April 17, 2025

Envision Endoscopy
Azadeh Khanicheh, Ph.D.
Co-Founder and President
204 Second Ave, 2nd Floor
Waltham, Massachusetts 02451

Re: K243750
Trade/Device Name: SimpleStitch Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCW
Dated: March 18, 2025
Received: March 18, 2025

Dear Azadeh Khanicheh:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243750

Device Name
SimpleStitch Suturing System

Indications for Use *(Describe)*
The SimpleStitch Suturing System is intended for endoscopic placement of suture(s) and approximation of soft tissue (e.g., closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks).

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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510(k) Summary

Submission Type: Traditional 510(k)

Submitter Information:

Envision Endoscopy
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Contact Person:

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Date Prepared:

December 5, 2024

Subject Device Information:

Proprietary Name:	SimpleStitch™ Suturing System
Common Name:	Endoscopic Tissue Approximation Device
Classification Name:	Endoscope and Accessories
Regulation:	21 CFR 876.1500
Product Codes:	OCW
Device Classification:	Class II
Classification Panel:	Gastroenterology and Urology

Predicate Devices:

Proprietary Name:	OverStitch™ Endoscopic Suturing System
Manufacturer:	Apollo Endosurgery
510(k) Number:	K171886
Common Name:	Endoscopic Tissue Approximation Device
Classification Name:	Endoscope and Accessories
Regulation:	21 CFR 876.1500
Product Codes:	OCW and HCF
Device Classification:	Class II

Device Description

The SimpleStitch Suturing System ("SimpleStitch SS") is a sterile, single patient-use device that enables endoscopic placement of sutures and approximation of soft tissue within the gastrointestinal tract using a flexible endoscope. The system includes the following components: SimpleStitch Suture Device, SimpleStitch Suture Cartridge, and SimpleStitch Suture Cinch. The SimpleStitch SS is designed for compatibility with single-channel endoscopes (gastroscopes and colonoscopes) with a minimum working channel inner diameter of 2.8mm. During use, the suturing device/suture cartridge is mounted to the endoscope's exterior; the cinching device goes through the endoscope's working channel. The SimpleStitch SS is available with a USP 2-0 and USP 0 nonabsorbable polyester suture. Tissue is secured using a cinch anchor once tissue approximation is complete.

Indications for Use:

The SimpleStitch SS is intended for endoscopic placement of suture(s) and approximation of soft tissue (e.g., closure and healing of ESD/EMR sites and closing of fistula, perforation, or leaks).

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

The SimpleStitch SS has the following similarities with the predicate OverStitch Endoscopic Suturing System ("OverStitch ESS").

- Regulated under 21 CFR § 876.1500 (Product Code OCW)
- Same intended use and similar indications for use
- Similar components, operating principle, and fundamental technology
- Similar basic design and materials
- Similar performance characteristics with the predicate OverStitch ESS. Both the subject and predicate device are compatible with a single-channel endoscope (i.e., Overstitch SX ESS) with a 2.8 mm working channel.
- Sterilized using a similar process (Ethylene Oxide sterilization).

A summary table comparing the SimpleStitch SS with the predicate OverStitch ESS is provided below**.** This table details the closely shared indications for use, materials, technological characteristics, design, and the principle of operation, establishing substantial equivalence of the subject device with the predicate OverStitch ESS. The comparison chart describes both similarities and differences between the SimpleStitch SS and the predicate OverStitch ESS.

Comparison of Technological Characteristics: SimpleStitch SS and Predicate OverStitch ESS			
Product Characteristics		**SimpleStitch™ Suturing System (This 510(k))**	**OverStitch™ Endoscopic Suturing System (K171886)**
Intended Use		Intended for endoscopic placement of suture(s) and approximation of soft tissue in the gastrointestinal tract.	Same
Indication For Use		Intended for endoscopic placement of suture(s) and approximation of soft tissue (e.g., closure and healing of ESD/EMR sites and closing of fistula, perforation, or leaks).	Intended for endoscopic placement of suture(s) and approximation of soft tissue.
Principle of Operation		▪ Device is mounted onto endoscope and deployed at target site. ▪ Tissue is approximated with suture (interrupted or running stitches). ▪ Cinch applied through working channel of scope. ▪ Implanted construct is closed with knotless fixation device and suture tension.	Same
Device Length		▪ 120cm; 175cm	▪ 117cm (SX); 130 cm (ESS)
Compatible Scopes		▪ Single channel endoscopes that are 9 – 10 mm in diameter and up to 110cm in working length. ▪ Single channel endoscopes that are 12 mm in diameter and up to 170cm in working length.	Single-channel (SX) or dual-channel Olympus endoscope • GIF-2TH180 • GIF-2T160
Needle Configuration/Driving Arm Motion		Circular / Circular – enables placement of full-thickness sutures	Straight/Curved enables placement of full-thickness sutures
Anchors and Sutures			
Suture Dimensions	▪ Suture length ▪ Suture sizes	185 cm USP 2-0 and 0	185 cm USP 2-0 and 3 0
Suture Materials	▪ Suture	Non-absorbable braided Polyester	Non-absorbable monofilament polypropylene (synthetic linear

Comparison of Technological Characteristics: SimpleStitch SS and Predicate OverStitch ESS			
Product Characteristics		**SimpleStitch™ Suturing System (This 510(k))**	**OverStitch™ Endoscopic Suturing System (K171886)**
	▪ Anchors	PEEK Stainless Steel	polyolefin) or long-term absorbable monofilament polydioxanone PEEK Cobalt-Chromium MP35 Stainless Steel
Suture Cinch Dimensions	Device: ▪ Length ▪ OD Deployed Cinch: ▪ Length ▪ OD	 160 cm; 230 cm 2.4mm (distal end) 7.6 mm 2.4 mm	 152cm 2.4mm (distal end) 8 mm 2.4 mm
Cinch/Suture UnLock Force Specification		2.4 lb	2.4 lb
Single-Use		Yes	Yes
Biocompatibility		Tested per ISO 19993	Tested per ISO 19993.
MRI Compatibility		MR Conditional with 1.5 and 3 T MR scanners with spatial field gradient of 2500 Gauss/cm (extrapolated or less) and SAR of 2.0 W/kg for 15 minutes of continuous scanning.	MR Conditional with 1.5 and 3 T MR scanners with spatial field gradient of 2500 Gauss/cm (extrapolated or less) and SAR of 2.0 W/kg for 15 minutes of continuous scanning.
Sterilization		Terminally sterilized to SAL 10^{-6} using a validated EO method	Terminally sterilized to SAL 10^{-6} using a validated EO method
Shelf-Life Claim		3 years	3 years

As noted above, the SimpleStitch Suturing System and Predicate OverStitch Endoscopic Suturing System share numerous technological and operational characteristics and similar indications for use statements. Both devices are sterile-single-use patient-only endoscopic tissue approximation systems designed to be used with compatible flexible gastroscopes and colonoscopes. Though the needle type and driving arm motion differ, both devices are designed to allow for placement of full-thickness sutures. The devices demonstrated equivalent performance in bench testing and within a controlled animal study that specifically evaluated the closure and healing of defects over one month, as assessed through direct visualization and histological analysis.

Although the indications for use statements differ, there is no difference in intended use. The patient populations are identical between the subject and predicate devices, and the

inclusion of the specific defects identified in the SimpleStitch SS indications for use statement does not alter the target tissue type or imply diagnosis or therapy of a specific disease. Further, there is a substantial body of evidence to demonstrate that the use of the SimpleStitch SS for closure of the specific defects cited in the indications for use falls within accepted parameters for the general use of the device, as defined by the clinical community evidenced via review of medical publications.

Performance Data

Performance testing of the final, sterilized SimpleStitch SS 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
    - Dimensional verification of components
    - Functionality testing (anchor retention, suture tensile strength, endoscope compatibility)
    - Destructive testing (product integrity, i.e., joints' tensile and ability to withstand minimum forces)
    - Side-by-side bench test of key device features compared with predicate OverStitch ESS
    - Usability testing to ensure design output meets user needs
    - Packaging verification (following environmental conditioning and transportation simulation) and Shelf-Life Testing
- 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*
- MRI safety testing
- Animal (swine) survival study to evaluate closure and healing success of mucosal defects using the SimpleStitch SS compared with the predicate OverStitch Endoscopic Suturing System.

Sterility

The SimpleStitch SS 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.

Shelf Life

The SimpleStitch SS has a shelf life of 3 years. Shelf life studies have demonstrated that the device maintains its performance, and the packaging will maintain its sterile barrier over the entire shelf life.

Clinical Performance Data

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

Conclusion

Envision Endoscopy has demonstrated that the SimpleStitch SS is as safe and effective as the legally marketed predicate OverStitch ESS and does not raise any additional questions of safety and effectiveness than the predicate device. Therefore, the SimpleStitch SS is substantially equivalent to the predicate OverStitch ESS.