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SUMMARY OF SAFETY AND EFFECTIVENESS
Spinal Concepts, Inc. (SCI) Anterior Cervical Plate System

I. General Information

Device Trade Name:	Spinal Concepts, Inc. (SCI) Anterior Cervical Plate System
Common Name:	Anterior Cervical Plate
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Classification Code:	87 Orthopedics - Class II as described in 21 CFR 888.3060 (product code KWQ).
Submitter's Name & Address:	Spinal Concepts, Inc. 8200 Cameron Road, Suite B-160 Austin, Texas 78754 U.S.A. Tel: (512) 339-4800 Fax: (512) 339-4878
Establishment Registration No:	1649384
	Contact Person: Pepper A. Chastain, Technical Specialist, Department of Clinical and Regulatory Affairs
Summary Preparation Date:	December 31, 1998

II. Predicate Device

The Spinal Concepts, Inc. (SCI) Anterior Cervical Plate System is claimed to be substantially equivalent in material, design, function, and intended use to the SOFAMOR DANEK ORION™ Anterior Cervical Plate System (K973854 and K922087) and to the SYNTHES Cervical Locking Plate System (K945700 and K926453).

III. Device Description

The Spinal Concepts, Inc. (SCI) Anterior Cervical Plate System components are temporary implants that are used to stabilize the cervical spine during the development of a solid spinal fusion. The SCI Anterior Cervical Plate System consists of single and multi-segmented titanium bone plates of various sizes and lengths, titanium bone screws in two diameters of various lengths, and associated instrumentation. Fixation is provided by the insertion of bone screws through the two openings at each end of a plate segment into the vertebral bodies of the cervical spine. Additional screws may be inserted into the variable-distance holes at the center of each plate segment, if needed, i.e., for multi-level interbody fusions or long strut graft reconstructions.

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IV. Sterilization

The SCI Anterior Cervical Plate 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 SCI Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

1. Degenerative disc disease (DDD) – as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
2. Trauma (including fractures);
3. Tumor;
4. Spondylolisthesis;
5. Spinal stenosis;
6. Deformity (i.e., scoliosis, kyphosis, lordosis);
7. Pseudarthrosis; and
8. Failed previous fusions.

VI. Substantial Equivalence

Spinal Concepts, Inc. believes that the SCI Anterior Cervical Plate System is substantially equivalent in design, materials, function and indications for use to the SOFAMOR DANEK ORION™ Anterior Cervical Plate System (K973854 and K922087) and the SYNTHES Cervical Locking Plate System (K945700 and K926453).

VII. Mechanical Testing

Static and fatigue testing was performed on the SCI Anterior Cervical Plate System. The results of the static tension and fatigue strength testing demonstrated that the SCI Anterior Cervical Plate System is able to withstand clinical loading and maintain mechanical integrity and is, therefore, suited for its intended use. Based upon the static tensile and fatigue strength testing, the Anterior Cervical Plate.

VIII. Conclusion

The Anterior Cervical Plate System is considered to be substantially equivalent in design, material, function, and intended use to the SOFAMOR DANEK ORION™ Anterior Cervical Plate System (K973854 and K922087) and the SYNTHES Cervical Locking Plate System (K945700 and K926453).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Ms. Pepper A. Chastain
Technical Specialist
Regulatory and Clinical Affairs
Spinal Concepts, Inc.
8200 Cameron Road, Suite B-160
Austin, Texas 78754

Re: K990005
Trade Name: Spinal Concepts, Inc. (SCI) Anterior Cervical Plate System
Regulatory Class: II
Product Code: KWQ
Dated: December 31, 1998
Received: January 4, 1999

Dear Ms. Chastain:

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,

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

Spinal Concepts, Inc.
SCI Anterior Cervical Plate System Premarket Notification
December 31, 1998

INDICATION FOR USE STATEMENT

510(k) Number (if known): K990005

Device Name: Spinal Concepts, Inc. (SCI) Anterior Cervical Plate System

Indications for Use: The Spinal Concepts, Inc. (SCI) Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

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2. Trauma (including fractures);
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4. Spondylolisthesis;
5. Spinal stenosis;
6. Deformity (i.e., scoliosis, kyphosis, lordosis);
7. Pseudarthrosis; and
8. Failed previous fusions.

(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 K990005