K071174
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ABBOTT SPINE
510(k) Summary

JUL 25 2007

SUBMITTER:	Abbott Spine (formerly Spinal Concepts, Inc.)
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	Roger Brown DVP Clinical and Regulatory Affairs Telephone: 512.533.1038 Fax: 512.258.0995
DATE:	June 22, 2007
TRADE NAME:	PathFinder® System
COMMON NAME:	Spinal Fixation System
CLASSIFICATION NAME:	PEDICLE SCREW SPINAL SYSTEM
CLASSIFICATION REFERNCE:	21 CFR § 888.3070 (MNI, MNH, NKB)
PREDICATE DEVICE:	PathFinder® System manufactured by Abbott Spine K030625 cleared March 28, 2003.

DEVICE DESCRIPTION:
The Abbott Spine, Inc. PathFinder® system is a pedicle screw fixation system designed to allow for use of an open or mini open surgical technique. The approved Pathfinder® system consists of various screws and rods and is intended to provide temporary stabilization following surgery to fuse the spine.

The subject device is the result of modifications to the existing PathFinder® 6.5mm polyaxial pedicle screws resulted in the inclusion of a 4.5mm polyaxial pedicle screw to the Pathfinder System. The subject device shares the same intended use and fundamental scientific technology as the predicate device.

INDICATIONS:

PathFinder® - Mini-Open Posterior Approach

When intended for pedicle screw fixation from L1-S1, the indications include immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, and failed previous fusion.

As pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established.

After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking info consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

COMPAIRSON TO PREDICATE DEVICE:

The subject device is the result of modifications to the existing PathFinder® 6.5mm polyaxial pedicle Screws resulted in the inclusion of a 4.5mm polyaxial pedicle screw to the Pathfinder System. The subject device has the same intended use and is substantially equivalent to the predicate device.

PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL):

NONCLINICAL PERFORMANCE AND CONCLUSION:

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2007

Abbot Spine
% Mr. Roger Brown
Divisional Vice President
Clinical and Regulatory Affairs
5301 Riata Park Court, Bldg. F
Austin, TX 78727

Re: K071174/S1
Trade/Device Name: Pathfinder® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: June 22, 2007
Received: June 26, 2007

Dear Mr. Brown:

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.

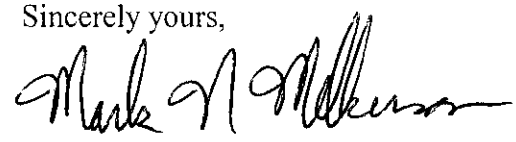
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
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): K071174

Device Name:

PathFinder® System (Adjunct to InCompass Spinal Fixation System)

Indications for Use:

PathFinder – Mini-Open Posterior Approach

When intended for pedicle screw fixation from L1-S1, the indications include immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, and failed previous fusion.

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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)

Mark N Milhern

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

510(k) Number K071174