June 27, 2023

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

Re: K213046
Trade/Device Name: AceConnex Pre-Sutured Fascia
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: May 25, 2023
Received: May 30, 2023

Dear Trevor 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. 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,

Jesse Muir -S

Jesse Muir, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213046

Device Name
AceConnex™ Pre-Sutured Fascia

Indications for Use *(Describe)*
The AceConnex™ Pre-Sutured Fascia is intended for use as a component in soft tissue surgical procedures where constructs including those with allograft tissues are used for reconstruction, replacement, or augmentation of the hip labrum.

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.

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510(k) Summary

Submitted by:	AlloSource 6278 S. Troy Circle Centennial, CO 80111 USA Telephone: 720-873-0213 Facsimile: 720-873-0212
Contact Person:	Trevor Wright
Date Prepared:	June 26, 2023
Proprietary Name:	AceConnex™ Pre-Sutured Fascia
Common Name:	Labrum Replacement and Augmentation Device
Classification Name:	Suture, Non-absorbable, Synthetic, Polyethylene 21 CFR 878.5000 GAT
Predicate Device:	Arthrex Suture Grafting Kit 510(k) # K041553
Reference Devices:	ReConnex™ Pre-Sutured Tendon 510(k) # K170957 Force Fiber® ultra-high molecular weight polyethylene (UHMWPE) non-absorbable surgical suture 510(k) # K063778

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

Device Description

The Labrum Replacement and Augmentation Device, marketed as AceConnex™ Pre-Sutured Fascia subject device is a pre-assembled surgical construct comprised of allograft tissue and non-absorbable, synthetic suture. The allograft fascia lata tissue is terminally cleaned and disinfected using a proprietary process. The fascia lata tissue is pre-sutured with Force Fiber® ultra-high molecular weight polyethylene (UHMWPE) non-absorbable surgical suture cleared under K063778, and the device is terminally sterilized by low dose electron beam irradiation.

The device has a smooth side for articulating against the rotating cartilage surface and a sutured side which is secured against the bone and comes in three sizes to accommodate the needs of surgeons performing segmental (40-60mm and 60-100mm) and full circumferential (100-140mm) augmentations or reconstructions. Each device contains two adjustable sections where the device may be cut to provide adjustment options so that the device may be trimmed to fit the needs of patient and surgeon.

Indications for Use

The AceConnex™ Pre-Sutured Fascia is intended for use as a component in soft tissue surgical procedures where constructs including those with allograft tissues are used for reconstruction, replacement, or augmentation of the hip labrum.

Technological Characteristics and Substantial Equivalence

The AceConnex™ Pre-Sutured Fascia subject device is a pre-assembled surgical construct derived from allograft tissue and non-absorbable synthetic surgical suture.

Donor tissue utilized in the subject AceConnex™ Pre-Sutured Fascia device meets eligibility requirements for Relevant Communicable Disease Agents or Diseases (RCDAD) 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; at no time is tissue from multiple donors pooled. Donor tissue utilized in the AceConnex™ Pre-Sutured Fascia subject device meets the requirements of the American Association of Tissue Banks (AATB) and 21 CFR Parts 820 and 1271.

The predicate device, Arthrex Suture Grafting Kit, is intended for use in soft tissue approximation and or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair. The AceConnex™ Pre-Sutured Fascia is substantially equivalent to this predicate device as the intended uses are the same. The subject device is a pre-assembled surgical construct, with an allograft tissue and suture component, and is intended to be used as a component in soft tissue surgical procedures where constructs are used for reconstruction, replacement, or augmentation of the hip labrum. Both devices contain nonabsorbable, synthetic, non-dyed suture. One difference between our device and this predicate, is that AceConnex Pre-Sutured Fascia is a pre-assembled sutured allograft, where the Arthrex Suture Grafting Kit is a device that is used in the assembly of sutured allografts in the operating room. This minor difference between AceConnex Pre-Sutured Fascia and this predicate device does not raise any questions regarding the safety and effectiveness and testing conducted has shown no apparent issue with the pre-assembly of the allograft in regards to the function and intended use of the device.

Product Performance Testing

Comprehensive product performance testing was conducted on the AceConnex™ Pre-Sutured Fascia subject device to assess visual, physical, mechanical, and clinical properties. The subject device passed all product performance tests: device integrity was maintained during surgical preparation and application, device length was adjustable, the device conformed to the acetabular rim, the device was securable with knotted and knotless suture anchors, had a suture pullout strength greater than the estimated force on the labrum in a healthy hip during jogging, retains the necessary tensile strength after two years frozen storage, and has similar physical properties of surgeon fascia allografts.

Bacterial Endotoxin Testing

Bacterial endotoxin testing was conducted in accordance with the following standards:

- USP chapter <85> *Bacterial Endotoxin Test*
- 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*

Bacterial endotoxin levels for the AceConnex™ Pre-Sutured Fascia subject device were tested using an adequate and acceptable representative endotoxin test sample for the device itself. Bacterial endotoxin levels were less than 20 EU/Device and met bacterial endotoxin testing requirements.

Conclusion

The AceConnex™ Pre-Sutured Fascia subject device and the Arthrex Suture Grafting Kit predicate device have substantially equivalent intended uses, indications for use, technological characteristics, and principles of operation.

The AceConnex™ Pre-Sutured Fascia subject device is a pre-assembled surgical construct, comprised of donated human allograft tissue and non-absorbable, synthetic suture. While not pre-assembled, the

Arthrex Suture Grafting Kit predicate device is a suture kit that contains non-absorbable, synthetic sutures that have been cleared for use, as components, in soft tissue surgeries where constructs, including those with allograft tissues, are used for repair.

Additionally, product performance testing demonstrated that the AceConnex™ Pre-Sutured Fascia subject device performs in accordance with its specifications and is as safe and effective as its predicate, indicating that the minor differences in indications for use, technological features, and materials do not raise questions of safety or effectiveness.

In conclusion, the AceConnex™ Pre-Sutured Fascia subject device is substantially equivalent to the listed predicate device.