December 14, 2017

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

Re: K173550
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: November 15, 2017
Received: November 16, 2017

Dear Charles 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173550

Device Name

Akros FibuLink™ Syndesmosis Repair Kit

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Prepared:	November 15, 2017
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:	• Akros FibuLink™ Syndesmosis Repair Kit, K162805 - primary predicate • Arthrex TightRopeTM 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.

The current submission is for minor design modifications to the components that make up

the tibia and fibula anchors and corresponding changes to some of the tools used to install them.

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 modified FibuLink™ Syndesmosis Repair Kit is substantially equivalent to the original device, cleared in K162805, in terms of its intended use and indications, materials, design and mechanical performance. The proposed modifications do not raise new types of safety and effectiveness questions, nor are there new technological issues.

Non-Clinical Testing:

Lateral pull-to-failure, offset load-to-failure, insertion torque, torque-to-failure, fatigue with pull-to-failure, were conducted. The results of these tests indicate that the performance of the FibuLink™ device is adequate for its intended use.

Clinical Testing:

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