K013887
1 of 2

FEB 1 2 2002

BacFix Spinal Fixation System
Pedicle Screw Indications
510(k) Premarket Notification

SUBMITTED BY	Spinal Concepts, Inc. 12012 Technology Blvd., Suite 100 Austin, TX 78727
ESTABLISHMENT REGISTRATION NUMBER	1649384
CONTACT PERSON	David M. Hooper, Ph.D. Manager, Regulatory and Clinical Affairs Phone: 512-918-2700 Fax: 512-918-2784
DATE PREPARED	November 21, 2001
CLASSIFICATION NAME	Pedicle Screw Spinal System Spinal Interlaminal Fixation Orthosis
COMMON NAME	Spinal Fixation System
PROPRIETARY NAME	BacFix Spinal Fixation System

DEVICE DESCRIPTION

The BacFix Ti Spinal Fixation System is intended to be used for posterior lumbar fusion procedures. The system is manufactured from titanium alloy, which complies with ASTM F136. The BacFix Spinal Fixation System includes screws, rods, hooks, transverse connectors and other ancillary components. The BacFix Ti Spinal Fixation System was cleared for market under K973687, and supplemented through additional 510k submissions: K002082 (addition of SpeedLink transverse connector), K003351 (addition of the ParsFix Cable Screw System), K010563 (addition of end-to-end and side-by-side connectors).

INDICATIONS FOR USE

The SCI BacFix® Ti Spinal Fixation System consists of a combination of components which include rods, hooks, locking wedges, screws, transverse connectors, cable-screws, cables and spinous process grommets which are indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1).

When intended for pedicle screw fixation, implants are 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 or 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range to T1 to the sacrum.

As a pedicle screw system, the BacFix® Spinal Fixation System is also intended for patients having Grade 3 or Grade 4 spondylolisthesis at L5-S1, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established. Levels of pedicle screw fixation for this indication are from L3 to the sacrum.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine, 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).
- Neoplastic disease.
- Spondylolisthesis.
- Spinal Stenosis.
- Failed previous fusion.

The cable-screws, cables and spinous process grommets are indicated for:

- Defect of pars lateralis.
- Spondylolisthesis.

Cables and spinous processes grommets may be used for interspinous wiring if additional stability is needed.

PREDICATE DEVICE

The BacFix Spinal Fixation System is substantially equivalent to the Isola Spinal System (DePuy Acromed Inc, Cleveland, OH) the indication of degenerative disc disease to be treated with pedicle screw fixation.

DISCUSSION OF NONCLINICAL TESTS

Mechanical testing was conducted on the stiffest and most flexible BacFix constructs in accordance with ASTM 1717-96. The experimentally collected BacFix data were compared to available data collected for the Isola Spinal System. It was demonstrated that the range of construct stiffnesses of the BacFix system is contained within the possible range of stiffnesses available with the Isola Spinal System.

COMPARISON TO THE PREDICATE DEVICE

The BacFix Ti Spinal Fixation System is substantially equivalent to the Isola Spinal System (DePuy Acromed Inc., Cleveland, OH). Both systems are composed of screws, rods, hooks, transverse connectors and other ancillary components to aid in spinal fixation. Materials used in both systems are biocompatible and the range of construct stiffnesses of the BacFix system is contained within the possible range of stiffnesses available with the Isola Spinal System. The two spinal fixation systems are substantially equivalent for all indications.

Table 1: TABLE OF SUBSTANTIAL EQUIVALENCE

Device Name	BacFix Spinal Fixation System	Isola Spinal System
Indications for use	See above.	Same.
Materials	Titanium 6Al-4V	Stainless steel or titanium
Components	Screws, rods, hooks, transverse connectors.	Same.
Product Labeling	Instructions for use and box labeling including all the necessary warning statements.	Same.
Packaging/Sterilization	Non-sterile, single use only.	Same.
Biomechanical Test Results	Stiffness range, per ASTM 1717-96, within the range of the Isola Spinal System.	Stiffness range, per ASTM 1717-96, is wider than the BacFix Spinal Fixation System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2002

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

Re: K013887
Trade Name: BacFix™ Ti Spinal Fixation System
Regulation Number: 21 CFR 888.3050 and 888.3070
Regulation Name: Spondylolisthesis Spinal Fixation Device System, Pedicle Screw Spinal System, and Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: November 21, 2001
Received: November 23, 2001

Dear Dr. Hooper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (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.

This letter will allow you to begin marketing your device as described in your 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 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/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

K013887
1 of 2

INIDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013887

Device Name:

Spinal Concepts, Inc. **BacFix Ti Spinal Fixation System**

Indications for Use:

The SCI BacFix® Ti Spinal Fixation System consists of a combination of components which include rods, hooks, locking wedges, screws, transverse connectors, cable-screws, cables and spinous process grommets which are indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1).

When intended for pedicle screw fixation, implants are 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 or 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range to T1 to the sacrum.

(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: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K013887

INIDICATIONS FOR USE STATEMENT

K013887

As a pedicle screw system, the BacFix® Spinal Fixation System is also intended for patients having Grade 3 or Grade 4 spondylolisthesis at L5-S1, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established. Levels of pedicle screw fixation for this indication are from L3 to the sacrum.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine, 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).
- Neoplastic disease.
- Spondylolisthesis.
- Spinal Stenosis.
- Failed previous fusion.

The cable-screws, cables and spinous process grommets are indicated for:

- Defect of pars lateralis.
- Spondylolisthesis.

Cables and spinous processes grommets may be used for interspinous wiring if additional stability is needed.

(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: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)