SUMMARY OF SAFETY AND EFFECTIVENESS
CFIX™ Cable System

DEC 19 1997

K974020

I. General Information

Classification Name:	87 Orthopedics - Class II as described in 21 CFR 888.3010 for Bone Fixation Cerclage (product code JDQ) and also Class II as described in 21 CFR 888.3050 for Spinal Interlaminal Fixation Orthosis.
Common Name:	Metallic Bone Fixation Appliance or Cable
Device Trade Name:	CFIX™ Cable 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. Augostino Director, Clinical and Regulatory Affairs
Summary Preparation Date:	October 20, 1997

II. Predicate Device

The Spinal Concepts, Inc. CFIX™ Cable System is claimed to be substantially equivalent in material, design, and function to the Songer™ Cable System K925812.

III. Device Description

The Spinal Concepts, Inc. CFIX™ Cable System consists of a flexible, multi strand medical grade titanium alloy cable and an adjustable cam/block assembly which is used to lock the cable securely in place. Flats on the head of the cam fit within an opening in the cam block formed by two "deflectable" ribs on the proximal end of the device. This configuration aligns the cam in the open position such that the cable may be threaded through with minimal resistance. A smooth cable leader allows for easy threading through the cam/block while a titanium ball welded at the other end of the cable functions as a stop when it engages with the cam/block. This ball end provides the surgeon with the option of final tensioning using a single cable end or both ends, as desired.

A re-usable Cable Tensioner is used to stabilize the cam/block and hold one or both cable ends while tensioning the cable into place. In addition, the Cable Tensioner is designed to accept a T-Handled hex wrench, which is inserted through a hollow barrel in the

instrument, for engagement with the cam. By turning the hex wrench, the cam is rotated 90 degrees within the block and locks the cable into place. The cam/block locking mechanism is designed to "snap" and provides the surgeon with tangible tactile confirmation that the cam has been rotated and locked. Once the cable is locked securely in place, cable cutters are used to cut the cable ends flush with the cam/block assembly.

IV. Sterilization

The CFIX™ Cable System implants may be provided sterile or non-sterile. Both implants and instrumentation must be sterilized prior to use in accordance with recommended sterilization parameters described in the package insert in order to achieve a sterility assurance level of 10^{-6}.

V. Indications for Use

The Spinal Concepts, Inc. (SCI™) CFIX™ Cable System is a temporary implant for use in orthopedic and cardiovascular surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include, but are not limited to the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinours or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis, etc.;
3. Spinal denerative surgery, as an adjunct to spinal fusions;
4. Orthopedic trauma surgery, to secure fractures of the olecranon, patella, femur, humerus, etc. Cables may also be used to reduce and secure dislocations of the acromioclavicular joint;
5. Orthopaedic reconstructive surgery, to reattach the greater trochanter after trochanteric osteotomy during total hip arthroplasty;
6. Cardiovascular surgery for closure of the sternum following sternotomy; and
7. Oral surgery, to repair and fix fractures of the mandible and other facial fractures.

The CFIX™ Cable System may also be used in conjunction with other medical implant grade implants made of titanium alloy (e.g. Luque rods) whenever "wiring" may help secure the attachment of other implants.

VI. Substantial Equivalence

Product	Material	System Components	Function/ Design	Indications
SCI CFIX™ Cable System	Ti-6AL-4V ELI (ASTM F-136) Unalloyed Titanium cable leader (ASTM F-1431 – not implanted)	Miltifilament Cable (18" & 24") Cam block	Flexible stranded titanium cable – "ball" stop on one end and cable leader on other – with cam block locking mechanism.	The indications for use of the CFIX™ Cable System is to cerclage and attach various objects, which include, but are not limited to the following applications: 1.Spinal trauma surgery, used in sublaminar, interspinours or facet wiring techniques; 2.Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis, etc.; 3.Spinal denerative surgery, as an adjunct to spinal fusions; 4.Orthopedic trauma surgery, to secure fractures of the olecranon, patella, femur, humerus, etc. Cables may also be used to reduce and secure dislocations of the acromioclavicular joint; 5.Orthopaedic reconstructive surgery, to reattach the greater trochanter after trochanteric osteotomy during total hip arthroplasty; 6.Cardiovascular surgery for closure of the sternum following sternotomy; and 7.Oral surgery, to repair and fix fractures of the mandible and other facial fractures. The CFIX™ Cable System may also be used in conjunction with other medical implant grade implants made of titanium alloy (e.g. Luque rods) whenever "wiring" may help secure the attachment of other implants.
Songer™ Cable System K925812 (K920201, K922952 and K941213 for the Songer™ Cable System may apply in part as well	Ti-6AL-4V ELI (ASTM F-136)	Multifilament Cable (single & double) with crimp at end, bars (one, two hole, flat and barrel shaped)	Flexible, stranded titanium cable – crimp on one end and stiff leader on other - with bar locking mechanism	Properly used, this device will aid in the repair or attachment of bony structures. The Songer Cable system can be utilized anywhere mono-filament wire has been previously found to be indicated. Such indications might include, but are not limited to:1.Spinal applications would include sublaminar and intraspinous process wiring for trauma applications. Another application would be the use of the Songer Cable system for instrumentation involved in the correction of scoliosis, kyphosis and lordosis deformities... 2.Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty. 3.Sternotomy indications would include the "re-wiring" of osteotomized sternums. 4.Trauma surgery indications would include olecranon, ankle, patella and some shoulder fracture rewiring.

VII. Mechanical Testing

Static tension and fatigue strength testing demonstrated that the CFIX™ Cable System is suited for its intended use.

VIII. Conclusion

The CFIX™ Cable System is considered to be substantially equivalent in design, material and function to the Songer™ Cable System (K925812).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

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

Re: K974020
Spinal Concepts CFIX™ Cable System
Regulatory Class: II
Product Code: JDQ
Dated: October 20, 1997
Received: October 22, 1997

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 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 (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

510(k) Number (if known): _____

Device Name: Spinal Concepts, Inc. CFIX™ Cable System

Indications for Use: The Spinal Concepts, Inc. (SCI™) CFIX™ Cable System is a temporary implant for use in orthopedic and cardiovascular surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include, but are not limited to the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis, etc.;
3. Spinal degenerative surgery, as an adjunct to spinal fusions;
4. Orthopedic trauma surgery, to secure fractures of the olecranon, patella, femur, humerus, etc. Cables may also be used to reduce and secure dislocations of the acromioclavicular joint;
5. Orthopaedic reconstructive surgery, to reattach the greater trochanter after trochanteric osteotomy during total hip arthroplasty;
6. Cardiovascular surgery for closure of the sternum following sternotomy; and
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The CFIX™ Cable System may also be used in conjunction with other medical implant grade implants made of titanium alloy (e.g. Luque rods) whenever "wiring" may help secure the attachment of other implants.

(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 K974020