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

Frontier Medical Devices, Incorporated
Ms. Bethany D. Byman
Director of Regulatory Affairs
512 Fourth Street
Gwinn, Michigan 49841

August 20, 2015

Re: K151346
Trade/Device Name: Frontier Medical Devices Posterior Cable Screw System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: May 15, 2015
Received: May 20, 2015

Dear Ms. Byman:

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,

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)*
K151346

Device Name
Frontier Medical Devices Posterior Cable Screw System

Indications for Use *(Describe)*
The Posterior Cable Screw System is intended to reduce pars defect and to stabilize the spinal operative site during fusion procedures as an adjunct to a rigid posterior fixation system cleared/approved for trauma and spondylolisthesis. The system is indicated for the following:
• Defect of the pars interarticularis
• Spondylolisthesis
The Posterior Cable Screw System is indicated for pedicle screw attachment for these indications between T1 and the sacrum. Cables may be used for interspinous wiring. The grommet may be used with the cable. The system is not intended to be used in conjunction with a stainless steel implant.

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 Pursuant to 21 CFR 807.92

Sponsor:	Frontier Medical Devices, Inc. 512 Fourth Street Gwinn, MI 49841 USA Contact: Bethany Byman Ph: 906-232-1200 Fx: 906-232-1222 Prepared: July 17, 2015
Name:	Posterior Cable Screw System
Trade name:	Frontier Medical Devices Posterior Cable Screw System
Common name:	Pedicle Screw and Spinal Cable System
Classifications:	§888.3010 Cerclage, Fixation, Metallic
Product Codes:	JDQ
Panel/ Branch:	Orthopaedic and Rehabilitation Devices Panel; Panel Code 87
Primary Predicate:	Pioneer Posterior Cable Screw System (K022908)
Reference Predicates:	ParsFix (K003351) Stainless Steel Wire (pre-1976)
Description:	The Posterior Cable Screw System consists of screws, cables, and grommets utilized for the correction of pars defects. A construct consists of two cable screws with locking set screws and a cable connecting the two screws. The screws are inserted into the pedicles and the cable is passed around the spinous process between the two screws. The grommet surrounds the cable at the location of the spinous process. The cable is tensioned and the set screws are tightened and fully locked per the surgical technique. The implants are manufactured from medical grade titanium alloy per ASTM F136 and cobalt chromium alloy per ASTM F90. The implants are provided sterile. The Posterior Cable Screw System utilizes Class I manual instruments to facilitate implantation of the device components.

Intended Use:	The Posterior Cable Screw System is intended to reduce pars defect and to stabilize the spinal operative site during fusion procedures as an adjunct to a rigid posterior fixation system cleared/approved for trauma and spondylolisthesis. The system is indicated for the following: • Defect of the pars interarticularis • Spondylolisthesis The Posterior Cable Screw System is indicated for pedicle screw attachment for these indications between T1 and the sacrum. Cables may be used for interspinous wiring. The grommet may be used with the cable. The system is not intended to be used in conjunction with a stainless steel implant.
Pre-Clinical Performance Data:	Dynamic tests were provided to support that the Posterior Cable Screw System performs in a manner substantially equivalent to that of predicate systems. No new issues of safety or effectiveness were raised.
Technological Characteristics:	The Posterior Cable Screw System and predicate devices are similar in terms of indications for use, material composition, technological characteristics, design characteristics, and mechanical strength. The minor differences in technological characteristics that do exist do not raise any new types of safety or efficacy issues.
Substantial Equivalence:	This submission supports the position that the subject Posterior Cable Screw System is substantially equivalent to previously cleared systems. There are no significant differences between the subject system and the predicates which would adversely affect the use of the product. Any differences were not considered significant based on mechanical bench testing.