SEP 11 2003

Spinal Concepts, Inc.
Nex-Link Spinal Fixation System

510(k) Summary

SUBMITTED BY	Spinal Concepts, Inc. 5301 Riata Park Court, Bldg. F Austin, TX 78727
ESTABLISHMENT REGISTRATION NUMBER	1649384
CONTACT PERSON	Primary Lisa Peterson Regulatory Affairs Specialist Phone: 512-533-1080 Fax: 512-249-6734 Alternate David M. Hooper, Ph.D. Director, Clinical and Regulatory Affairs Phone: 512-533-1038 Fax: 512-249-6734
DATE PREPARED	June 26, 2003
CLASSIFICATION NAME	KWP - Spinal Interlaminal Fixation Orthosis MNI - Pedicle Screw Spinal System MNH – Spondylolisthesis Spinal Fixation Device System NKB – Pedicle Screw Fixation System, DDD
COMMON NAME	Posterior Spinal Implant
PROPRIETARY NAME	Spinal Concepts Inc. Nex-Link Spinal Fixation System
PREDICATE DEVICE	Medtronic Sofamor Danek VERTEX™ Reconstruction System

DEVICE DESCRIPTION

The Spinal Concepts, Inc. Nex-Link Spinal Fixation System consists of a series of longitudinal members, anchors, and transverse connectors. The Nex-Link system is intended for fixation to, and stabilization of, the cervicothoracic spine.

Nex-Link implants are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F-136 or commercially pure titanium per ASTM-F-67.

INDICATIONS:

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the NexLink Spinal Fixation System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The use of multiaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. The multiaxial screws are not intended to be placed in the cervical spine.

MECHANICAL TEST DATA

Mechanical testing data, collected in accordance with ASTM F1717-01 and ASTM F1798-97, were provided to support this 510(k) notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2003

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

Re: K031985
Trade Name: Nex-Link Spinal Fixation System
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: MNI, KWP
Dated: June 26, 2003
Received: July 9, 2003

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,

for Miriam C. Provost

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): K031985

Device Name: Spinal Concepts, Inc. **Nex-Link Spinal Fixation System**

Indications for Use:

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the NexLink Spinal Fixation System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ 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 K031985