June 23, 2023

RTI Surgical, Inc
Ellen Rounds
Director Regulatory Affairs
11621 Research Circle
Alachua, Florida 32615

Re: K230036
Trade/Device Name: 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: May 24, 2023
Received: May 24, 2023

Dear Ellen Rounds:

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)*
K230036

Device Name
Pre-Sutured Tendon

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

The 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."

510(k) Summary K230036

<table>
<tr><td>Date Prepared</td><td>June 22, 2023</td></tr>
<tr><td>Submitter</td><td>RTI Surgical, Inc. 11621 Research Circle
Alachua, FL 32615 USA</td></tr>
<tr><td>Contact Information</td><td>Ellen Rounds
Sr. Regulatory Affairs Specialist
Email: erounds@rtix.com</td></tr>
<tr><td>Name of Device</td><td>Pre-Sutured Tendon</td></tr>
<tr><td>Common Name</td><td>Pre-Sutured Tendon</td></tr>
<tr><td>Classification Name</td><td>Suture, Nonabsorbable, Synthetic, Polyethylene</td></tr>
<tr><td>Regulation Number</td><td>21 CFR 878.5000</td></tr>
<tr><td>Regulatory Class</td><td>Class II</td></tr>
<tr><td>Product Code</td><td>GAT</td></tr>
<tr><td>Panel</td><td>General and Plastic Surgery</td></tr>
<tr><td>Legally Marketed Predicate Device(s)</td><td>K181633 MTF Pre-Sutured Tendon
K170957 Allosource ReConnex Pre-Sutured Tendon</td></tr>
<tr><td>Device Description</td><td>The Pre-Sutured Tendon is a donated human nonbone tendon pre-sutured with sterile Ultra-high-molecular-weight polyethylene (UHMWPE) nonabsorbable sutures. The tendon is processed via the BioCleanse® Tissue Sterilization Process (The BioCleanse Process). The Pre-Sutured Tendon device is offered as a single strand and as a quadruple (quad) strand.
<table>
<tr><th rowspan="2">Implant</th><th colspan="2">Dimensions</th></tr>
<tr><th>Length (mm)</th><th>Folded Diameter (mm)</th></tr>
<tr><td>Single Strand</td><td>180-220</td><td>8.5-12</td></tr>
<tr><td>Quadruple Strand</td><td>50-70</td><td>9.0-13</td></tr>
</table></td></tr>
<tr><td>Indications for Use</td><td>The Pre-Sutured Tendon is intended for use as a construct in anterior cruciate ligament and posterior cruciate ligament reconstruction.

The Pre-Sutured Tendon is for single patient use only.</td></tr>
<tr><td>Comparison of Technological Characteristics with the Predicate Device</td><td>The subject and predicate devices are based on the following same technological characteristics and both function as constructs for anterior cruciate ligament and posterior cruciate ligament reconstruction.

The subject device is composed of donated human nonbone tendon pre-sutured with sterile Ultra-high-molecular-weight polyethylene (UHMWPE) nonabsorbable sutures. The tendon is processed via the BioCleanse® Tissue</td></tr>
</table>

	Sterilization Process (The BioCleanse Process). Donors meet eligibility requirements for all communicable diseases via a medical doctor review of donor medical and social history and all applicable infectious disease screening tests. The donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA. The blood samples are screened for the following: HIV-1 / HIV-2 Antibody, Hepatitis C Virus Antibody, Hepatitis B Surface Antigen, Hepatitis B Core Antibody (Total), Treponema pallidum (Syphilis), Human T-Cell, Lymphotropic Virus I/II Antibody, and HIV-1/HCV/ HBV* NAT-TMA. The donor tissue utilized meets the requirements of the American Association of Tissue Banks (AATB). All infectious disease test results passed acceptability for screening. The Pre-Sutured Tendon has been determined to be suitable for implantation. There are no technological differences between the subject and predicate device. However, there are minor dimensional differences between the subject device and the predicate devices. These differences do not affect the intended use, performance, safety, design or function of the subject device for its intended use in anterior cruciate ligament and posterior cruciate ligament reconstruction.
Performance Data	Visual characteristics and bench testing such as Ultimate Load, Cyclic Displacement, and Suture Pull Out Testing of the Pre-Sutured Tendons were evaluated and are found to meet requirements that are clinically relevant. Non-clinical testing data submitted to demonstrate substantial equivalence includes packaging validation, tissue sterilization and viral inactivation, shelf-life, and biocompatibility. Biocompatibility testing was conducted using methods described in ISO 10993. Bacterial endotoxin testing was also performed and was substantially equivalent to the predicates. A human cadaver study was conducted to demonstrate the feasibility of using the Pre-Sutured Tendon for ACL/PCL reconstruction. The results of this end user validation establish that the Pre-Sutured Tendon implants labeling, packaging, dimensions (form), configuration (single/quadruple strand), and functionality meet user needs and expectations. Additionally, the results establish that the single and quadruple strand Pre-Sutured Tendon constructs met the intended use and therefore are appropriate for ACL and PCL reconstruction. The study also concluded that the subject device, the Pre-Sutured Tendon, constructs can be implanted using traditional clinical methods by an orthopedic surgeon.
Substantial Equivalence	The subject device was demonstrated to be substantially equivalent to the predicate devices cited above with respect to indications for use, aseptic processing, design, size, materials, function, storage, and performance.
Conclusion	The Pre-Sutured Tendon is substantially equivalent to the predicate devices with respect to indications for use, tissue sterilization processes, aseptic packaging, design, function, materials, and performance. Product safety and performance are adequately supported by the substantial equivalence information and test results.