April 6, 2020

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

Re: K200361
Trade/Device Name: Akros Scruture Anchor LisFranc 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: February 10, 2020
Received: February 14, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jesse Muir, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K200361

Device Name

Akros Scruture Anchor LisFranc Repair Kit

Indications for Use *(Describe)*

The Akros Scruture Anchor LisFranc 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 in external fixation systems involving plates, with fracture braces and casting. Specifically, the Akros Scruture Anchor LisFranc Repair Kit is intended to provide fixation during the healing process following Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction).

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:	February 10th, 2020
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 Scruture Anchor LisFranc Repair Kit
Common Name:	Lisfranc 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 Mini TightRope™ (K061925)
Reference Device:	Akros FibuLink™ (K162805)

Device Description:

The Akros Scruture Anchor Lisfranc 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 bones of the midfoot during the healing process following a Lisfranc injury. The design of the implant permits placement through any fracture repair plate that can accept a 4.0mm 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 Scruture Anchor LisFranc 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 in external fixation systems involving plates, with fracture braces and casting. Specifically, the Akros Scruture Anchor LisFranc Repair Kit is intended to provide fixation during the healing process following Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a LisFranc injury (Midfoot Reconstruction).

Summary of Technologies/Substantial Equivalence:

The Akros Scruture Anchor Lisfranc 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:

Lateral pull-to-failure testing was conducted. Data from simulated use, offset load-to-failure, insertion torque, torque-to-failure, fatigue with pull-to-failure, fretting, pitting corrosion, magnetic resonance, cytotoxicity, and pyrogenicity testing were adopted from the reference device (the Akros FibuLink Syndesmosis Repair System) given the similarity of its design and manufacture. The results of these tests indicate that the performance of the Scruture Anchor device is adequate for its intended use.

Bacterial Endotoxin Testing was performed on the reference device, which is considered worst case, using the Limulus Amebocyte Lysate (LAL) test. Results demonstrated that the reference device meets an endotoxin limit of <20 EU/device.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Akros Scruture Anchor Lisfranc Repair Kit to the predicate device.