



Food and Drug Administration
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X-spine Systems, Incorporated
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

May 5, 2016

Re: K160428
Trade/Device Name: Certex Spinal Fixation System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: February 29, 2016
Received: March 4, 2016

Dear Mr. Eggleton:

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 Parts 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)

K160428

Device Name

Certex Spinal Fixation System

Indications for Use (Describe)

The intended use of the Certex Spinal Fixation System is to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- Instability or deformity;
- Failed previous fusions (e.g., pseudoarthrosis);
- Tumors involving the cervical/thoracic spine; and
- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The X-spine Certex Spinal Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The X-spine Certex Spinal Fixation System can be linked to X-spine Fortex® Pedicle Screw System and X-spine Xpress™ Minimally Invasive Pedicle Screw System with rod-to-rod connectors and transition rods.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) Summary

Device Trade Name: Certex Spinal Fixation System

Manufacturer: X-spine Systems, Inc.
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Contact: Kriss Anderson
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Date Prepared: April 27, 2016

Classifications: Unclassified

Class: Unclassified

Product Codes: NKG, KWP

Primary Predicate: Aesculap S4 Cervical Occipital Plate Spinal System (K151938)

Additional Predicates: Certex Spinal Fixation System (K133094, K122163)
Aesculap S4 Cervical Occipital Plate Spinal System (K151938)

Indications For Use:

The intended use of the Certex Spinal Fixation System is to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- Instability or deformity;
- Failed previous fusions (e.g., pseudoarthrosis);
- Tumors involving the cervical/thoracic spine; and

- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The X-spine Certex Spinal Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The X-spine Certex Spinal Fixation System can be linked to X-spine Fortex® Pedicle Screw System and X-spine Xpress™ Minimally Invasive Pedicle Screw System with rod-to-rod connectors and transition rods.

Device Description:

The Certex Spinal Fixation System consists of polyaxial screws, hooks, rods, occipital plates, occipital bone screws, cross bar connectors, lateral offset connectors and rod-to-rod connectors. System components can be connected and locked together to promote fusion of the occipito-cervico-thoracic spine (Occiput-T3). System components are offered in various sizes and configurations to accommodate variations in pathology and individual patient anatomy. All Certex Spinal Fixation System components are manufactured from Titanium alloy (Ti6Al4V) in accordance with ASTM F136.

The purpose of this submission is to expand the indications of the Certex Spinal Fixation System to include cervical pedicle screw indications.

Predicate Device:

The subject Certex Spinal Fixation System is substantially equivalent to predicate devices Certex Spinal Fixation System (K133094, K122163), and Aesculap S4 Cervical Occipital Plate Spinal System (K151938)) with respect to indications, design, function, and performance.

Summary of Technological Characteristics:

Certex Spinal Fixation System and the primary predicate, Aesculap S4 Cervical Occipital Plate Spinal System (K151938), are similar in indications for use, design, material, function, and performance. Additional comparisons were made to alternate predicate devices with the same indications for use, design, material, function, and performance.

Performance Testing:

Performance testing and a detailed literature search indicates the Certex Spinal Fixation System is as mechanically sound as predicate devices. Testing included static compression, static torsion, dynamic compression, and dynamic torsion per a modified version of ASTM F1717, ASTM F2706 and sub-assembly testing in ASTM F1798. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Conclusion:

The 510(k) demonstrates substantial equivalence to the predicate devices cited in this summary.