K100970

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

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:	7/28/2010

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B. Device Information

Trade Name:	Stainless Steel Spinal System
Common Name:	Screw / Hook and Rod Spinal Instrumentation System
Classification:	**MNI** 888.3070 (Class II) – Orthosis, Spinal Pedicle Fixation **MNH** 888.3070 (Class II) – Orthosis, Spondylolisthesis Spinal Fixation **NKB** 888.3070 (Class III) – Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease **KWP** 888.3050 (Class II) – Appliance, Fixation, Spinal Interlaminal **KWQ** 888.3060 (Class II) – Appliance, Fixation, Spinal Intervertebral Body
Predicate Devices:	Theken Surgical Coral Spinal System, K041592 Theken Spine Coral Pedicle Screw System, K070962 Theken Spine Modification to Coral Spinal System, K081414 IST Pedicle Screw system, K053276
Device Description:	The Stainless Steel Spinal System consists of a variety of shapes and sizes of screws, rods, hooks, and cross-connectors. The Stainless Steel Spinal System components can be rigidly locked together creating a rigid construct for promoting fusion. The individual implant components are fabricated from medical grade stainless steel alloy 316 LVM described by such standards as ASTM F-138 and ISO 5832-1.
Intended Use:	The Stainless Steel Spinal System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system (T1-S2/ilium), a posterior non-pedicle screw fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). 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.
Technological Characteristics:	The Stainless Steel Spinal System is equivalent to the Coral Spinal System in design and indications for use and substantially equivalent to the predicates listed in terms of design concepts, feature comparisons, indications for use and known biocompatible materials.

Summary of Test Data: Mechanical testing of the subject device consisted of static axial compression, static torsion, and dynamic axial compression. Testing was conducted in accordance with ASTM F-1717. The construct performed as designed and met or exceeded all product specifications.

C. Substantial Equivalence

Theken Spine believes sufficient evidence exists to reasonably conclude that the indications are substantially equivalent to the predicate device Coral Spinal System (K041592 SE 9/04, K070962 SE 8/07 and K081414 SE 06/08), manufactured by Theken Spine, LLC and the Paramount Pedicle Screw System (K053276 SE 12/05), manufactured by Innovative Spinal Technologies. This is based on the design concept, the use of established, known materials, feature comparisons, indications for use, and engineering analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

Re: K100970
Trade/Device Name: Stainless Steel Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: July 28, 2010
Received: July 29, 2010

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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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bruehwd
for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K100970**

Device Name: Stainless Steel Spinal System

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Indications for Use:

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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 Surgical, Orthopedic,
and Restorative Devices

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