

K973687

MAR 18 1998

## SUMMARY OF SAFETY AND EFFECTIVENESS

### BacFix™ ti Spinal Fixation System

#### I. General Information

Classification Name: 87 Orthopedics

Common Name: Appliance, Fixation, Spinal Interlaminar

Device Trade Name: BacFix™ ti Spinal Fixation System

Classification Code: This device has been placed in Class II by the Orthopedics Panel.

Submitter's Name & Address: Spinal Concepts, Inc.  
8200 Cameron Road, Suite B-160  
Austin, Texas 78754 U.S.A.  
(512) 339-4800

Establishment Registration No: 1649384

**Contact Person:**

Teena M. Augustino  
Director, Clinical and Regulatory Affairs

Summary Preparation Date: March 3, 1998

#### II. Predicate Device

The Spinal Concepts, Inc. BacFix™ ti Spinal Fixation System claimed to be substantially equivalent in material, design, and function to the existing BacFix™ Spinal Fixation System and the Synthes Universal Spinal System.

#### III. Device Description

The Spinal Concepts, Inc. BacFix™ ti Spinal Fixation System consists of a combination of titanium components which include rods, hooks, locking wedges, screws and transverse connectors which are indicated to provide temporary stability of the thoracic, thoracolumbar or lumbar spine (T1-S1). The BacFix™ Spinal Fixation System consists of longitudinal members (spinal rods), in diameters of 5.5 and 6.0mm, in two hardnesses, and a variety of lengths; spinal anchor components, hooks and screws (mono-axial and multi-axial) of various diameters (5.0, 6.0, 7.0 and 8.0mm) and lengths; locking connectors (threaded wedge and nut or non-threaded wedge and locking clip) sized to fit the spinal rods; and a transverse connector assembly (link), also in various lengths. Hooks and screws may be placed at any position along the spinal rods. Wedges are used to connect the spinal rods to screws (hooks and links). These components are pre-assembled outside the wound, eliminating the need to pre-plan the position of each eyebolt on the spinal rod. A spinal rod is positioned within the open face of the wedge. Fixation of the construct is accomplished using an instrument that applies a three point shear clamp. Addition of the hex nut (when using threaded wedge) and optional use of the

locking clip (when using the non-threaded wedge) complete the implant. Anchor components may be added to (or removed from) the construct at any time during the procedure.

#### IV. Sterilization

The BacFix™ ti Spinal Fixation System implants and instrumentation may be provided sterile or non-sterile. Both implants and instruments must be sterilized prior to use in accordance with the recommended sterilization parameters described in the package insert in order to achieve a sterility assurance level of 10<sup>-6</sup>.

#### V. Indications for Use

When intended for pedicle screw fixation, the implants are intended for use in Grade 3 and 4 spondylolisthesis at L5-S1, utilizing autologous bone graft, having the device fixed or attached to the lumbar and sacral spine and intended to be removed after solid fusion is attained. Levels of pedicle screw attachment for this indication range from L3 to the sacrum.

When intended for non-pedicle, posterior screw fixation, the system is intended for hook and/or sacral/iliac screw fixation from the thoracic spine to the ileum/sacrum. The indications are:

1. Idiopathic scoliosis.
2. Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity.
3. Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.
4. Spinal fractures (acute reduction or late deformity).
5. Degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
6. Neoplastic disease.
7. Spondylolisthesis.
8. Spinal stenosis.
9. Revision surgery.

#### VI. Substantial Equivalence

Product	Material	System Components	Function/ Design	Indications
SCI BacFix™ ti Spinal Fixation System	Ti-6AL-4V ELI (ASTM F-136) or Ti-6AL-7Nb (ASTM F-1295) & unalloyed titanium (ASTM F-67)	Rods (hard and soft - various lengths) Hooks (laminar, pedicle, lumbar – right and left), Rod links/wedges (various sizes and lengths) Screws (angled, straight, various sizes and	Bilateral, dual spinal rods connected with transverse rod linkages. Spinal rods are attached to thoracic & lumbar spine with hooks & to sacral spine	When intended for pedicle screw fixation, the implants are intended for use in Grade 3 and 4 spondylolisthesis at L5-S1, utilizing autologous bone graft, having the device fixed or attached to the lumbar and sacral spine and intended to be removed after solid fusion is attained. Levels of pedicle screw attachment for this indication range from L3 to the sacrum.  When intended for non-pedicle, posterior screw fixation, the system is intended for hook and/or sacral/iliac screw fixation from the thoracic spine to the ileum/sacrum. The indications are: 1. Idiopathic scoliosis, 2. Neuromuscular

		diameters)	with screws	scoliosis/kyphoscoliosis with associated paralysis or spasticity, 3. Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, 4. Spinal fractures (acute reduction or late deformity), 5. Degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). 6. Neoplastic disease, 7. Spondylolisthesis, 8. Spinal stenosis, 9. Revision surgery.
<b>SCI BacFix Spinal Fixation System (K964404)</b>	316L Stainless Steel & 22-13-5 Stainless Steel	Rods (hard and soft - various sizes and lengths) Hooks (laminar, pedicle, lumbar – right and left), Rod links/wedges (various sizes and lengths) Screws (angled, straight, various sizes and diameters)	Bilateral, dual spinal rods connected with transverse rod linkages. Spinal rods are attached to thoracic & lumbar spine with hooks & to sacral spine with screws	Same as above
<b>Synthes Universal Spine System (K921948), (K922855), (K943725) may all apply in part.</b>	Ti-6AL-7NB & CP (chemically Pure) titanium	Rods (hard and soft-various sizes and lengths), Hooks (laminar, pedicle, lumbar, transverse process), rod collar, transverse bars, Screws (various sizes and diameters)	Bilateral, dual spinal rods connected with transverse rod linkages. Spinal rods are attached to thoracic & lumbar spine with hooks & to sacral spine with screws	Intended for correction of anterolateral lordotic deformities of the spine, scoliosis, pseudarthrosis and fracture or dislocation of the thoracolumbar spine (T8-L5).

## VII. Mechanical Testing

Static and fatigue testing was performed on the BacFix™ ti and the existing, BacFix™ Systems. These data were compared with published data of various other hook, rod and screw spinal fixation systems. The results of this testing demonstrated the BacFix™ ti to be substantially equivalent to the BacFix™ and the Synthes Universal Spine System and able to withstand clinical loading and maintain mechanical integrity.

## VIII. Conclusion

The BacFix™ ti Spinal Fixation System is considered to be substantially equivalent in design, material and function to the existing BacFix™ System and the Synthes Universal Spine System.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 18 1998

Ms. Teena M. Augostino  
Director  
Regulatory and Clinical Affairs  
Spinal Concepts, Inc.  
8200 Cameron Road, Suite B-160  
Austin, Texas 78754

Re: K973687  
BacFix™ ti Spinal Fixation System  
Regulatory Class: II  
Product Codes: MNH and KWP  
Dated: January 7, 1998  
Received: January 8, 1998

Dear Ms. Augostino:

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 Act may be obtained from the Division of Small Manufacturers 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* 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

INDICATION FOR USE STATEMENT

Page 1 of 2

510(k) Number (if known): K973687

Device Name: Spinal Concepts, Inc. BacFix™ ti Spinal Fixation System

Indications for Use: The Spinal Concepts, Inc. BacFix™ ti Spinal Fixation System consists of a combination of components which include rods, hooks, locking wedges, screws and transverse connectors which are indicated to provide temporary stability of the thoracic, thoracolumbar or lumbar spine (T1-S1).

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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  
(Per 21 CFR 801.109)

Or

Over-The-Counter \_\_\_\_\_  
(Optional Format 1-2-96)

*for C.M.W.*  
Mark A. Melkunas  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K973687

When intended for non-pedicle, posterior screw fixation, the system is intended for hook and/or sacral/iliac screw fixation from the thoracic spine to the ileum/sacrum. The indications are:

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