

SEP 17 2003

K 031855

**Spinal Concepts, Inc.
InSight™ Pedicle Screw System**

112

510(k) Summary of Safety and Effectiveness

SUBMITTED BY Spinal Concepts, Inc.
5301 Riata Park Court, Bldg. F
Austin, TX 78727

**ESTABLISHMENT
REGISTRATION NUMBER** 1649384

CONTACT PERSON

<u>Primary</u>	<u>Alternate</u>
Lisa Peterson Regulatory Affairs Specialist	David Hooper, Ph.D. Director, Clinical and Regulatory Affairs
Phone: 512-533-1080	Phone: 512-533-1038
Fax: 512-249-6734	Fax: 512-249-6734

DATE PREPARED June 11, 2003

CLASSIFICATION NAME KWQ 888.3060- Spinal Intervertebral Body Fixation
Orthosis
KWP 888.3050- Spinal Interlaminar Fixation Orthosis
MNI 888.3070- Pedicle Screw Spinal System
MNH 888.3070 – Spondylolisthesis Spinal Fixation System
NKB 888.3070 – Pedicle Screw Fixation System,
Degenerative Disc Disease

COMMON NAME Spinal Fixation System

PROPRIETARY NAME Spinal Concepts Inc. InSight™ Pedicle Screw System

**SUBSTANTIAL
EQUIVALENCE** The Spinal Concepts Inc. InSight Pedicle Screw System
was determined to be substantially equivalent to several
commercially available systems.

DEVICE DESCRIPTION

InSight constructs consist of bone screws, lock screws, set screws, connectors, swivels, and rods, which when assembled create a polyaxial range of motion. InSight only allows the placement of 5.5 mm titanium rods. InSight screws may be implanted in an open manner; or via cannulation, which allows a subset of procedures to be completed through a mini open procedure.

K031 055
2/2

INDICATIONS:

When intended for pedicle screw fixation from L1-S1, the indications include immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, and failed previous fusion.

As a pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established.

After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

MECHANICAL TEST DATA

Mechanical testing data, including data collected in accordance with ASTM 1717 and ASTM 1798, was collected to verify that the design changes met established design requirements.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Ms. Lisa Peterson
Regulatory Affairs Specialist
Spinal Concepts, Inc.
5301 Riata Park Court, Bldg. F
Austin, TX 78727

Re: K031855

Trade/Device Name: InSight™ Pedicle Screw System
Regulation Numbers: 21 CFR 888.3060, 888.3070, 888.3050
Regulation Names: Spinal intervertebral body fixation orthosis. Pedicle screw spinal system, Spinal interlaminar fixation orthosis

Regulatory Class: III
Product Codes: KWQ, MNI, MNH, KWP, NKB
Dated: June 11, 2003
Received: June 24, 2003

Dear Ms. Peterson:

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.

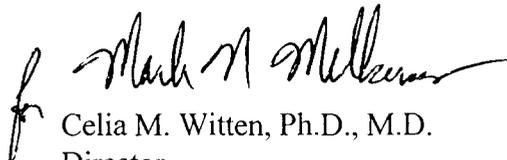
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Ms. Lisa Peterson

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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

K031855

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name:

Spinal Concepts, Inc. InSight™ Pedicle Screw System

Indications for Use:

When intended for pedicle screw fixation from L1-S1, the indications include immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, and failed previous fusion.

As a pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established.

After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____
(Per 21 CFR 801.109)

OR

Over-The-Counter: _____
(Optional Format 1-2-96)

for Mark A. Williams
(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K031855