DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 10, 2017

Akros Medical
Mr. Charles Horrell
CEO and Co-Founder
3503 Pleasant Green Rd
Durham, North Carolina 27705

Re: K162805
Trade/Device Name: Akros FibuLink Syndesmosis Repair Kit
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: December 9, 2016
Received: December 12, 2016

Dear Mr. Horrell:

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

Indications for Use

510(k) Number (if known): K162805

Device Name: Akros FibuLink™ Syndesmosis Repair Kit

Indications for Use:

The Akros FibuLink™ Syndesmosis Repair Kit is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated and as an adjunct to fixation systems involving plates, with fracture braces and casting. Specifically, the Akros FibuLink™ Syndesmosis Repair Kit is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

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)

510(k) Summary

Prepared:	September 30, 2016
Submitter:	Akros Medical 3503 Pleasant Green Rd Durham, NC 27705
Contact:	Charles Horrell Chief Executive Officer and Co-Founder 248.259.5535 chuck@akrosmedical.com
Proprietary Name:	Akros FibuLink™ Syndesmosis Repair Kit
Common Name:	Syndesmosis Repair Kit
Regulation and Class:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories; Class II
Product Code:	87/HTN
Predicate Device:	◆ Arthrex TightRope™ Syndesmosis Device, K043248

Device Description:

The Akros FibuLink™ Syndesmosis Repair Kit is a multiple-anchor orthopedic fixation device system, offered in both a stainless steel and a titanium version. The system is designed as an adjunct in repair of unstable joints, specifically as a means to provide fixation between the tibia and fibula during the healing process following a disruption of the ankle syndesmosis. If a fracture of the fibula is present, the design of the fibula anchor permits placement through any fibula fracture repair plate that can accept a 3.5mm cortical screw conforming to ASTM F543-13. The anchors are provided pre-threaded and pre-loaded on their installation tools in a one-time-use pre-sterilized kit, with the Kirschner wire and drill bit needed for site preparation included.

Intended Use / Indications:

The Akros FibuLink™ Syndesmosis Repair Kit is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated and as an adjunct to fixation systems involving plates, with fracture braces and casting. Specifically, the Akros FibuLink™ Syndesmosis Repair Kit is intended to provide fixation during the healing process

following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Summary of Technologies/Substantial Equivalence:

The FibuLink™ Syndesmosis Repair Kit is substantially equivalent to the predicate device in terms of its intended use and indications, materials, basic design and mechanical performance. Any noted differences do not raise new types of safety and effectiveness questions, nor are there new technological issues.

Non-Clinical Testing:

Simulated use, lateral pull-to-failure, offset load-to-failure, insertion torque, torque-to-failure, fatigue with pull-to-failure, fretting, pitting corrosion, magnetic resonance, cytotoxicity, pyrogenicity and endotoxin testing were conducted. The results of these tests indicate that the performance of the FibuLink™ device is adequate for its intended use. Endotoxin results demonstrated that the FibuLink™ device met the recommended limit of <20 EU/device.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the FibuLink™ Syndesmosis Repair Kit to the predicate device.