



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

Frontier Medical Devices, Inc.
Allison Rogers
Director of Regulatory Affairs
512 Fourth Street
Gwinn, Michigan 49841

January 13, 2016

Re: K153242

Trade/Device Name: Frontier Medical Devices In-Line Orthopedic Cable Cerclage System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: November 6, 2015
Received: November 9, 2015

Dear Ms. Rogers:

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

Indications for Use

510(k) Number (if known)

K153242

Device Name

Frontier Medical Devices In-line Orthopedic Cable Cerclage System

Indications for Use (Describe)

The In-Line Orthopedic Cable Cerclage System is intended for use in general orthopedic trauma surgery involving olecranon, patella, femur (including periprosthetic fractures), pelvic, acetabular, humeral, and ankle fractures, acromioclavicular dislocations, prophylactic banding during total joint procedures, and temporary reduction during open reduction internal fixation (ORIF) procedures.

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: Allison K. Rogers
Ph: 906-232-1200
Fx: 906-232-1222
Prepared: November 4, 2015

Trade name: Frontier Medical Devices In-Line Orthopedic Cable Cerclage System

Common name: Cerclage Cable System

Classification: §888.3010 Bone Fixation Cerclage

Product Code: JDQ

Panel/ Branch: Orthopaedic and Rehabilitation Devices Panel; Panel Code 87

Predicates: Frontier Medical Devices In-Line Orthopedic Cable Cerclage System (K151888)
Zimmer Cable-Ready Cable Grip System (K935481 Pioneer Laboratories' Songer Cable System, K940729 Pioneer Laboratories' Bone Plate with Cerclage Cable, K941213 Pioneer Laboratories' Songer Cable System)

Description: The In-Line Orthopedic Cable Cerclage System consists of a cable and crimp assembly to allow cerclage fixation of various long bone, pelvic and acetabular fractures as well as tension band fixation of the patella, olecranon, ankle and shoulder. The implants are manufactured from medical grade stainless steel per ASTM 138. The implants are provided sterile. Instrumentation has been designed for use with this implant system.

Indications for Use: The In-Line Orthopedic Cable Cerclage System is intended for use in general orthopedic trauma surgery involving olecranon, patella, femur (including periprosthetic fractures), pelvic, acetabular, humeral, and ankle fractures, acromioclavicular dislocations, prophylactic banding during total joint procedures, and temporary reduction during open reduction internal fixation (ORIF) procedures.

Non-Clinical Performance Data: Static and dynamic testing supports that the In-Line Orthopedic Cable Cerclage System performs in a manner substantially equivalent to that of the predicate system; no new issues of safety or effectiveness were raised.

Technological
Characteristics:

The In-Line Orthopedic Cable Cerclage 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 In-Line Orthopedic Cable Cerclage 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.