Spinal Concepts, Inc. Tandem Spinous Process Plate System

510(k) Summary of Safety and Effectiveness

JUL 0 1 2004

SUBMITTED BY	Spinal Concepts, Inc. 5301 Riata Park Court, Bldg. F Austin, TX 78727
ESTABLISHMENT REGISTRATION NUMBER	1649384
CONTACT PERSON	Lisa Peterson Regulatory Affairs Specialist
DATE PREPARED	January 14, 2004
CLASSIFICATION NAME	Spinal interlaminal fixation orthosis, 21 CFR 888.3050. Class II.
COMMON NAME	Posterior Spinal Fixation System
PROPRIETARY NAME	Spinal Concepts, Inc. Tandem Spinous Process Plate System
PREDICATE DEVICES	Meurig-Williams Plate

DEVICE DESCRIPTION

The Tandem system consists of spinous process plates and interconnecting male and female grommets. The implants are used in combination with a vertebral body replacement device such as the Spinal Concepts, Inc. InFix System. The plates feature a slim profile, several rows of spikes, and holes on each end with a spherical seat for grommet attachment. The spikes around the plate holes resist plate rotation after implantation, while a row of spikes over the intraspinous ligament aids in fixation to any optional bone graft.

INDICATIONS

The Tandem Spinous Process Plate is intended for fixation to adjacent spinous processes (L1-L5) as an adjunct to anterior interbody fusion and bone graft. The indications for the spinous process plate include spinal trauma, degenerative spondylolisthesis and degenerative disc disease. The spinous process plate should only be used in the presence of a vertebral body replacement device such as the Spinal Concepts, Inc. InFix® System.

MECHANICAL TEST DATA

Mechanical testing demonstrated that the Tandem System exhibits the functional requirements to support its use as a spinous process plate system under normal physiologic loads in the spine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

Ms. Lisa Peterson
Regulatory Affairs Specialist
Spinal Concepts Incorporated
5301 Riata Park Court, Bldg. F
Austin, Texas 78727

Re: K040096
Trade Name: Tandem Spinous Process Plate System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: April 15, 2004
Received: April 20, 2004

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040096

Device Name: Spinal Concepts, Inc. **Tandem Spinous Process Plate System**

Indications for Use:

The Spinous Process Plate is intended for fixation to adjacent spinous processes (L1-L5) as an adjunct to anterior interbody fusion and bone graft. The indications for the spinous process plate include spinal trauma, spondylolisthesis and degenerative disc disease. The spinous process plate should only be used in the presence of a vertebral body replacement device such as the Spinal Concepts, Inc. InFix® System.

(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 K040096