

510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name: X-spine Systems, Inc.
7026 Corporate Way #212
Centerville, OH 45459-4288

Telephone (800) 903-0640
FAX (866) 481-0740

Official Contact: David Kirschman, MD

Representative/Consultant: Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130
Telephone (858) 792-1235
FAX (858) 792-1236

DEVICE NAME

Classification Names: Orthosis, Spondylolisthesis Spinal Fixation
Orthosis, Pedicle Spinal Fixation

Trade/Proprietary Name: Capless™ 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 Capless 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 Capless 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

Capless Rod

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

Capless Pedicle Screw Assembly

Each Capless pedicle screw assembly consists of a pedicle screw, yoke, and screw cap. Self-tapping pedicle screw assemblies are provided in diameters of 5.5 mm, 6.5 mm, and 7.5 mm. The 5.5 mm diameter screw assemblies are provided in lengths of 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, and 55 mm. The 6.5 mm diameter screw assemblies are provided in lengths of 40 mm, 45 mm, 50 mm, and 55 mm. The 7.5 mm diameter screw assemblies are provided in lengths of 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, and 55 mm.

Capless Cross Bar Assembly

The Capless 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 transverse links of the Capless Pedicle Screw System are made of titanium alloy conforming to ASTM F136.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Capless Pedicle Screw System is substantially equivalent in indications and design principles to predicate devices, that have been determined by FDA to be substantially equivalent to pre-amendment devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2005

X-spine Systems, Inc.
c/o Mr. Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130

Re: K052847

Trade/Device Name: Capless Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: MNI, MNH
Dated: October 5, 2005
Received: October 7, 2005

Dear Mr. Larson:

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

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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 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,



for 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): K052847

Device Name: Capless™ Pedicle Screw System

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The Capless 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 Capless 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)



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

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