510(k) Summary

OCT 23 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, MD Chief Medical Officer
Initial Date Prepared:	March 16, 2012

DEVICE NAME

Trade/Proprietary Name:	Fortex Pedicle Screw System
Common Name(s):	Pedicle Screw Spinal System
Classification Name(s):	Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Pedicle Spinal Fixation
Device Class:	Class II
Classification(s):	§888.3070
Product Codes(s):	MNH, MNI

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.

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.

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).

DEVICE DESCRIPTION AND TECHNOLOGICAL CHARACTERISTICS

The purpose of this 510(k) submission is to add rods made of a different material to the Fortex Pedicle Screw System. The modified system has the same intended use and fundamental scientific technology as the previously-cleared Fortex Pedicle Screw System.

Both the modified and predicate Fortex Pedicle Screw System consist of various screws, rods, and cross bar connectors that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion.

The components of the predicate Fortex Pedicle Screw System are fabricated from medical grade titanium alloy per ASTM F136. The modified system includes components fabricated from medical grade cobalt chrome alloy per ASTM F1537, in addition to the titanium components. As documented within this premarket notification, the addition of cobalt chrome alloy rods does not raise new issues of safety or effectiveness. Titanium and cobalt chrome components may be used together within the same construct. These components should never be used with stainless steel implant components.

PERFORMANCE DATA

Non-clinical performance testing was conducted to characterize the modified Fortex Pedicle Screw System. Static and dynamic axial compression bending and static torsion tests in accordance with ASTM F1717 were performed on the modified and predicate systems, and the results compared. The modified device functioned as intended and the observed test results demonstrate substantial equivalence to the predicate devices.

EQUIVALENCE TO MARKETED PRODUCT

The modified Fortex Pedicle Screw System has the same intended use, indications, technological characteristics, and principles of operation as the predicate Fortex Pedicle Screw System, and the material change is to a type of material that has been used in other legally marketed devices within the same classification regulation for the same intended use such as the K2M, Inc. Range Spinal System (K080792). The modifications to the Fortex Pedicle Screw System do not raise new issues of safety or effectiveness. Also, mechanical testing demonstrated comparable mechanical properties to the predicate devices. Thus, the modified Fortex Pedicle Screw System is substantially equivalent to the predicate devices.

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

X-spine Systems, Incorporated
% David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

OCT 23 2012

Re: K120832
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: October 5, 2012
Received: October 9, 2012

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. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K120832

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.

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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)

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

510(k) Number K120832