DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 10, 2015

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

Re: K150834
Trade/Device Name: Atrax™ Anterior Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 29, 2015
Received: June 1, 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150834

K150834

Device Name

Atrax™ Anterior Cervical Plating System

Indications for Use *(Describe)*

The Atrax Anterior Cervical Plating System is intended for anterior fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following: Degenerative Disc Disease (as identified by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), Spondylolisthesis, Trauma (i.e., fracture or dislocation), Spinal tumors, Deformity (e.g., kyphosis, lordosis, scoliosis), Pseudarthrosis, and/or Failed previous fusion.

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.

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510(k) Summary

I. Submitter/Manufacturer:

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342

Telephone (937) 847-8400
FAX (937) 847-8410

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

Date Prepared: 03/27/2015

Establishment Registration Number: 3005031160
Owner/Operator Number: 9063903

II. DEVICE NAME

Trade/Proprietary Name:	Atrax™ Anterior Cervical Plating System
Common Name:	Cervical Plating System
Classification Name:	Spinal intervertebral body fixation orthosis
Regulation Number:	21 CFR §888.3060
Device Class:	Class II
Product Code:	KWQ

III. PREDICATE DEVICES

- Primary Predicate: X-spine Systems, Inc. – Spider Cervical Plating System (K052292)
  - This predicate has not been subject to a design related recall.
- Additional Predicate: Medronic Sofamor Danek, Inc. – ZEPHIR Anterior Cervical Plate System (K994239)

IV. DEVICE DESCRIPTION

The Atrax Anterior Cervical Plating System consists of screws and plates offered in various sizes so that adaptations can be made to take into account pathology and individual patient anatomy. The Atrax System allows for anterior fixation of between one and four intervertebral segments between C2 and C7.

The Atrax Anterior Cervical Plating System implants are manufactured from Titanium alloy in accordance with ASTM F136 and will be provided sterile (gamma irradiation). All implants are intended for single use only and should not be reused under any circumstances.

The system includes a series of manual surgical instruments intended to assist the insertion and placement of the implants. The instrumentation will be packaged and sold clean but non-sterile. A steam sterilization cycle is recommended in the Atrax System draft Instructions for Use.

V. INDICATIONS FOR USE

The Atrax Anterior Cervical Plating System is intended for anterior fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following: Degenerative Disc Disease (as identified by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), Spondylolisthesis, Trauma (i.e., fracture or dislocation), Spinal tumors, Deformity (e.g., kyphosis, lordosis, scoliosis), Pseudarthrosis, and/or Failed previous fusion.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Temporary stabilization of the anterior spine during the development of cervical spinal fusion is the technological principle for both the subject and predicate devices. It is based on screw and plate fixation of the anterior spine.

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

- Components manufactured using the same titanium alloy
- Plates contain screw socket designs for variability in screw placement
- Screws contain bone threads to aid in fixation
- Screws offered in multiple lengths to account for variations in patient anatomy
- Plates offered in multiple lengths to account for variations in patient anatomy
- Equivalent Intended uses
- Same anatomical region
- Same surgical approach
- Mechanical Performance

The following technological differences exist between the subject and predicated devices:

- Overall envelope size of the Atrax System plates are slightly larger, however the axial and lordotic curvatures are equivalent.
- Mechanical testing performances were greater in bending, torsional, and fatigue resistance.
- The Atrax implants will be supplied sterile. The predicate devices are supplied non-sterile.

VII. PERFORMANCE DATA

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

Biocompatibility

Implants of the Atrax Anterior Cervical Plating 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. The product is ultrasonically cleaned using a validated cleaning process. ISO 10993-5 cytotoxicity studies will be performed on production.equivalent implants to confirm no cytotoxic residue has been left on the implant following manufacture.

All instrument pieces that will be contacting 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

To demonstrate substantial equivalence based on mechanical performance, X-spine's proposed device, Atrax Anterior Cervical Plating System device, and the predicate device, Medtronic Sofamor Danek's ZEPHIR Anterior Cervical Plate System, were subjected to testing per FDA guidance and recommendations. Mechanical testing was performed on both systems per ASTM F1717-14, *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.* The tests performed were:

- Static Compression Bending
- Static Torsion
- Dynamic Compression Bending

The mechanical testing results indicate that the Atrax Anterior Cervical Plating System is substantially equivalent to the predicate device performance and is capable of safely and effectively performing in accordance with its intended use.

VIII. CONCLUSION

Based on evaluations referenced in this summary, X-spine finds that the Atrax Anterior Cervical Plating System is substantially equivalent to the referenced predicate device systems.