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InCompass Spinal Fixation System, with Polyaxial Screws

510(k) Summary

SUBMITTED BY	Spinal Concepts, Inc. 12012 Technology Blvd., Suite 100 Austin, TX 78727
ESTABLISHMENT REGISTRATION NUMBER	1649384
CONTACT PERSON	David M. Hooper, Ph.D. Director, Regulatory and Clinical Affairs
DATE PREPARED	October 25, 2002
CLASSIFICATION NAME	Spinal Intervertebral Body Fixation Orthosis Spinal Interlaminal Fixation Orthosis Pedicle Screw Spinal System
COMMON NAME	Spinal Fixation System
PROPRIETARY NAME	InCompass Spinal Fixation System, with polyaxial screws
PREDICATE DEVICE	InCompass Fixation System (K021564)

DEVICE DESCRIPTION

The Spinal Concepts, Inc. InCompass Spinal Fixation System consists of various hooks, screws, rods and connectors and is intended to provide temporary stabilization following surgery to fuse the spine. This system includes open styled hooks and screws, which allow the surgeon to use a top loading technique for dropping the spinal rod down to the fixation components. Closed styled implants are also provided. Offset connectors are included to provide both offset between the screw and rod and also and reduce the effort needed to contour the spinal rod. Crosslinks are provided to increase rotational stiffness to longer constructs. Two sizes of spinal rods are included with this system. Screws are provided in both fixed angle and polyaxial design.

This 510(k) covers the addition of polyaxial screws in The InCompass system.

MATERIALS

The InCompass Spinal Fixation System includes components made from stainless steel (ASTM F-138) and titanium alloy Ti6Al4V ELI (ASTM F-136). The polyaxial screws are made of titanium alloy only.

WARNING: Stainless steel and titanium components should not be used in the same construct.

INDICATIONS

When intended for pedicle screw fixation from T1-S1, the InCompass Spinal Fixation System is intended to provide 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 thoracic, 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.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine (T1-S1), the indications are idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), tumor, spondylolisthesis, spinal stenosis and failed previous fusion.

When intended for anterolateral screw, rod and or cable fixation of the T6-L5 spine the indications are degenerative disc disease (back pain of discogenic origin 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 and failed previous fusion

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.

The use of posterior spinal instrumentation in children has been reported in the literature. The InCompass Spinal Fixation System may be used for non-pedicle posterior use in this patient group.

MECHANICAL TEST DATA

Mechanical testing data, collected in accordance with ASTM 1717, were collected to verify the designs. Static and fatigue data were provided to demonstrate that the design met all functional requirements.

BASIS OF SUBSTANTIAL EQUIVALENCE

The modified InCompass Spinal Fixation System is substantially equivalent to the unmodified InCompass Spinal Fixation System in terms of fit, form and function, with no change to the intended use or fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2002

David M. Hooper, Ph.D.
Manager, Regulatory and Clinical Affairs
Spinal Concepts, Inc.
12012 Technology Boulevard, Suite 100
Austin, Texas 78727

Re: K023644
Trade/Device Name: InCompass Spinal Fixation System
Regulatory Number: 21 CFR 888.3070(b)(1), 888.3050, 888.3060
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: III; II
Product Code: MNI, MNH, KWP, KWQ
Dated: October 29, 2002
Received: October 30, 2002

Dear Dr. Hooper:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N. Melkerson

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

INIDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023644

Device Name: Spinal Concepts, Inc. **InCompass Spinal Fixation System**

Indications for Use:

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

510(k) Number K023644

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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