AlloSource  
Trevor Wright  
Director, Regulatory Affairs  
6278 S. Troy Circle  
Centennial, Colorado 80111  

Re: K170957  
Trade/Device Name: ReConnex™ 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, 2018  
Received: February 14, 2018  

March 20, 2018

Dear Mr. Wright:

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
Indications for Use

510(k) Number (if known):  K170957

Device Name:  RECONNEX™ PRE-SUTURED TENDON

Indications for Use:

Pre-sutured allograft tendons are intended for use as a construct in anterior cruciate ligament and posterior cruciate ligament reconstruction.

Prescription Use  X  AND/OR  Over-The-Counter Use  
(21 CFR 801 Subpart D)  (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

Submitted by: AlloSource
6278 S. Troy Circle
Centennial, CO 80111 USA
Telephone: 720-873-0213
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Contact Person: Trevor Wright
Date Prepared: March 20, 2018

Proprietary Name: ReConnex™ Pre-Sutured Tendon
Common Name: Pre-Sutured Tendon
Classification Name: Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000) GAT

Predicate Device: Arthrex Suture Grafting Kit
510(k) # K041553

Reference Device: Force Fiber UHMWPE Non-absorbable Surgical Suture
510(k) # K092533

This 510(k) Summary information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Device Description
This device consists of a combination of tendons that have been cleaned and disinfected using a proprietary process. The tendons are pre-sutured and terminally sterilized by low dose electron beam irradiation. The device may include anterior tibialis, posterior tibialis, peroneus longus, semitendinosus and/or gracilis tendons and is pre-sutured with Force Fiber® UHWMPE non-absorbable surgical suture. Through a contractual agreement with Teleflex Medical, AlloSource has the license rights to manufacture pre-sutured tendons using their UHMWPE non-absorbable surgical suture cleared 15-Sept-2009 under pre-market clearance K092533. All products are provided sterile and for single patient use.

Intended Use of Device
Pre-sutured allograft tendons are intended for use as a construct in anterior cruciate ligament and posterior cruciate ligament reconstruction.

Technological Characteristics and Substantial Equivalence
The predicate device that received market clearance under K041553 is a suture kit intended to be incorporated as a component into surgical constructs including allograft tissues used for repair. The components of the proposed ReConnex™ pre-sutured tendon device are equivalent to the device described in K041553 in that tendon allografts are sutured together with UHMWPE sutures to generate a surgical construct for the soft tissue reconstruction described above. Therefore, AlloSource concludes based on the intended use described in K041553 that our ReConnex™ pre-sutured tendon is considered substantially equivalent to the predicate device cleared 10-Dec-2004.

Donors meet eligibility requirements for all relevant communicable diseases via a medical director review of donor medical and social history and all applicable infectious disease screening tests, including human immunodeficiency virus type 1 (HIV-1 and HIV-1 NAT), human immunodeficiency virus type 2 (HIV-2), hepatitis B virus (HBV NAT, HBCAb and HBsAg), hepatitis C virus (HCV and HCV-NAT), and syphilis (Rapid Plasma Reagin or Serologic Test for Syphilis). The tissue recovered from each individual donor is processed as an individual batch in a segregated manner to avoid
cross contamination with other donor tissue. The donor tissue utilized meets the requirements of the American Association of Tissue Banks (AATB) and 21 CFR Parts 820 and 1271.

**Product Performance Testing**
Visual characteristics and tensile strength of the pre-sutured tendons 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 when subjected to pull testing, and the suture knot pull strength is equivalent to or better than USP Non-absorbable Surgical Sutures average knot pull strength.

**Cadaver Feasibility Testing**
A cadaver study was conducted to demonstrate the feasibility of using the ReConnex™ pre-sutured tendon construct for ACL reconstruction, and that the construct is equivalent to, or better than a quadruple bundled construct sutured by the surgeon at the time of the surgery. The results of the human cadaver knee ACL reconstruction show that biomechanically, there is no statistical difference between a sutured tendon bundle constructed in the operating room using allograft tendons, and a pre-sutured tendon constructed by AlloSource. It was also shown that ReConnex™ pre-sutured tendon construct can be implanted using traditional clinical methods by an orthopedic surgeon.

**Literature Review**
A literature review provided significant data regarding the use of individual tendons, and sutured tendon bundles in ACL reconstruction, but provided limited data specific to clinical outcome. The literature supports the combination of any two tendon types, i.e. gracilis, semitendinosus, anterior tibialis, posterior tibialis, or peroneus longus to produce the sutured tendon bundles. The number of strands is limited to a maximum of four strands as is commonly seen in a quadruple bundle. Testing performed and referenced in the literature shows that sutured tendon bundles of any of the tendon types referenced are suitable for ACL reconstruction.

**Bacterial Endotoxin Testing**
Bacterial Endotoxin Testing was conducted in accordance with the following standards:
- USP chapter <85>, Bacterial Endotoxin Test
- USP chapter <161>, Transfusion And Infusion Assemblies And Similar Medical Devices
- ANSI/AAMI ST72:2011, Bacterial endotoxins — Test methods, routine, monitoring, and alternatives to batch testing
- FDA Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers

Each final Reconnex™ Pre-sutured Tendon device is tested using a representative sample which has been shown to be an acceptable and representative test sample for bacterial endotoxin testing. The final construct and its associated sample were tested to ensure they met the BET requirement of 20 EU per Device.

**Conclusion**
The components of the proposed ReConnex™ pre-sutured tendon device, which includes the reference device cleared under K092533, are equivalent to the device covered under K041553 in that tendon allografts are sutured together with UHMWPE sutures. Product safety and performance are adequately supported by the substantial equivalence information and test results.