K983260

OCT 21 1998

# SUMMARY OF SAFETY AND EFFECTIVENESS
## BacFix™ ti Spinal Fixation System (K983260)

### I. General Information

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| Classification Name: | 87 Orthopedics |
| Common Name: | Appliance, Fixation, Spinal Interlaminal |
| 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.<br>8200 Cameron Road, Suite B-160<br>Austin, Texas 78754 U.S.A.<br>(512) 339-4800 |
| Establishment Registration No: | 1649384 |
| | **Contact Person:**<br>Teena M. Augostino<br>Director, Clinical and Regulatory Affairs |
| Summary Preparation Date: | October 15, 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 $10^{-6}$.

## V. Indications for Use

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 and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range from T1 to the sacrum.

In addition, when intended for pedicle screw fixation, implants are intended for treatment of severe spondylolisthesis (grades 3 and 4) of the vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of implants after the attainment of solid fusion. The levels of screw fixation for these indications range from L3 to the sacrum.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine, the indications are:

1. Idiopathic scoliosis.
2. Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spacticity.
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. Failed previous fusion.

## VI. Substantial Equivalence

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| SCI Backup 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 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 | 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 and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range from T1 to the sacrum.<br><br>In addition, when intended for pedicle screw fixation, implants are intended for treatment of severe spondylolisthesis (grades 3 and 4) of the vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of implants after attainment of solid fusion. The levels of screw fixation for these indications range from L3 to the sacrum.<br><br>When intended for non-pedicle, posterior screw fixation of the non-cervical spine, the indications are" 1. Idiopathic scoliosis, 2. Neuromuscular scoliosis/ kyphoscoliosis with associated paralysis or spacticity, 3. Scoliosis with deficient posterior elements such as that resulting from laminectomy or myeolmeningocele, 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 and 9. Failed previous fusion. |

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| [redacted] | 316L Stainless Steel & 22-13-5 Stainless Steel | Rods (hard and soft - various sizes and lengths)<br>Hooks (laminar, pedicle, lumbar – right and left),<br>Rod links/wedges (various sizes and lengths)<br>Screws (angled, straight, various sizes and diameters) | Bilateral, dual spinal rods connected with transverse rod linkages.<br>Spinal rods are attached to thoracic & lumbar spine with hooks & to sacral spine with screws | Same as above |
| [redacted] | Ti-6AL-7NB & CP (chemically Pure) titanium | Rods (hard and soft-various sizes and lengths),<br>Hooks (laminar, pedicle, lumbar, transverse process),<br>rod collar,<br>transverse bars,<br>Screws (various sizes and diameters) | Bilateral, dual spinal rods connected with transverse rod linkages.<br>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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

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

Re: K983260
BacFix™ ti Spinal Fixation System - expanded uses
Regulatory Class: II
Product Codes: MNI, KWP, and MNH
Dated: September 11, 1998
Received: September 16, 1998

Dear Ms. Augostino:

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 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). 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 requirements, 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" (21CFR 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/dsma/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



510(k) Number (if known): K983260

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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7. Spondylolisthesis.
8. Spinal stenosis.
9. Failed previous fusion.

(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)~~

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983260