KWQ** 888.3060 – Spinal Intervertebral Body Fixation Orthosis **KWP** 888.3050 – Spinal Interlaminal Fixation Orthosis **NKB** 888.3070 – Spondylolisthesis Spinal Fixation System
Predicate Device:	Theken Surgical Coral™ Spinal System, K041592 Theken Surgical Coral™ Spinal System, K070962
Device Description:	The purpose of this submission is to add rod to rod connectors and lateral rod connectors to the Coral™ Spinal System. The Coral™ Spinal System components can be rigidly locked together in a variety of configurations to promote fusion for a wide variety of patient anatomies.
Intended Use:	The Coral™ Spinal System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system, a posterior non-pedicle screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.
Material Composition:	Implant grade titanium alloy Ti 6Al-4V (ELI) per ASTM F-136 and ISO 5832-3.

C. Substantial Equivalence

Theken Spine believes sufficient evidence exists to reasonably conclude that the additional components are substantially equivalent to the predicate device Coral™ Spinal System (K041592 SE 9/04 and K070962 SE 8/07), manufactured by Theken Spine, LLC. 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, possess the same precautions and contraindications for use, and equivalent potential for complications for the risk of use.

The subject device similarities include:

- The same indications for use
- The same operating principle
- The same materials
- Implanted using the same surgical techniques and equipment type
- The same manufacturing environment
- The same sterilization process
- The same packaging configurations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2008

Theken Spine, LLC
% Mr. Dale Davison
Vice President of Engineering
1800 Triplett Boulevard
Akron, Ohio 44306

Re: K081414
Trade/Device Name: Coral™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system.
Regulatory Class: III
Product Code: NKB, KWP, KWQ, MNI, MNH
Dated: May 19, 2008
Received: May 20, 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
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): K081414

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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)

Neil R Ogden for mkm

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081414