December 20, 2024

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

Re: K242923
Trade/Device Name: SimpleSnip Endoscopic Suture Cutter (SC500160); SimpleSnip Endoscopic Suture Cutter (SC500230)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCZ
Dated: September 24, 2024
Received: September 24, 2024

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,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242923

Device Name

SimpleSnip Endoscopic Suture Cutter (SC500160)
SimpleSnip Endoscopic Suture Cutter (SC500230)

Indications for Use *(Describe)*

The SimpleSnip Suture Cutter is intended to cut sutures during all flexible endoscopic procedures.

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:

September 20, 2024

Subject Device Information:

Proprietary Name:	SimpleSnip Endoscopic Suture Cutter (SC500160); SimpleSnip Endoscopic Suture Cutter (SC500230)
Common Name:	Endoscopic Grasping/Cutting Instrument, Non-powered
Classification Name:	Endoscope and Accessories
Regulation:	21 CFR 876.1500
Product Code: Device	OCZ
Classification:	Class II
Classification Panel:	Gastroenterology and Urology

Predicate Devices:

Proprietary Name:	Ensizor Endoscopic Scissors
Manufacturer:	Slater Endoscopy LLC
510(k) Number:	K150939
Common Name:	Endoscopic Grasping/Cutting Instrument, Non-powered
Classification Name:	Endoscope and Accessories
Regulation:	21 CFR 876.1500
Product Code:	OCZ
Device Classification:	Class II

Device Description

The SimpleSnip Endoscopic Suture Cutter is sterile, single patient-use device intended to cut sutures during flexible endoscopic procedures. The cutting device goes through the working channel of the endoscope and is compatible with flexible endoscopes with a minimum channel diameter of 2.8mm. The device is available in two working lengths: 160cm working length for gastroscopes and 230 cm working length for colonoscopes. The device consists principally of a proximal handle assembly, a catheter with core wire, and a blade to cut the suture. Once the SimpleSnip device is inserted in the working channel of the endoscope, the blade is advanced from the catheter, the suture is captured within the blade such that when the blade is pulled back toward the catheter the suture is cut. The blade is rotatable to allow easy suture capturing and cutting.

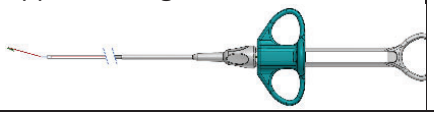
Indications for Use:

The SimpleSnip Suture Cutter is intended to cut sutures during all flexible endoscopic procedures.

Comparison of Technological Characteristics to the Predicate Device:

The SimpleSnip Suture Cutter is substantially equivalent in intended use, principles of operation and fundamental technological characteristics to the legally marketed predicate device. The table below summarizes the similarities and differences in design, materials, and dimensions between the subject and predicate device.

Substantial Equivalence Comparison Chart of the SimpleSnip Suture Cutter to the Ensizor Endoscopic Scissors

Product Characteristics	SimpleSnip Suture Cutter	Ensizor Endoscopic Scissors (K150939)
Regulation Number	21 CFR Part 876.1500	21 CFR Part 876.1500
Product Code	OCZ	OCZ
Intended Use	The EnVision Endoscopic Suture Cutter is intended to cut sutures during all flexible endoscopic procedures.	Slater Endoscopy Ensizor Endoscopic Scissors are designed to cut and dissect tissue and sutures during all flexible endoscopic
Product Configuration	Proximal actuation handle, flexible catheter (shaft), pull wire terminating with a single blunt-tipped cutting blade. 	Proximal actuation handle, flexible shaft terminating in a pair of blunt-tipped cutting scissors. 

Substantial Equivalence Comparison Chart of the SimpleSnip Suture Cutter to the Ensizor Endoscopic Scissors

Product Characteristics		SimpleSnip Suture Cutter	Ensizor Endoscopic Scissors (K150939)
Dimensions	▪ Device length ▪ Shaft Diameter ▪ Blade Length	▪ 160 cm or 230 cm working lengths ▪ 2.5 mm ▪ 5.0 mm	▪ 165 cm or 235 cm working lengths ▪ 2.6 mm ▪ 10 mm
Compatible Scopes		Flexible colonoscopes or endoscopes with ≥2.8mm working channel	Flexible colonoscopes or endoscopes with ≥2.8mm working channel
Principal of Operation		Cutter device is inserted into the working channel of the endoscope while the blade is inside the catheter shaft, the blade is advanced from the catheter by advancing the handle slide forward, the suture is captured by the "J-hook" shaped blade. The blade cuts the suture when the blade is pulled back toward the catheter by moving the handle slide backward.	The device is advanced through the working channel of an endoscope to the target area. Scissors function just like standard scissors for mechanical cutting. By operating the handle, the scissors are opened and closed to cut the suture.
Electrocautery Capability		No	No
Packaging configuration		Single Unit Packaged in a Tyvek/ LDPE-Nylon Pouch and 10 each placed in a shelf-box	Single unit packaged in a Tyvek/Clear film Pouch and placed in a shelf-box shipped in single or by 3.
Disposable, Single Patient Use		Yes	Yes
Sterilization		Terminally sterilized to SAL 10^{-6} using a validated EO method	Terminally sterilized to SAL 10-6 using a validated EO method

As noted above, the SimpleSnip Suture Cutter and predicate Ensizor Endoscopic Scissors share numerous technological and operational characteristics and share similar indications for use statements. Both devices are sterile-single-use patient-only suture-cutting devices designed to be used with compatible flexible gastroscopes and colonoscopes. Both the SimpleSnip and predicate Ensizor devices are referred to as

"through the scope" devices as they are designed to be used through the working channel of the endoscopes. Further, both devices are actuated to cut sutures using a proximal sliding handle.

Key differences between the devices are as follows:

- Indications for Use Statement: The SimpleSnip device is for suture cutting only, whereas the predicate Ensizor can be used to dissect and cut tissues in addition to cutting sutures. As the indications for use for the SimpleSnip is a subset of the Ensizor, this difference does not negatively impact a determination of substantial equivalence – both devices are intended for the same patient population, i.e., patients undergoing flexible endoscopic procedures.
- Configuration of Cutting Blades: The SimpleSnip device has a single-cutting blade, whereas the Enzisor uses a double-blade scissor configuration. Bench testing has established that the SimpleSnip device performs as well as the predicate.
- The working lengths of the gastroscope and colonoscope versions of the SimpleSnip device are 5 cm shorter than that of the Ensizor device. Through performance testing, both the SimpleSnip and predicate Ensizor devices were found to be compatible with standard flexible endoscopes. The shorter working length of the SimpleSnip Suture Cutter does not adversely affect product performance.

Performance Data

Performance testing of the final, sterilized SimpleSnip Suture Cutter included bench testing and functional testing to verify specifications fundamental to the design of the device. Testing included the following:

- Visual Inspection of Components
- Dimensional Verification of Components
- Functionality Testing (ability to cut test sutures at least 20 times, endoscope compatibility)
- Destructive Testing (Product Integrity, i.e., Tensile of joints and ability to withstand minimum forces)
- Packaging Verification (following environmental conditioning and transportation simulation) and Shelf-Life Testing
- Sterilization Validation

Furthermore, comparative testing with the Ensizor Endoscopic Scissors as it relates to the ability to rotate cutting blades in a tortuous path, actuation testing (ability to cut various suture types/sizes and force to cut sutures), and bending stiffness established that the

SimpleSnip Suture Cutter performed as well or better than the Ensizor Endoscopic Scissors.

Biocompatibility Testing

A biocompatibility evaluation was 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,"* consistent with a device with exposure to breached or compromised tissue for a limited duration (≤24 hours). The following biocompatibility tests were successfully completed on the final sterilized SimpleSnip Suture Cutter with passing results.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous toxicity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

Sterility

The SimpleSnip Suture Cutter 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 SimpleSnip Suture cutter has a shelf life of 1 year. Shelf life studies have been conducted to demonstrate that the device maintains its performance and the packaging will maintain its sterile barrier over the entirety of the intended shelf life.

Clinical Performance Data

No clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

Conclusion

Envision Endoscopy has demonstrated that the SimpleSnip Suture Cutter is substantially equivalent in intended use/ indication for use, fundamental design, function, operating principle, and fundamental technology to the legally marketed predicate device, i.e., the Ensizor Endoscopic Scissors, which was cleared under 510(k) Premarket Notification K150939 on June 8, 2015.