zimmer spine

510(K) SUMMARY
PathFinder® II Minimally Invasive Pedicle Screw System

SEP 2 1 2010

Submitter Information

Company/Address: Zimmer Spine, Inc.
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Austin, TX. 78727
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Contact Person: David Padgett, RAC (US)
Senior Regulatory Affairs Specialist

Date Prepared: 17 June 2010

Device Identification

Proprietary Name: PathFinder® II Minimally Invasive Pedicle Screw System
Common Name: Spinal Fixation System
Classification: NKB - 21 CFR § 888.3070 - Spinal Interlaminal Fixation Orthosis

Predicate Device Information

Sequoia Pedicle Screw System, K082032 (S.E. 10/7/2008)
PathFinder Minimally Invasive Pedicle Screw System, K030625 (S.E.3/28/2003)
Depuy Viper II, K090648 (S.E. 6/10/09)

Device Description and Technological Characteristics:

The purpose of this 510(k) submission is to modernize the existing PathFinder Pedicle Screw System. A set of percutaneous insertion rods and new instrumentation have been included for minimally invasive procedures.

The Zimmer Spine PathFinder II system consists of polyaxial cannulated screws and rods and is intended to provide temporary stabilization following surgery to fuse the spine. A range of spinal rod lengths included in this system allows the surgeon to place polyaxial pedicle screws through an open or mini-open procedure. This system is intended only to provide stabilization during the development of a solid fusion with autograft or allograft. These implants are intended to be removed after the development of a solid fusion mass.

The predicate device, Sequoia Pedicle Screw System and the proposed PathFinder II device are fabricated from medical grade titanium alloy per ASTM F136 and commercially pure titanium per ASTM F67.

Intended Use / Indications for Use:

When intended for pedicle screw fixation from T1-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 a pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autograft or allograft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established.

Performance Data:

For a determination of substantial equivalence, the following non-clinical mechanical tests were performed:

Static and dynamic axial compression bending and static torsion tests in accordance with ASTM F1717 were performed on the proposed PathFinder II system and predicate Sequoia Pedicle Screw system and the results compared. The proposed device functioned as intended and the observed test results demonstrate substantial equivalence to the aforementioned predicate device.

Substantial Equivalence:

The PathFinder II Minimally Invasive Pedicle Screw System has the same intended use and indications for use as the predicate Sequoia Pedicle Screw System. Additionally, no new issues of safety or effectiveness are raised. Based on the supporting documentation presented within this premarket notification, the proposed device is as safe and effective and performs as well as or better than the predicate device identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Spine Inc.
% Mr. David Padgett
Senior Regulatory Affairs Specialist
5301 Riata Park Court, Building F
Austin, Texas 78727

SEP 21 2010

Re: K100845
Trade/Device Name: PathFinder® II Minimally Invasive Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: September 09, 2010
Received: September 10, 2010

Dear Mr. Padgett:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100845

SEP 21 2010

Indications for Use

510(k) Number (if known): K100845

Device Name: PathFinder® II Minimally Invasive Pedicle Screw System

Indications for Use:

When intended for pedicle screw fixation from T1-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_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100845