April 18, 2025

STERIS Corporation
Gregory Land
Manager, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K250842
Trade/Device Name: PADLOCK CLIP EFTR Kit (00713229)
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL, FDI, KNS, OCZ
Dated: March 20, 2025
Received: March 20, 2025

Dear Gregory Land:

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
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)*

K250842

Device Name

PADLOCK CLIP EFTR Kit (00713229)

Indications for Use *(Describe)*

The PADLOCK CLIP™ EFTR Device is an electrosurgical device that is designed for a flexible endoscope. It is intended for diagnostic tissue acquisition and full-thickness resection through the removal of lesions
in the colon and rectum.

The PADLOCK CLIP™ EFTR Device is indicated for the resection of lesions less than 3cm in the colon and rectum. Resection sizes may be less than 3cm due to targeted tissue thickness and degree of fibrosis.

The disposable RAPTOR Grasping Device is intended to be used to grasp tissue and/or retrieve foreign bodies, excised tissue and stents during endoscopic procedures.

The TOUCHSOFT Coagulator is used to provide monopolar therapeutic hemostasis and tissue ablation in the gastrointestinal tract through a flexible endoscope by a trained physician or clinician.

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.

STERIS Special 510(k) PREMARKET NOTIFICATION
Modification to the PADLOCK CLIP EFTR Kit

1. Device Name

Trade Name:	PADLOCK CLIP EFTR Kit
Device Class:	Class II
Common/usual Name:	Endoscopic Full-Thickness Resection Device
Classification Name:	Hemorrhoidal Ligator
Classification Number:	21 CFR 876.4400
Product Code:	PKL
Associated Product Codes:	FDI, KNS, and OCZ

2. Predicate Device

K240274 PADLOCK CLIP EFTR Kit

Table 1. Device Comparison Table for proposed and Predicate devices

Features	PADLOCK CLIP EFTR Device K240274 (Predicate Device)	PADLOCK CLIP EFTR Device (Proposed Device)	Comparison
Indications for Use	The PADLOCK CLIP EFTR Device is an electrosurgical device that is designed for flexible endoscopy. It is intended for diagnostic tissue acquisition and full-thickness resection through the removal of lesions in the colon and rectum. The PADLOCK CLIP EFTR Device is indicated for the resection of lesions less than 3 cm in the colon and rectum. Resection sizes may be less than 3 cm due to targeted tissue thickness and degree of fibrosis.	The PADLOCK CLIP EFTR Device is an electrosurgical device that is designed for flexible endoscopy. It is intended for diagnostic tissue acquisition and full-thickness resection through the removal of lesions in the colon and rectum. The PADLOCK CLIP EFTR Device is indicated for the resection of lesions less than 3 cm in the colon and rectum. Resection sizes may be less than 3 cm due to targeted tissue thickness and degree of fibrosis.	Same

Features	PADLOCK CLIP EFTR Device K240274 (Predicate Device)	PADLOCK CLIP EFTR Device (Proposed Device)	Comparison
Construction	A -Molded handle (components consisting of:) 1. Thumb ring 2. Handle shaft 3. Spool B -Connector C-Handle stay D-Linking wires E -Clip actuator F -Clip housing assembly G -Clip H -Snare I -Drive Cable N/A -Safety cap	A -Molded handle (components consisting of:) 1. Thumb ring 2. Handle shaft 3. Spool B -Connector C-Handle stay D-Linking wires E -Clip actuator F -Clip housing assembly G -Clip H -Snare I -Drive Cable N/A -Safety cap	Same
Sterile/ Non-sterile	Sterile	Sterile	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterilization Assurance Level	10-6	10-6	Same
Usage	Single-Use	Single-Use	Same
Materials (by component)	-Molded handle (components consisting of:) Thumb ring – ABS & Colorant Handle shaft- ABS & Colorant Spool – ABS & Colorant -Connector – ABS & Colorant, Stainless steel -Handle stay – ABS & Colorant -Linking wires – HDPE, PTFE & Stainless steel -Clip actuator – Stainless steel & PTFE Sandvik Glidefilm coating -Clip housing assembly – Polycarbonate & TPE -Clip – Super Elastic Nitinol -Snare – Stainless Steel -Safety cap – ABS & Colorant	-Molded handle (components consisting of:) Thumb ring – ABS & Colorant Handle shaft- ABS & Colorant Spool – ABS & Colorant -Connector – ABS & Colorant, Stainless steel -Handle stay – ABS & Colorant -Linking wires – HDPE, PTFE & Stainless steel -Clip actuator – Stainless steel & PTFE Sandvik Glidefilm coating -Clip housing assembly – Polycarbonate & TPE -Clip – Super Elastic Nitinol -Snare – Stainless Steel -Safety cap – ABS & Colorant	Same
Target Population	Adult patients requiring diagnostic tissue acquisition	Adult patients requiring diagnostic tissue acquisition	Same

	and full-thickness resection through the removal of lesions in the colon and rectum.	and full-thickness resection through the removal of lesions in the colon and rectum.	
Energy Used/Delivered	Monopolar High Frequency	Monopolar High Frequency	Same
Device Specs:	Overall Length: 230cm Cap outer diameter: 20mm Cap inner diameter: 13.3mm Cap depth: 23mm	Overall Length: 230cm Cap outer diameter: 20mm Cap inner diameter: 13.3mm Cap depth: 23mm	Same
Compatible Endoscopes	Suitable for endoscopes with a distal tip O.D. of 10.9mm - 12.5mm	Suitable for endoscopes with a distal tip O.D. of 10.9mm - 12.5mm	Same
MRI safety status	MR Conditional	MR Conditional	Same
Number of Devices/Box	1	1	Same

The proposed device has the same intended use as the predicate with the same technological characteristics. Based on the testing, which can be viewed in summary format in this submission, the change to the labeling does not impact safety and effectiveness of the proposed device.

3. Description of Device

The PADLOCK CLIP Endoscopic Full Thickness Resection (EFTR) Device is an electrosurgical, single use tissue resection system. The system is part of a kit that consists of a preloaded, radiopaque, Super Elastic NiTi (Nitinol) single use clip within a mechanical delivery system along with a preloaded snare for tissue resection. The PADLOCK CLIP EFTR Device is mounted over the distal tip of a flexible endoscope. The linking cables run along the outside of the endoscope and are attached to the handle. The PADLOCK CLIP EFTR Device includes a tissue chamber that resides on the distal tip of the endoscope.

The kit's two additional devices, the TOUCHSOFT Coagulator Monopolar Single Use Device, and RAPTOR Grasping Device are used in conjunction with the PADLOCK CLIP EFTR Device through the flexible endoscope's accessory channel. The TOUCHSOFT Coagulator Monopolar Single Use Device (ablation device) will be used to mark a lesion by ablating the lesion's perimeter, thereby indicating the area for resection. Instructions for Use for the TOUCHSOFT Coagulator Monopolar Single Use Device are included within the kit. The RAPTOR Grasping Device will be used to grasp and retract the target lesion into the tissue chamber. Instructions for Use for the RAPTOR are included within the kit.

These devices are used for colorectal lesions that would otherwise not be resectable by standard polypectomy techniques.

The PADLOCK CLIP EFTR Device includes a resection clip made of super elastic nitinol and a snare made of stainless steel. The PADLOCK CLIP EFTR Device also includes handle components molded from ABS material, Stainless Steel drive wires, HDPE catheter, and a scope attachment assembly made of TPE and Polycarbonate.

4. Intended Use/Indications for Use

The PADLOCK CLIP EFTR Device is an electrosurgical device that is designed for a flexible endoscope. It is intended for diagnostic tissue acquisition and full-thickness resection through the removal of lesions in the colon and rectum.

The PADLOCK CLIP EFTR Device is indicated for the resection of lesions less than 3cm in the colon and rectum. Resection sizes may be less than 3cm due to targeted tissue thickness and degree of fibrosis.

The disposable RAPTOR Grasping Device is intended to be used to grasp tissue and/or retrieve foreign bodies, excised tissue and stents during endoscopic procedures.

The TOUCHSOFT Coagulator is used to provide monopolar therapeutic hemostasis and tissue ablation in the gastrointestinal tract through a flexible endoscope by a trained physician or clinician.

5. Summary of Verification Testing

The proposed and predicate devices are the same device with an updated Instructions for Use. Verification testing was performed to show that following the updated Instructions for Use does not raise any new questions or concerns of safety and/or effectiveness as compared to the predicate device.

Testing	Acceptance Criteria	Result
Verification Testing	Clip deploys, and the snare closes on the simulated tissue	Pass.

6. Conclusion

Based on the non-clinical verification testing results, and updated risk analysis, the subject device is as safe and effective and performs at least as well as the legally cleared predicate device K240274, Class II (21 CFR 876.4400), product code PKL and associated codes FDI, KNS, and OCZ.