

K980288

JUL 29 1998

510(k) Summary of Safety and Effectiveness

Company Name:	Spine Tech, Inc. 7375 Bush Lake Road Minneapolis, MN 55439-2027 (612) 832-5600
510(k) Contact:	David A. Cannistraci Director of Regulatory Affairs (612) 832-5600
Trade Name:	Spine-Tech Silhouette™ Spinal Fixation System
Common Name:	Hook, rod and screw spinal instrumentation
Classification:	888.3050 Spinal interlaminar fixation orthosis
Device Product Code:	87 KWP and MNH
Substantially Equivalent Devices:	Depuy Motech MOSS Miami Spinal System Sofamor Danek Multi Axial Screw Sofamor Danek TSRH™ Spinal System Wright Medical Technology Wrightlock™ Spinal System Wright Medical Technology Versalok™ Low Back Fixation System

Device Description

The Spine-Tech Silhouette™ Spinal Fixation System is a temporary implant system used to correct spinal deformity and facilitates 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 polyaxial screws of varying diameters and lengths, fixed screws of varying diameters and lengths, rods in varying lengths, hooks in varying designs, and transverse connectors both fixed and adjustable. All implant components are top loading and top tightening. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V), conforming to ASTM F-136.

The implants of this system are for single use only. An implant should never be reused after being removed from the body or sterilized after coming into contact with body fluids or tissues.

Intended Use

The Spine-Tech Silhouette Spinal Fixation 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.

When used as a hook and sacral screw system, the Spine-Tech Silhouette Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with 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 fusion. When used for this indication, screws of the Spine-Tech Silhouette Spinal Fixation System are intended for sacral/iliac attachment only. Hook and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

Testing

Biomechanical testing was performed and supplied in support of the Spine-Tech Silhouette Spinal Fixation System premarket notification. Components of the Spine-Tech Silhouette Spinal Fixation System demonstrated equivalent mechanical performance as compared to several commercially available spinal fixation systems.

Basis for Substantial Equivalence

The Spine-Tech Silhouette Spinal Fixation System is substantially equivalent in Material, design, and function to the Depuy Motech MOSS Miami Spinal System, Sofamor Danek Multi Axial Screw and TSRH™ Spinal Fixation Systems, and the Wright Medical Technology Wrightlock™ and Versalok™ Low Back Fixation Systems.

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, Spine-Tech believes that the Spine-Tech Silhouette Spinal Fixation System does not raise any new safety or effectiveness issues.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David A. Cannistraci
Director of Regulatory Affairs
Sulzer Spine-Tech
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2027

Re: K980288
Silhouette™ Spinal Fixation System
Regulatory Class: II
Product Codes: KWP and MNH
Dated: July 13, 1998
Received: July 14, 1998

Dear Mr. Cannistraci:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal, Food, Drug, and Cosmetic Act (Act). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.
2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

WARNINGS:

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:
 - device component fracture,
 - loss of fixation,
 - non-union,
 - fracture of the vertebra,
 - neurological injury, and
 - vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment for intended uses other

than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

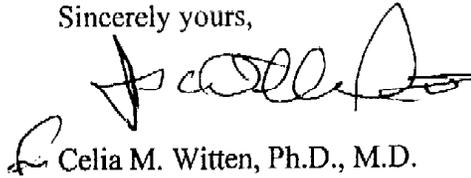
FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or those of other manufacturers, may also be required. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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 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" (21 CFR 807.97). Other general information on your responsibilities under the

Page 4 - Mr. David A. Cannistraci

Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

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

Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) #K980288

Device Name: Spine Tech Silhouette™ Spinal Fixation System

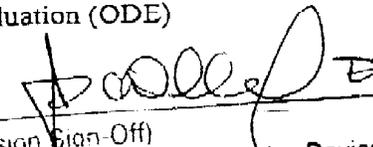
Indications for Use:

The Spine-Tech Silhouette Spinal Fixation 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.

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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)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 12980288

Prescription Use X
(Per 21 CFR 801.109)

OR

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