510 (K) Summary of Safety and Effectiveness

JAN 3 0 2002

Company Name:	Spinal Innovations, Inc. 7850 Stage Hills Blvd. Suite 105 Bartlett, TN 38133 (901) 373-8855 (901) 373-8303 fax
510(k) Contact:	Marc Richelsoph President and CEO (901) 373-8855
Trade Name:	Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System
Common Name:	Hook, Rod and Screw Spinal Fixation System
Classification:	888.3050 Spinal Interlaminal Fixation Orthosis – class II 888.3070 Spondylolisthesis Spinal Fixation Device System – class II 888.3070 Pedicle Screw Spinal System – class II
Device Product Code:	87 KWP, MNH and MNI
Predicate Devices:	Spinal Innovations Ascend™ Spinal Fixation System Sulzer Spine-Tech Silhouette™ Spinal System

Device Description

The Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System is a temporary implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar and sacral areas of the spine. Implants of this system consist of hooks and/or screws connected to rods and are intended to be removed after solid fusion has occurred. This system includes fixed and polyaxial screws of varying diameters and

lengths, and hooks in varying designs in varying designs and lengths. The Shadow™ components are product line additions to complement the Ascend™ system components.

Intended Use

The Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System, when used as a pedicle screw fixation system, is indicated for use in patients: a) having severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint; b) who are receiving fusion using autogenous graft only; c) who are having the device fixed or attached to the lumbar or sacral spine; and d) who are having the device removed after the development of a solid fusion mass. When used for this indication, the fusion mass may not go above the L5-S1 joint, the levels of pedicle screw fixation may span from L3 to the sacrum.

The Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System is a pedicle screw system 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 spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a hook and sacral screw system (other than pedicle screw fixation system for high grade spondylolisthesis), the Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with the degeneration of the disc confirmed by a history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal surgery/fusion. When used for this indication, screws of the Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System are intended for sacral/iliac attachment only. Hooks of the system are intended for posterior thoracic and/or lumbar use only. The levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

Technological Characteristics

The Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System adds a locking nut to the Ascend™ screw and hook implants. This is substantially equivalent to the locking nut on other predicate devices. The remaining technological characteristics are substantially the same as Ascend™.

Testing

Biomechanical testing demonstrated that the components of the Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System exhibit equivalent mechanical performance compared to predicate devices. Testing included the following:

1) Corpectomy model testing per ASTM F 1717-96 Standard Test Methods for Static and Fatigue for Spinal Products in a Corpectomy Model. This included static compression bending, static torsion, and compression bending fatigue.
2) Interconnection testing of individual system components per ASTM F 1798-97. The tests included axial gripping capacity of hooks, screws, and rod-to-rod connectors, torsional gripping capacity, and polyaxial screw flexion/extension static and fatigue testing.

Testing results of the various system components show that the data compares directly to predicate device testing and meets or exceeds other predicate devices. Therefore, the results support that the Ascend™ Spinal Fixation System with the Shadow™ Spinal System is substantially equivalent to the predicate devices.

Basis for Substantial Equivalence

The Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System is substantially equivalent in material, design and function to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Mr. Marc Richelsoph
President and Chief Executive Officer
Spinal Innovations, Inc.
7850 Stage Hills Boulevard – Suite 105
Bartlett, Tennessee 38133

Re: K013196
Trade/Device Name: Ascend™ Spinal System with the Shadow™ Spinal System
Regulation Number: 21 CFR §888.3050; §888.3070
Regulation Name: Spinal interlaminal fixation orthosis; pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP; MNH; MNI
Dated: December 20, 20001
Received: December 21, 2001

Dear Mr. Richelsoph:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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
HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

510(K) Number K013196

Device Name: Spinal Innovations Ascend™ Spinal Fixation System with the Shadow™ Spinal System.

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013196