K072943

510(k) Summary

ADMINISTRATIVE INFORMATION

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

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

Official Contact: David Kirschman, MD
Chief Medical Officer

JAN 28 2002

DEVICE NAME

Classification Names: Spinal Intervertebral Body Fixation Orthosis

Trade/Proprietary Name: Butrex ™ Buttress Plating System

Common Name: Buttress Plating System

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

DEVICE CLASSIFICATION

FDA has classified Spinal Intervertebral Body Fixation Orthoses as Class II devices (21 CFR 888.3060). The product code for spinal intervertebral body fixation Orthosis is KWQ. This device classification is reviewed by the Orthopedic Devices Branch.

INTENDED USE

The intended use of the Butrex Plating system and associated components is substantially equivalent to the intended use of predicate devices. The Butrex Plating System is intended for anterior intravertebral 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.

DEVICE DESCRIPTION

Butrex Plates

Butrex plates are titanium alloy plates containing two sockets for screw placement on one end of the plate and a buttressing surface one the other end. The plate incorporates a locking mechanism to prevent screw back-out. The plates are provided in lengths of 22 mm, 26 mm, and 32 mm.

Butrex Screws

Butrex screws are titanium alloy screw with a self tapping thread design. Screw lengths of 16mm, 18mm and 20mm are available. The screws heads are dimensioned for either fixed or variable placement into the Butrex plate sockets.

Material composition

The components of the Butrex Buttress Plating System are made of titanium alloy conforming to ASTM F136.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Butrex Buttress Plating System is substantially equivalent in indications and design principles to predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2008

X-spine Systems, Inc.
% David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville, Rd.
Miamisburg, OH 45342

Re: K072943
Trade/Device Name: Butrex™ Buttress Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 5, 2007
Received: December 6, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072943

Device Name: Butrex™ Buttress Plating System

Indications for Use:
The Butrex Buttress Plating System is intended for anterior intravertebral 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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072943

(revised 12/2/07)