March 15, 2019

Musculoskeletal Transplant Foundation
Katrina Carroll
Regulatory Affairs Manager
125 May Street
Edison, New Jersey 08837

Re: K181633
Trade/Device Name: MTF Pre-Sutured Tendon
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: February 13, 2019
Received: February 13, 2019

Dear Ms. Carroll:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Laurence D. Coyne -S

For 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)*
K181633

Device Name
MTF Pre-Sutured Tendon

Indications for Use *(Describe)*
The MTF Pre-Sutured Tendon is intended for use as a construct in anterior cruciate ligament and posterior cruciate ligament reconstruction.

The MTF Pre-Sutured Tendon is for single patient use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary

Device Trade Name:	MTF Pre-Sutured Tendon
Manufacturer:	Musculoskeletal Transplant Foundation 125 May Street Edison, NJ 08837
Contact:	Ms. Katrina Carroll Phone: (732) 661-3154 Fax: (732) 661-2189 Katrina_Carroll@mtf.org
Prepared by:	Mr. Dave McGurl Director, Regulatory Affairs Musculoskeletal Clinical Regulatory Advisers, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: 202.552.5797 Fax: 202.552.5798 dmcgurl@mcra.com
Date Prepared:	March 13, 2019
Common Name:	Pre-Sutured Tendon
Classification Name:	Nonabsorable poly(ethylene terephthalate) surgical suture
Classification:	21 CFR § 878.5000
Class:	II
Product Codes:	GAT
Predicate Device:	Allosource ReConnex™ Pre-Sutured Tendon (K170957) Arthex Suture Grafting Kit (K041553)
Reference Device:	Riverpoint Medical HS Fiber™ Polyblend Non-Absorbable (K100006) MTF Fascia™ (K120479)

Indications for Use:
The MTF Pre-Sutured Tendon is intended for use as a construct in anterior cruciate ligament and posterior cruciate ligament reconstruction.

The MTF Pre-Sutured Tendon is for single patient use only.

Device Description:
The MTF Pre-Sutured Tendon is a construct consisting of a single tendon pre-sutured with UHWMPE non-absorbable surgical suture. The device may include a semitendinosus tendon, bilateral anterior and posterior tibialis tendon, or bilateral peroneus longus tendon., The Pre-Sutured Tendon passes USP<71> sterility testing and is provided for a single patient use.

Performance Testing:
The performance of the MTF Pre-Sutured Tendon was characterized through a comparison study to show that the MTF Pre-Sutured Tendon was comparable to the Arthrex suture grafting kit as described in K041553. Visual characteristics and tensile strength of the pre-sutured tendon were evaluated and are equivalent to or better than the tensile strength data for the predicate device cleared under K041553. The suture does not pull out, or fail when subjected to pull testing. The suture knot pull strength is equivalent to or better than USP non-absorbable Surgical Sutures average knot pull strength.

A cadaveric knee study was conducted to assess clinically relevant performance of the graft in combination with its intended fixation methods. The results of the human cadaveric knee study demonstrate that the construct is equivalent to or better than a quadruple bundled construct sutured by a surgeon at the time of surgery. The biomechanical assessment comparing the sutured tendon bundle constructed in the operating room using an allograft tendon, and a pre-sutured tendon constructed by MTF shows no statistical difference either acutely or post-cyclin. It was also demonstrated that the pre-sutured tendon construct can be implanted using traditional clinical methods by an orthopedic surgeon.

The MTF Pre-Sutured Tendon has an endotoxin level of less than 20 EU/device. Every lot of the MTF Pre-Sutured Tendon must pass a validated limulus amebocyte lysate (LAL) USP <85> Tests. The Pre-Sutured Tendon passes USP<71> sterility testing.

Risk Assessment:
MTF has performed a risk assessment in order to compare the risk profile of its Pre-Sutured Tendon to another predicate device that is also a pre-sutured, quadruple-bundled tendon (Allosource's ReConnex, K170957) as well as to a predicate device (Arthrex's Suture Grafting Kit, K041553) which is used to suture a standard allograft tendon into a quadruple-bundled construct in the operating room at the time of surgery. The risk assessment completed provides a sufficient risk/benefit profile to support the equivalence to both Arthrex Suture Grafting Kit and Allosource ReConnex.

Substantial Equivalence:
The MTF Pre-Sutured Tendon is substantially equivalent with respect to materials, indications, function and performance to the Allosource ReConnex™ Pre-Sutured Tendon (K170957) and Arthex Suture Grafting Kit (K041553).

Technological Features and Substantial Equivalence:
The MTF Pre-Sutured Tendon and Allosource ReConnex™ Pre-Sutured Tendon (K170957) have identical indications, they are intended for use as a construct in anterior cruciate ligament and posterior cruciate ligament reconstruction. The Arthex Suture Grafting Kit (K041553) is intended for use in soft tissue approximation and or ligation including, but not limited to anterior cruciate ligament and posterior cruciate ligament reconstruction. Like the subject device, the predicate devices incorporate nonabsorbable UHMWPE sutures and are indicated for single patient use only. The MTF Pre-Sutured Tendon is described for the identical patient population, intended use, and indication as the predicates, Allosource ReConnex™ Pre-Sutured Tendon (K170957) and Arthex Suture Grafting Kit (K041553). Any differences do not raise new questions of safety or effectiveness. In addition, comparison testing demonstrates that the MTF Pre-Sutured Tendon is equivalent in ultimate load strength. Therefore, the MTF Pre-Sutured Tendon is substantially equivalent to the Allosource ReConnex™ Pre-Sutured Tendon (K170957) and Arthex Suture Grafting Kit (K041553).

Prior to donation, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Board of Trustees. Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA. The donor blood samples were tested for: Hepatitis B virus (HBV) surface antigen, HBV core antibody, Hepatitis C virus (HCV) antibody, HIV-1/12 antibody, Syphilis, HIV-1 NAT, HCT NAT, and HBV Nat.

All infectious disease test results passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, consent, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening, including laboratory testing, meet or exceed current standards established by the American Association of Tissue Banks.