

SEP 14 2005

K052247
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ABBOTT SPINE, INC.
SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER: Abbott Spine (formerly Spinal Concepts, Inc.)

ESTABLISHMENT REGISTRATION NUMBER: 1649384

CONTACT PERSON: Noah Bartsch
Specialist, Regulatory Affairs
Telephone: 512.533.1840
Fax: 512.918.2784

DATE: August 17, 2005

TRADE NAME: Nex-Link Spinal Fixation System Variable Crosslink

COMMON NAME: Posterior Spinal Implant

CLASSIFICATION NAME: KWQ: Spinal Intervertebral Body Fixation Orthosis
MNI: Pedicle Screw Spinal System

CLASSIFICATION REFERENCE: 21 CFR § 888.3050, 888.3070

PREDICATE DEVICE: Spinal Concepts, Inc. (now Abbott Spine, Inc.)
Nex-Link Spinal Fixation System, K031985,
cleared September 11, 2003.

DEVICE DESCRIPTION:

The Nex-Link Spinal Fixation System is intended for fixation to, and stabilization of, the cervicothoracic spine (C1-T3). The system consists of a series of longitudinal members, anchors, transverse connectors, and instruments for inserting and securing the implants.

The subject device, the Variable Crosslink, represents a design modifications made to the previously existing transverse connectors. The subject device shares the same intended use and fundamental scientific technology as the predicate.

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.

COMPARISON TO PREDICATE DEVICE: The subject device is the result of design modifications to the predicate device, has the same intended use, and is substantially equivalent to the predicate device.

PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL): NON-CLINICAL PERFORMANCE AND CONCLUSIONS:
Laboratory and bench testing results demonstrate that the proposed device is substantially equivalent to the predicate device.

CLINICAL PERFORMANCE AND CONCLUSIONS:

Clinical data and conclusions were not needed for this device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Noah Bartsch
Regulatory Affairs Specialist
Spinal Concepts Incorporated
5301 Riata Park Court, Bldg. F
Austin, Texas 78727

Re: K052247

Trade Name: Nex-Link™ Spinal Fixation System Variable Crosslink
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: MNI, KWP
Dated: August 17, 2005
Received: August 18, 2005

Dear Mr. Bartsch:

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.

Page 2 - Mr. Bartsch

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 (240) 276-0120. 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/industry/support/index.html>.

Sincerely yours,



so Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052247

Device Name: 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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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Respiration,
and Neurological Devices**

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