K090224



**510(k) Summary**

ADMINISTRATIVE INFORMATION

JUL 30 2009


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| Manufacturer Name: | X-spine Systems, Inc.<br>452 Alexandersville Rd.<br>Miamisburg, OH 45342<br><br>Telephone (937) 847-8400<br>FAX (937) 847-8410 |
| Official Contact: | David Kirschman, MD<br>Chief Medical Officer |


DEVICE NAME

| | |
|---|---|
| Classification Names: | Orthosis, Spondylolisthesis Spinal Fixation<br>Orthosis, Pedicle Spinal Fixation |
| Trade/Proprietary Name: | Fortex Pedicle Screw System |
| Common Name: | Pedicle Screw Spinal System |

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

DEVICE CLASSIFICATION

FDA has classified pedicle screw spinal systems as Class II devices (21 CFR 888.3070). The product code for Orthosis, Spondylolisthesis Spinal Fixation is (MNH). The product code for Orthosis, Spinal Pedicle Fixation is (MNI). These device classifications are reviewed by the Orthopedic Devices Branch.

INTENDED USE

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Fortex Pedicle Screw System is intended to provide 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 spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

DEVICE DESCRIPTION

*Fortex Rod*

Fortex rods are 5.5 mm diameter solid cylinders with spherically rounded ends, provided in 40 mm, 60 mm, 70 mm, 80 mm, 100 mm, 120 mm, 140 mm, 160 mm, 180 mm, 200 mm, and 300 mm lengths.

*Fortex Pedicle Screw Assembly*

Each Fortex pedicle screw assembly consists of a pedicle screw, yoke, and screw cap. Self-tapping pedicle screw assemblies are provided in diameters of 4.75mm, 5.5 mm, 6.5 mm, 7.5 mm and 8.25mm. All screw assemblies are provided in lengths of 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, and 55 mm. Screws are provided in canulated and non-canulated configurations.

*Fortex Cross Bar Assembly*

The Fortex cross bar assembly is an optional component and can be used for additional stabilization. Cross bar assemblies are available in lengths from 25 mm to 81 mm.

Material composition

The rods, pedicle screws and cross bars of the Fortex Pedicle Screw System are made of titanium alloy conforming to ASTM F136.

STATEMENT OF TECHNOLOGICAL COMPARISON

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Fortex Pedicle Screw System is substantially equivalent in indications and design principles to the predicate Capless Pedicle Screw System (K052847) and Capless LI Pedicle Screw System (K072282).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

X-Spine Systems, Inc.
c/o Dr. David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Rd
Miamisburg, OH 45342

JUL 30 2009

Re: K090224
Trade/Device Name: Fortex™ Pedicle Screw System
Regulation Number: 21 CFR 888. 3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 26, 2009
Received: June 30, 2009

Dear Dr. Kirschman:

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 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.

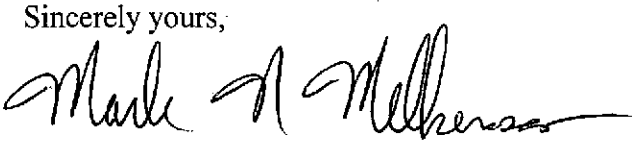
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark M. Melkerson
Director
Division of Surgical, Orthopaedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K090224

Device Name: Fortex™ Pedicle Screw System

Indications for Use:

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Fortex Pedicle Screw System is intended to provide 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 spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for M&M)

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

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