K013979
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# SC-AcuFix Thinline Anterior Cervial Plate System
# 510(k) Summary

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| **SUBMITTED BY** | Spinal Concepts, Inc.<br>12012 Technology Blvd., Suite 100<br>Austin, TX 78727 |
| **ESTABLISHMENT REGISTRATION NUMBER** | 1649384 |
| **CONTACT PERSON** | David M. Hooper, Ph.D.<br>Manager, Regulatory and Clinical Affairs |
| **DATE PREPARED** | November 30, 2001 |
| **CLASSIFICATION NAME** | KWQ: Spinal Intervertebral Body Fixation Orthosis. Class II. |
| **COMMON NAME** | Spinal Fixation System |
| **PROPRIETARY NAME** | SC-AcuFix Thinline Anterior Cervical Plate System |
| **PREDICATE DEVICE** | SCI Anterior Cervical Plate System, later trademarked SC-AcuFix (K990005). This is a design modification per established design control procedures. |

**DEVICE DESCRIPTION**

The SC-AcuFix Thinline Anterior Cervical Plate System consists of various sizes of bone plates, screws and surgical instruments. The screws are used to secure the plates to the vertebral bodies of the cervical spine through an anterior approach. The plates have an integrated locking mechanism that captures the screw upon full insertion, preventing screw-backout. Plates and screws are manufactured from titanium alloy (ASTM F-136) and may be supplied sterile or non-sterile.

**INDICATIONS**

The SC-AcuFix Thinline 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 degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e., scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.

**MECHANICAL TEST DATA**

Mechanical testing data, collected in accordance with ASTM 1717, was collected to verify the design changes. Static and fatigue data were provided to demonstrate that the design changes met design requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2002

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

Re: K013979
Trade Name: SC-AcuFix Thinline
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: January 28, 2002
Received: January 29, 2002

Dear Dr. Hooper:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

K013979

INIDICATIONS FOR USE STATEMENT



510(k) Number (if known):

Device Name:
Spinal Concepts, Inc. **SC-AcuFix Thinline Anterior Cervical Plate System**

Indications for Use:

The SC-AcuFix Thinline 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 degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumor, spondylolisthesis, spinal stenosis, deformity (i.e., scoliosis, kyphosis, lordosis), pseudarthrosis, and failed previous fusions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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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)

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

510(k) Number K013979