K121482

510(k) Summary
(21 CFR Part 807.92)

AUG 28 2012

Submitter's Name:	Theken Spine, LLC
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Date Prepared:	May 14, 2012

Trade Name:	Instrument System for Endoscopic Spinal Surgery
Common Name:	Spinal Endoscopic System
Device Classification:	Class II per 21 CFR 888.1100 – Arthroscope and accessories
Product Code:	HRX, HAE
Classification Panel:	Orthopedic
Predicate Device:	maxMore Spinal Endoscopy System, Hoogland Spine Products (K090132). THESSYS Multiscope System, Joimax (K051827)
Device Description:	The Integra Spine Instrument System for Endoscopic Spinal Surgery is an assembled, comprehensive set of instruments for use in endoscopic decompression techniques. The instrument set includes guide wires, pituitaries, ronguers, trephines, trocar / dilators, cannulas, reamers, dural elevator, nerve hook, mallet, forceps, chisels, and associated handles. The instrument set will be used with an FDA cleared endoscope with a length of no more than 254mm and working channel of at least 4.1mm.
Intended Use:	The Instrument System for Endoscopic Spinal Surgery is intended for use in spinal surgical procedures such as: arthroplasty, nucleotomy, discectomy, and foraminotomy. These manual surgical instruments are hand-held devices intended to manipulate tissue in spinal surgery. The rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the spinal column.
Material Composition:	The Integra Spine Instrument System for Endoscopic Spinal Surgery is manufactured from stainless steel, silicone, and nitinol.
Technological Characteristics:	The technological characteristics of the Instrument System are equivalent to the predicate instrument system including use of similar designs, materials, procedure, sterilization methods, and operating principle.

Summary of test data:	There were no clinical or animal tests performed for this submission. Mechanical testing consisted of verification testing of the individual instrument functions as there are no known performance standards. The instruments all performed as designed and met or exceeded all product specifications. The Instrument System for Endoscopic Spinal Surgery was utilized in a cadaver setting by a surgeon skilled in percutaneous and endoscopic spinal procedures. All instruments performed as designed and met or exceeded all product specifications.
Conclusion:	The specifications and intended use of the Instrument System for Endoscopic Spinal Surgery is the same as the predicate devices. There are no significant differences in design or manufacturing materials between this submission and the predicate device. This is based on the designs, the use of established known materials, feature comparisons, and indications for use. The instrument systems represent a basic design concept in terms of safety and effectiveness, and differ only in minor details.

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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
1153 Medina Road
Medina, Ohio 44256-0000

AUG 28 2012

Re: K121482
Trade/Device Name: Instrument System for Endoscopic Spinal Surgery
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX, HAE
Dated: July 19, 2012
Received: July 20, 2012

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,

Mark 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 (if known): **K121482**

Device Name: Instrument System for Endoscopic Spinal Surgery

Indications For Use:

The Instrument System for Endoscopic Spinal Surgery is intended for use in spinal surgical procedures such as: arthroplasty, nucleotomy, discectomy, and foraminotomy. These manual surgical instruments are hand-held devices intended to manipulate tissue in spinal surgery.

The rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the spinal column.

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 MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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