DEC 0 6 2002

510 (K) Summary of Safety and Effectiveness

Company Name:	Spinal Innovations, Inc. 7850 Stage Hills Blvd. Suite 105 Bartlett, TN 38133 (901) 373-8855 (901) 373-8303 fax
510(k) Contact:	Joseph S. Clift Vice President of Regulatory And Clinical Affairs (901) 373-8855
Trade Name:	Spinal Innovations SPECTRUM™ Cervical Spinal System
Common Name:	Plate and Screw Cervical Spinal Fixation System
Classification:	888.3060 Spinal Intervertebral Body Fixation Orthosis - classII
Device Product Code:	87 KWQ
Predicate Devices:	Sofamor Danek Orion™ Anterior Cervical Plate System, Sofamor Danek Atlantis™ Anterior Cervical Plate System, Medtronic Sofamor Danek Zephir™ Anterior Cervical Plate System, Synthes Cervical Spine Locking Plate System, and

Device Description

The Spinal Innovations SPECTRUM™ Cervical Spinal System is intended for anterior intervertebral body screw fixation of the cervical spine. This system includes plates in varying designs and both fixed angle and variable angle screws. The screws are available in diameters of 4.0 mm and 4.5 mm and varying lengths. The plates have two widths: Standard width of .750 inches and Narrow width of .680 inches. The plates will be available in two lordotic curve geometries. The Cervical Screws are cancellous bone screws. The screw locking means is assembled to the plate during the manufacturing process.

Intended Use

The Spinal Innovations SPECTRUM™ Cervical Spinal System is intended for anterior intervertebral body screw fixation of the cervical spine. The system implants are indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures or dislocation), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Testing

Biomechanical testing demonstrated that the components of the Spinal Innovations SPECTRUM™ Cervical Spinal System exhibit equivalent mechanical performance, compared to predicate devices.

Basis for Substantial Equivalence

The Spinal Innovations SPECTRUM™ Cervical 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

DEC 0 6 2002

Mr. Joseph S. Clift
Vice President, Regulatory Affairs
Spinal Innovations, Inc.
7850 Stage Hill Blvd
Suite 105
Bartlett, Tennessee 38133

Re: K022997
Trade Name: SPECTRUM™ Cervical Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: September 6, 2002
Received: September 9, 2002

Dear Mr. Clift:

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 http://www.fda.gov/cdrh/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

510(K) Number K022997

Device Name: Spinal Innovations SPECTRUM™ Cervical Spinal System.

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for Mark N Milhous

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

510(k) Number K022997

(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 Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)