August 20, 2025

SofTac Medical Technologies
Rickey Hart
CEO and Founder
111 Washington St.
Suite 204
Plainville, Massachusetts 02762

Re: K251229
Trade/Device Name: EndoFix™Tissue Fixation System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE, PKL, OCW
Dated: April 21, 2025
Received: July 16, 2025

Dear Rickey Hart:

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,

ANTHONY LEE -S

Anthony C. Lee, Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
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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.	K251229

Please provide the device trade name(s).

EndoFix™Tissue Fixation System

Please provide your Indications for Use below.

The EndoFix™ Tissue Fixation System is an endoscopic tissue approximation system intended for anchoring the gallbladder to the stomach or duodenum to aid placement of a luminal apposing metal stent (LAMS) for EUS-guided gallbladder drainage.

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

Submission Type: Traditional 510(k)

Submitter Information:

SofTac Medical Technologies Inc.
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Contact Person:

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Date Prepared:

June 12, 2025

Subject Device Identification:

Device Trade Name:	EndoFix™ Tissue Fixation System
Common Name:	Endoscopic Tissue Approximation Device
Classification Name:	Biliary Catheter and Accessories
Regulation Number:	21 CFR 876.5010
Product Codes:	FGE, PKL, and OCW
Regulatory Class:	Class II
Classification Panel:	Gastroenterology and Urology

Predicate Devices:

	Primary Predicate Device	Secondary Predicate Device
Device Trade Name:	Entuit Secure Gastrointestinal Suture Anchor Set, Entuit Secure Adjustable Gastrointestinal Suture Anchor Set	X-Tack Endoscopic HeliX Tacking System
Manufacturer:	Cook Incorporated	Apollo Endosurgery, Austin TX (currently Boston Scientific Corp.)
510(k) Number:	K152524	K201808
Product Code	FGE- Biliary catheter and accessories	PKL- Hemorrhoidal ligator OCW- Endoscope and accessories
Classification/ Regulation:	Class II per 21 CFR 876.5010	Class II per 21CFR 876.4400
Classification Panel:	Gastroenterology/Urology	Gastroenterology/Urology

Device Description

The EndoFix™ Tissue Fixation System (TFS) is an endoscopic (through the scope) tissue approximation device consisting of two main components:

1. EndoFix Tissue Fixation Device – Enables the approximation of soft tissue in the gastrointestinal (GI) tract using a suture-based implant delivered through an 18 gauge echogenic needle.
2. Secure Suture Locking Device – Secures the implant assembly with an implant grade suture lock and cuts the suture once approximation is complete.

The EndoFix TFS is designed to place an implant for endoscopic tissue approximation to anchor the gallbladder to the stomach or duodenum to aid placement of a luminal metal apposing stent (LAMS). During use, the EndoFix Tissue Fixation Device is advanced through a ≥3.2 mm working channel of a commercially available echoendoscope (EUS). Under ultrasound guidance, the EndoFix TFS needle is advanced through the target tissues and the implant subassembly is deployed to approximate the luminal tissues (either transgastric or transduodenal based on clinical requirements). With applied suture tension, a Suture Lock is deployed to secure the tissues using the Secure Suture Locking Device. The implant subassembly and Suture Lock are considered permanent implants. Each of the respective delivery systems used to deliver the implant assembly/Suture Lock are short term contact devices.

Indications for Use:

The EndoFix™ Tissue Fixation System is an endoscopic tissue approximation system intended for anchoring the gallbladder to the stomach or duodenum to aid placement of a luminal apposing metal stent (LAMS) for EUS-guided gallbladder drainage.

Comparison of Technological Characteristics to the Predicate Device and Basis of Substantial Equivalence

To demonstrate substantial equivalence of the EndoFix TFS to a commercially marketed device, two predicate devices are identified as follows:

- **Primary Predicate: Entuit® Secure Gastrointestinal Suture Anchor Set (Cook Inc., K152524**) – a cleared device for anchoring the stomach to the abdominal wall. This predicate is highly relevant because it shares the same intended use as the EndoFix TFS, namely the fixation of GI tissue using an anchored suture and suture lock device. The Entuit device is specifically indicated for anchoring the anterior stomach wall to the abdominal wall prior to interventional procedures. It demonstrates an established principle of using an implantable suture anchor to achieve tissue fixation in GI procedures, which is fundamentally what the EndoFix TFS also accomplishes. The Entuit predicate provides a benchmark for the proposed device's overall function (securing GI tissues with a suture-anchor type mechanism), target anatomy (gastrointestinal tract), and clinical role (maintaining apposition of tissue layers during an interventional procedure).
- **Secondary Predicate: X-Tack™ Endoscopic HeliX Tacking System (Apollo Endosurgery, K201808**) – a cleared endoscopic device for tissue approximation inside the GI lumen. This predicate is selected to support technological characteristics that differ from the primary predicate, particularly the EndoFix TFS's through-the-scope endoscopic delivery method. The X-Tack predicate is relevant because the EndoFix TFS likewise is deployed endoluminally (via endoscope) and

employs an implantable tissue tack with tethered suture and Cinch device (similar to the EndoFix TFS Suture Lock) to secure the construct to achieve tissue approximation. In particular the design and deployment of the X-Tack Endoscopic HeliX Tacking System suture "Cinch" is similar to that of the EndoFix Suture Lock device. In areas where the EndoFix TFS deviates from the Entuit predicate (for example, using a through-the-endoscope delivery instead of a percutaneous kit to approximate tissues), the X-Tack's design and clinical use illustrate that those features are already well-established in a legally marketed device.

Using these two predicates in combination is consistent with FDA's 510(k) guidance on multiple predicates. The Entuit anchor set provides the primary comparison for intended use and overall principle of operation, while the X-Tack system serves as an additional predicate to address differences in technological features (endoscopic delivery and internal tissue approximation). This approach ensures that each new or modified aspect of the EndoFix TFS is substantiated by a predicate device, and none of the differences introduce new questions of safety or effectiveness.

A summary table comparing the EndoFix TFS with the predicate Entuit and X-Tack devices is provided below**.** This table details the closely shared indications for use, materials, and design and principle of operation between the subject device and the selected predicates; therefore, establishing substantial equivalence of the subject device with the predicate products. The comparison chart provides a description of both similarities and differences between the devices.

Table 6-1. Comparison of Technological Characteristics Between the EndoFix Tissue Fixation System and Primary and Secondary Predicate Tissue Fixation Devices

Technological Characteristic	EndoFix TFS (K251229)	Primary Predicate Entuit Secure GI Suture Anchor (K152524)	Secondary Predicate X- Tack (K201808)
Regulation Number	21 CFR 876.5010	21 CFR 876.5010	21 CFR 876.4400
Product Code	FGE/PKL/OCW	FGE	PKL/OCW
Common Name	Endoscopic tissue approximation device	Suture Anchor Set	Endoscopic tissue approximation device
Regulation Medical Specialty	Gastroenterology/Urology	Gastroenterology/Urology	Gastroenterology/Urology
Intended Use	For approximation of soft tissue (apposing structures) in a minimally invasive gastroenterology procedure to facilitate placement of an interventional device.	For approximation of apposing structures to facilitate placement of an interventional device.	For approximation of soft tissue in minimally invasive gastroenterology procedures for closure of defects.
Indication For Use	The EndoFix Tissue Fixation System is an endoscopic tissue approximation system intended for anchoring the gallbladder to the stomach or duodenum to aid placement of a luminal apposing metal stent (LAMS) for EUS-guided gallbladder drainage.	The Entuit Secure Gastrointestinal Suture Anchor Set is intended for anchoring the anterior wall of the stomach to the abdominal wall prior to introduction of interventional catheters.	The X-Tack™ Endoscopic HeliX Tacking System is intended for approximation of soft tissue in minimally invasive gastroenterology procedures (e.g. closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks). X-tack is not intended for hemostasis of acute bleeding ulcers.

Method of Use	Endoscopic through the scope	Percutaneous	Endoscopic through the scope
Description	Includes 2 components: (1) the EndoFix Tissue Fixation Device that enables the user to approximate the soft tissue in the GI tract using a suture-based Implant; and (2) the EndoFix Suture Locking Device designed to secure and cut the suture once tissue approximation is complete.	Includes 2 components: (1) Introducer Needles with preloaded suture with T-shaped stainless-steel anchor and a wire guide; and (2) suture lock designed to secure the suture once tissue approximation is complete.	Includes 2 components: (1) the X-Tack Endoscopic HeliX tacking System that enables the user to approximate soft tissue in the GI tract using metal helix tacks and a 3-0 suture; and (2) The OverStitch Suture Cinch component designed to secure and cut the suture once tissue approximation is complete.
Principle of Operation	• Device is inserted into an endoscope and positioned at target site. • The handle is pushed forward to drive the needle forwards to penetrate target tissue. • The implant assembly is deployed through the needle at the target site. The suture knot serves as an anchor for the implant to prevent implant pull-through the tissue. • The needle is removed. • A separate component (the Suture Lock Fixation Device) is used to deliver the Suture Lock implant. • With the tissues under tension, the Suture Lock facilitates final suture tension for tissue approximation, locks the construct, and cuts excess suture. • Implanted construct approximates the soft tissue using a suture implant assembly and polymer Suture Lock (no metallic materials). The integrity of tissue approximation is only required until the LAMS is deployed.	• With forward pressure the introducer needle is used to pierce the abdominal wall into the stomach. • The wire guide is used to push the T-shaped anchor with tethered suture into the insufflated stomach. The T- shaped anchor prevents implant pull-through the tissue. • The needle is removed. • With wire guide still in position, tension is applied to the suture to pull the anterior wall to approximate the stomach to the abdominal wall. • With tissue under tension, the suture lock is placed over the suture and slid to the desired position. Excess suture is cut manually. • Implanted construct approximates the soft tissue using a tensioned metallic anchor with tethered suture and external polymer lock. The integrity of tissue approximation is only required until the interventional device is deployed.	• Device is inserted into an endoscope and positioned at target site. • With forward pressure on the delivery catheter the Helix X-Tack is pushed forward to penetrate target tissue. • Helix tacks are deployed independently at the target tissue. The Delivery Catheter is removed. • A separate component (the Cinch delivery system) is used to deliver the Suture Cinch implant. • With the tissues under tension, the Suture Cinch facilitates final suture tension for tissue approximation, locks the construct, and cuts excess suture. • Implanted construct approximates the soft tissue using a metallic tack, suture tension and polymer/metallic suture cinch. The integrity of tissue approximation is required until the defect has healed.

Technological Characteristic		**EndoFix TFS (K251229)**	**Primary Predicate Entuit Secure GI Suture Anchor (K152524)**	**Secondary Predicate X- Tack (K201808)**
Physician control over placement and final locking		Yes	Yes	Yes
Number of Implants		One or two implants may be used to anchor gallbladder to stomach/duodenum.	One implant used to anchor stomach to abdominal wall.	Multiple implants may be used to close a defect.
Compatible Scopes		Echoendoscopes with a working channel of 3.2mm or larger.	Not applicable	Endoscopes with a working channel of 2.8 mm or larger
Endoscopic Working Length		Gastroscope up to 140 cm	Not applicable	Gastroscope up to 155 cm
Needle Penetration Depth		Adjustable up to 10 cm	Needle length is 12 cms	5mm (Tack Penetration)
Needle gauge (in.)		18 g	17 g	Not Applicable
Suture Implant and Suture Lock				
Suture Implant, Anchor or Tack Dimensions	▪ Implant OD x Length	4 segments each 0.75 mm x 12.5 mm	1 mm x 22 mm	2.4 mm x 6 mm
Suture Lock/Cinch Anchor Dimensions	▪ Suture Lock/Cinch diameter and length	2.4 mm (diameter) x 8 mm long	11 mm x 20 mm	2.4 mm (diameter) x 8 mm long
Full System				
Implanted Material		• Suture Loop Implant: Polyester and polypropylene. • Suture Lock: VESTAKEEP i4 (PEEK)	• Anchor: Stainless Steel • Suture: Braided suture (type unknown)	• Helix Tack: 316L Stainless Steel • Suture: Polypropylene • Cinch: VESTAKEEP i4 (PEEK) • Cinch Anchor: Stainless Steel
Single Use		Yes	Yes	Yes
Biocompatibility		Tested per ISO 19993	Tested per ISO 19993.	Tested per ISO 19993.
MRI Compatibility		Yes: No metallic component	MR Conditional	MR Conditional
Sterilization		Provided sterile. Terminally sterilized to SAL 10-6 using a validated EO method	Provided sterile. Terminally sterilized to SAL 10-6 using a validated EO method	Provided sterile. Terminally sterilized to SAL 10-6 using a validated EO method

The EndoFix TFS, Entuit Secure, and X-Tack HeliX systems share a similar intended use and the same fundamental technological characteristics in that all three devices achieve gastrointestinal tissue fixation or approximation using suture-based implants delivered via a catheter and/or needle-based delivery system. Each system deploys an implant fixed to a tethered nonabsorbable suture, which is then tensioned and secured using a locking or cinching mechanism to maintain tissue apposition. The core principles utilized with the EndoFIX TFS for implant deployment, suture-mediated tissue approximation, and tissue fixation as demonstrated via the device comparison demonstrate that the EndoFix TFS is substantially equivalent to the predicate devices.

Although the indications for use statements differ, there is no difference in intended use. The intended use of the EndoFix TFS (endoscopic GI tissue fixation/apposition) is essentially the *combination* of the predicates' uses – it covers internal tissue

approximation (like X-Tack) and stomach anchoring for intervention (like Entuit) under the broader umbrella of GI tissue apposition.

Performance Data

Performance testing of the final, sterilized EndoFix TFS included bench testing and a preclinical animal study to verify specifications and performance fundamental to the device's design. Testing included the following all with acceptable results:

- Performance Testing
  - Visual Inspection of Components
  - Dimensional Verification of Components
  - Endoscope compatibility
  - Functionality Testing (ability to approximate/suture tissue)
  - Destructive Testing (Product Integrity, i.e., Tensile of joints and ability to withstand minimum forces)
- Packaging Verification (following environmental conditioning and transportation simulation)
- Biocompatibility testing for both limited and permanent patient contacting components conducted in accordance with the FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process*
- Usability Evaluation
- Sterilization Validation

Additionally, a survival animal study was conducted in a porcine model to evaluate the safety and performance of the EndoFix TFS when used to approximate luminal structures prior to deployment of a luminal apposing metal stent (LAMS), as compared to LAMS deployment without tissue fixation. The findings of the study support that the device is safe and appropriately designed as a pre-stenting tissue fixation device for EUS-guided gallbladder drainage.

Sterility

The EndoFix TFS is sterilized via a validated ethylene oxide (EO) process to a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization process was validated per ISO 11135 *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation, and routine control of a sterilization process for medical devices.* EO residuals were within accepted limits.

Clinical Performance Data

No clinical studies were deemed necessary to demonstrate the substantial equivalence of the subject device.

Conclusion

SofTac Medical has demonstrated that the EndoFix TFS is substantially equivalent to the predicate Entuit Secure GI Suture Anchor Set and the X-Tack Endoscopic HeliX Tacking System.