



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

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

September 25, 2015

Re: K152132
Trade/Device Name: X-spineSM Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: July 30, 2015
Received: August 4, 2015

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K152132

Device Name

X-spineSM Pedicle Screw System

Indications for Use (Describe)

The X-spineSM 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 X-spineSM Pedicle Screw System is intended for posterior, non-cervical (T1-S2/ilium) pedicle spinal fixation 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).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY**X-spinesm Pedicle Screw System**

I. Submitter/Manufacturer: X-spine Systems, Inc.
 452 Alexandersville Rd.
 Miamisburg, OH 45342

Telephone (937) 847-8400
 FAX (937) 847-8410
 Email: dk@X-spine.com

Official Contact: David Kirschman, M.D.
 Chief Medical Officer

Date Prepared: July 30, 2015

Establishment Registration Number: 3005031160
Owner/Operator Number: 9063903

II. DEVICE NAME

Trade/Proprietary Name: X-spinesm Pedicle Screw System

Common Name: Pedicle screw spinal system

Device Class: Class II

Regulation Number: 21 CFR §888.3070

Product Codes/Classification Names:

- MNI -- Orthosis, Spinal Pedicle Fixation – Pedicle screw spinal system
- MNH -- Orthosis, Spondylolisthesis Spinal Fixation – Pedicle screw spinal system

Note: Proprietary Names included in the X-spinesm Pedicle Screw System are:

- Fortex[®] Pedicle Screw System
- Xpress[™] Minimally Invasive Pedicle Screw System

III. PREDICATE DEVICES

- Primary Predicate: Lanx Spinal Fixation System [Silverton; Silverton-D] (K122145)
 - This predicate has not been subject to a design related recall.
- Additional Predicate: Fortex Pedicle Screw System (K090224, K120832) [X-spine, Inc.]
 - This predicate has not been subject to a design related recall.

IV. DEVICE DESCRIPTION

The X-spinesm Pedicle Screw System consists of pedicle screws, rods, cross bar connectors, and associated instruments. Various forms and sizes of these implants are available so that adaptations can be made to take into account the pathology and anatomy of an individual patient. The system components are manufactured from Titanium based alloy which complies with ASTM F136. Alternatively, rods are also offered manufactured from Cobalt Chromium alloy which complies with ASTM F1537. The single use only implants are provided non-sterile, and should not be reused under any circumstances.

V. INDICATION FOR USE

The X-spinesm 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 X-spinesm Pedicle Screw System is intended for posterior, non-cervical (T1-S2/ilium) pedicle spinal fixation 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).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological principle for both the subject and predicated devices is temporary posterior, non-cervical pedicle spinal fixation in order to provide immobilization and stabilization of spinal segments in skeletally mature patients, including spinal fusion and including *posterior, non-cervical (T1-S2/ilium) pedicle spinal fixation*.

Specific features of Comparison:

- The predicate device Lanx System includes longer pedicle screws and *S2/ilium* in their Intended Use statement.
- X-spine proposes the addition of longer pedicle screws and the inclusion of *S2/ilium* in their Intended Use statement.

At a high level, the subject device and the predicate devices (primary and additional) are based on the following same or equivalent technological elements:

- FDA Product Codes: MNI and MNH
- Implants use the same materials: titanium alloy and/or cobalt chrome alloy.
- Multiple lengths of pedicle screws to account for variations in patient anatomy.
- Rods offered in multiple lengths and configurations to account for variations in patient anatomy.
- Equivalent Intended uses.
- Same anatomical region.
- Same surgical approach.
- Mechanical Performance.
- Cross-connectors available in fixed and variable designs.

The addition of one more vertebra, *S2/ilium*, does not pose additional risk, as this same intended use has already been cleared for use in the labeling of the primary predicate device, Lanx Spinal Fixation System [Silverton; Silverton-D] (K122145).

The following minor technological difference of screw sizes exists between the subject and predicate devices. However, the basic range of sizes is equivalent, as shown in the table below.

Table 5-1: Range of Screw Sizes

	X-spine Proposed Longer Screws	Primary Predicate Lanx Pedicle Screws;, Silverton, Silverton-D	Additional Predicate Current X-spine Fortex Pedicle Screws
Diameter of screws	6.5 mm to 8.25 mm	4.5 mm to 8.5 mm	4.75 mm to 8.25 mm
Length of screws	60 mm to 100 mm	25 mm to 100 mm	30 mm to 55 mm

X-spine does not propose adding longer screws for the smaller diameters of 4.75 and 5.5.

VII. PERFORMANCE DATA

The following performance data is provided in support of the substantial equivalence determination.

Biocompatibility

Implants of the X-spine Pedicle Screw System are made of titanium alloy. The titanium alloy conforms to ASTM F136 – *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*. The titanium material has a long history of use as surgical implants and has been proven to be biocompatible, corrosion-resistant, and not toxic to the biologic environment.

X-spine System rods are also available in an alternate material choice, cobalt chrome alloy. The cobalt chrome alloy conforms to ASTM F1537 – *Standard Specification for Wrought Cobalt-28 Chromium-6Molybdenum Alloys for Surgical Implants*. The cobalt chrome alloy material has a long history of use as surgical implants and has been proven to be biocompatible, corrosion-resistant, and not toxic to the biologic environment.

The products are ultrasonically cleaned using a validated cleaning process.

All instrument pieces that contact patient anatomy are manufactured of medical-grade materials, with long history of use in the medical setting and have been proven to be biocompatible: (medical-grade stainless steel, medical-grade Radel® plastic). The tissue contact is in limited-exposure settings.

Mechanical Performance

A review of the proposed changes shows that a lengthening of the screw (extension of the distal portion of the screw shank) has no material change to the proximal aspect of the screw, no change to the screw cup, no change to the set screw, no change to the locking mechanism, and no change to the locking functionality. There is also no change to the manufacture or finishing process of the system components. Engineering evaluation of the proposed additions to the X-Spine Pedicle Screw System shows that the performance of the system is unaffected by the modifications and raises no new concerns of safety or effectiveness.

VIII. CONCLUSION

Based on a review of the information provided, X-spine finds that the X-spine Pedicle Screw System is substantially equivalent to the referenced predicate device systems.