DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 15, 2016

X-spine Systems, Incorporated
Kriss Anderson
Director, Regulatory Affairs
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K160114
Trade/Device Name: Xspan™ Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: January 15, 2016
Received: January 19, 2016

Dear Kriss Anderson:

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" (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 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)*

K160114

Device Name

Xspan™ Laminoplasty Fixation System

Indications for Use *(Describe)*

The Xspan™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Xspan Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent expulsion of the allograft or impingement of the spinal cord.

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.

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510(K) SUMMARY (21 CFR 807.92)

Xspan™ Laminoplasty Fixation System
January 15, 2016

I. SUBMITTER/MANUFACTURER:

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

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

Establishment Registration Number: 3005031160

Official Contact: Mr. Kriss Anderson
Director, Regulatory Affairs
Email: kanderson@X-spine.com
Telephone (937) 847-8400, ext. 137

II. OWNER/OPERATOR:

Xtant Medical Inc.
604 Cruiser Lane
Belgrade, MT 59714

Owner/Operator Number: 10028385

Official Correspondent: Stephen Smith, Vice President
Regulatory Assurance/ Quality Assurance
Xtant Medical, Inc.
Telephone (406) 388-0480

III. DEVICE

Trade/Proprietary Name:	Xspan™ Laminoplasty Fixation System
Device Common Name:	Orthosis, Spine, Plate, Laminoplasty, Metal
Device Class:	Class II
Regulation Number:	21 CFR §888.3050
Product Code:	NQW – Orthosis, Spine, Plate, Laminoplasty, Metal
Review Panel:	Orthopedic

IV. PREDICATE DEVICES

- Aesculap Implant Systems (AIS): AIS Laminoplasty Plating System (K103284; K090354) (Primary Predicate)
    - This predicate has not been subject to a design related recall.
- NuVasive Laminoplasty Fixation System (K091623)
    - This predicate has not been subject to a design related recall.

V. INTENDED USE

The Xspan™ Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Xspan™ Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent expulsion of the allograft or impingement of the spinal cord.

VI. DEVICE DESCRIPTION

The Xspan™ Laminoplasty Fixation System is a posterior implant system comprised of laminoplasty plates, hinge plates, and mounting screws. 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 in accordance with ASTM F136. The single use only implants are provided sterile [gamma radiation] and should not be reused under any circumstances.

The system also includes instrumentation to aid with implantation. The instruments are supplied in a tray which is used for instrument sterilization and storage.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological principle for both the subject and predicate devices is posterior fixation in the lower cervical and upper thoracic spine (C3 to T3), used in laminoplasty procedures. At a high level, the subject device Xspan™ Laminoplasty Fixation System and the predicate devices AIS Laminoplasty Plating System (K103284; K090354) and NuVasive Laminoplasty Fixation System (K091623) are based on the following same or equivalent technological elements:

- FDA Product Code: NQW – Orthosis, Spine, Plate, Laminoplasty, Metal.
- Implants use the same material: Titanium alloy.
- Equivalent intended uses.
- Variety of implant sizes and forms providing a range of options to accommodate variations in patient anatomy.
- Same anatomical region.
- Same surgical approach.
- Equivalent mechanical performance.

The following difference exists between the subject device and the predicate devices:

- Sterility – the Xspan™ implants are provided in sterile, single use packages. The predicate devices are provided non-sterile, and are sterilized by the user.

VIII. PERFORMANCE DATA

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

Biocompatibility Evaluation

The implants of the Xspan™ Laminoplasty Fixation 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 comprehensive history of biocompatibility of the implant materials provides a rationale basis for not specifically performing additional testing for each additional biological effect.

Mechanical Testing

Mechanical testing was performed with reference to ASTM F2193 *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System and* ASTM F382 *Standard Specification and Test Method for Metallic Bone Plates.* Performance data is provided in support of the substantial equivalence determination. The Xspan™ Laminoplasty Fixation System demonstrated equivalent performance to the predicate systems through static and dynamic 4-point bend testing.

IX. CONCLUSION

Based on a review of the information provided, X-spine finds that the Xspan™ Laminoplasty Fixation System is substantially equivalent to the referenced predicate device systems. The Xspan™ Laminoplasty Fixation System was found to have an equivalent safety and effectiveness profile compared to the referenced predicate systems.