DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 22, 2017

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

Re: K170530
Trade/Device Name: Butrex® Lumbar Buttress Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 21, 2017
Received: February 22, 2017

Dear Mr. 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 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,

Mark N. Melkerson -S

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)*

K170530

Device Name

Butrex® Lumbar Buttress Plating System

Indications for Use *(Describe)*

The Butrex® Lumbar Buttress Plating System is intended for anterior intervertebral body screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent intervertebral space. Due to variations in the anatomy, the plate is designed for applications caudal to the bifurcation of the great vessels. Specifically, the device is intended for stabilization and buttressing of bone graft over one motion segment following anterior structural reconstruction for degenerative disc disease (DDD). DDD is defined as follows: back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

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 (21 CFR 807.92)

Butrex® Lumbar Buttress Plating System

February 21, 2017

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. 2137

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:	Butrex® Lumbar Buttress Plating System
Device Common Name:	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number:	21 CFR §888.3060
Product Code:	KWQ – Spinal intervertebral body fixation orthosis
Regulatory Class:	Class II
Review Panel:	Orthopedic

IV. PREDICATE DEVICES

- Primary: X-spine, Inc.: Butrex™ Buttress Plating System (K072943)
- Additional: Synthes Titanium Locking Plate System: (K970048)

V. INDICATIONS FOR USE

The Butrex® Lumbar Buttress Plating System is intended for anterior intervertebral body screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent intervertebral space. Due to variations in the anatomy, the plate is designed for applications caudal to the bifurcation of the great vessels. Specifically, the device is intended for stabilization and buttressing of bone graft over one motion segment following anterior structural reconstruction for degenerative disc disease (DDD). DDD is defined as follows: back pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

VI. DEVICE DESCRIPTION

The Butrex® Lumbar Buttress Plating System consists of a variety of shapes and sizes of bone plates and screws. The Butrex plates contain two sockets for screw placement on one end and a buttressing surface on the other end. The system is intended for anterior screw fixation to the L1 to S1 spine. The components are manufactured from titanium alloy (Ti 6Al 4V ELI). The titanium conforms with ASTM F136, *Standard Specification Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) alloy for Surgical Implant Applications (UNS R56401)*. A separate intervertebral fixation construct, such as posterior pedicle screws, must be used for proper stabilization to be achieved.

The system does not contain software/firmware.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The technological principle for both the Subject and Primary Predicate Device is anterior screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent intervertebral space.

Primary Predicate Device -- Butrex™ Buttress Plating System (K072943):

The subject device, Butrex® Lumbar Buttress Plating System and the primary predicate device, Butrex™ Buttress Plating System (K072943) are based on the following technological elements:

- Same FDA Product Code: KWQ – Spinal intervertebral body fixation orthosis
- Same implant material: Titanium alloy (Ti 6Al 4V ELI) – ASTM F136
- Same Indications for Use.
- Plates: same multiple lengths to account for variations in patient anatomy.
- Screws: same multiple lengths of screws with the exception of several additional sizes being added to the subject device.
- Same anatomical region: L1-S1 spine over one vertebral body extending onto the adjacent intervertebral space.
- Same surgical approach: Anterior

Additional Predicate Device -- Synthes Titanium Locking Plate System, K970048:

An additional predicate device is Synthes Titanium Locking Plate System, K970048. The Synthes Titanium Locking Plate System was the primary predicate device in the original Butrex™ Buttress Plating System, K970048. The Synthes system has the same or similar technological elements that are listed above for the Butrex® Lumbar Buttress Plating System subject device and the Butrex™ primary predicate device. One slight difference: the Synthes system uses CP titanium instead of titanium alloy which is used for the Butrex System.

VIII. Conformance Assessment

In compliance with Design Control requirements and in accordance with the Special 510(k) Guidance, X-spine assessed the impact of the Butrex System device modifications. A review of Risk Analysis/Failure Mode and Effects Analysis was performed, and the Butrex System Inputs and Outputs were reviewed. The conclusion reached during Design Review, is that the design changes did not change the risk profile.

IX. CONCLUSION

The subject device, Butrex® Lumbar Buttress Plating System, has been modified to add several screw sizes to the system. Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject Butrex® Lumbar Buttress Plating System demonstrates substantial equivalence to legally marketed predicate devices.