October 22, 2025

RTI Surgical, Inc.
Ellen Rounds
Senior Regulatory Affairs Specialist
11621 Research Circle
Alachua, Florida 32615

Re: K253145
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: September 25, 2025
Received: September 25, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253145

Please provide the device trade name(s).

Pre-Sutured Tendon

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared:	October 22nd, 2025
Submitter:	RTI Surgical, Inc. 11621 Research Circle Alachua, FL 32615 USA
Contact Information:	Ellen Rounds Senior Regulatory Affairs Specialist Email: erounds@rtix.com
Name of Device:	Pre-Sutured Tendon
Common Name:	Pre-Sutured Tendon (PST)
Classification Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Regulation Number:	21 CFR 878.5000
Regulatory Class:	Class II
Product Code:	GAT
Panel:	Orthopedic
Legally Marketed Predicate Device(s):	K230036 - Pre-Sutured Tendon
Device Description:	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.
Indications for Use:	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.
Comparison of Technological Characteristics with the Predicate Device:	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, and gracilis tendon has been added as a source tendon for the subject device. 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:	Bench tests, which included ultimate load, cyclic displacement, and suture pull out confirmed that the Pre-Sutured Tendon with expanded ranges of length and diameter and the Gracilis source tendon meets the same requirements as the predicate device. Therefore, the predicate demonstrates substantial equivalence and meets the functional requirements set for the PST device. There is no change to the non-clinical testing data submitted in the original submission K230036 to demonstrate substantial equivalence including packaging validation, tissue sterilization and viral inactivation, shelf-life, and

Implant	Dimensions	
	Length (mm)	Diameter (mm)
Single Strand	180-300	8-12 (folded)
Quadruple Strand	50-85	8-13

	biocompatibility. Bacterial endotoxin testing was also completed and results demonstrated that the subject device is substantially equivalent to the predicate.
Substantial Equivalence:	The subject device was demonstrated to be substantially equivalent to the predicate device 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 device 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 of information and test results.