September 17, 2024

STERIS Corporation
Jackie Oliver
Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K240274
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: August 16, 2024
Received: August 16, 2024

Dear Jackie Oliver:

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,
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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)*

K240274

Device Name

PADLOCK CLIP EFTR Kit (00713229)

Indications for Use *(Describe)*

The PADLOCK CLIP™ EFTR Device is a 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.

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STERIS®

510(k) Summary
For the
PADLOCK CLIP EFTR Kit

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Summary Date: August 16, 2024

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION PADLOCK CLIP EFTR Kit

1. Device Identification

Trade Name:	PADLOCK CLIP EFTR Kit (00713229)
Device Class:	Class II
Common/usual Name:	Endoscopic Full-Thickness Resection Device
Regulation Name:	Hemorrhoidal Ligator
Regulation Number:	21 CFR 876.4400
Product Code:	PKL
Associated Product Codes:	FDI, KNS, and OCZ

2. Predicate Device

K170867 FTRD System

Table 1. Device Comparison Table for proposed and Predicate devices

Features	FTRD System K170867 (Predicate Device)	PADLOCK CLIP EFTR Device (Proposed Device)	Comparison
Intended Use	Instrument designed for flexible endoscopy. Instrument is designed for diagnostic tissue acquisition and full-thickness resection through the removal of suitable lesions in the colon and rectum. The FTRD System is indicated for the resection of lesions < 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.	Identical

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
PADLOCK CLIP EFTR Kit

Features	FTRD System K170867 (Predicate Device)	PADLOCK CLIP EFTR Device (Proposed Device)	Comparison
Construction	A -Molded Handle (components consisting of:) 1. Thumb Ring 2. Handle Shaft 3. Sliding Handle B -Connector C -Safety lock D -Endoscope sleeve & Linking wire E -Hand Wheel F -System/Applicator Cap G -Clip H -Snare I -Thread N/A-Thread Retriever	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	Similar: Though the parts of these 2 devices have different naming conventions they are very similar devices, any differences not mentioned here from the table to the left are purely differences in naming convention. This has no impact on safety, effectiveness or how the device is used. The proposed device uses 3 Linking wires and the predicate device uses one Linking wire and an endoscope sleeve. These components perform the same function of connecting the handle of the device to the distal cap. There is no impact on safety, effectiveness, or how the device is used. The proposed device uses stainless steel drive cables and the predicate device uses thread.; to actuate the clip. There is no impact on safety, effectiveness, or how the device is used because both components perform the same function. The proposed device does not require a thread retriever because threads are not used to deploy the device There is no impact to the safety and effectiveness of the proposed device. The proposed device has a safety cap that protects the user from inadvertent deployment and injury. The

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
PADLOCK CLIP EFTR Kit

			predicate device does not have this safety feature.
Sterile/ Non-sterile	Sterile	Sterile	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Sterilization Assurance Level	Not disclosed	10-6	Subject device conforms with EO sterilization requirements of ISO 11135
Usage	Single-Use	Single-Use	Identical
Materials (by component)	-Clip – Super Elastic Nitinol -Snare – Stainless Steel	-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	Similar Both devices have a nitinol clip, and both devices have stainless steel snares. The materials for other components of the predicate device have not been disclosed.
Target Population	Patients who require full thickness resection of lesions in the rectum and colon.	Adult patients requiring diagnostic tissue acquisition and full-thickness resection through the removal of lesions in the colon and rectum.	Identical
Energy Used/Delivered	Monopolar High Frequency	Monopolar High Frequency	Identical
Device Specs:	Overall Length: 220cm Cap outer diameter: 20mm Cap inner diameter: 13mm Cap depth: 23mm	Overall Length: 230cm Cap outer diameter: 21mm Cap inner diameter: 13.3mm Cap depth: 23mm	Similar: The differences in size are negligible
Compatible Endoscopes	Suitable for endoscopes with a diameter of 11.5 - 13.2 mm	Suitable for endoscopes with a distal tip O.D. of 10.9mm - 12.5mm,	Similar: The size of the compatible scopes does not affect the safety and effectiveness of the device as it performs its intended use.
MRI safety status	MR Conditional	MR Conditional	Identical
Number of Devices/Box	1	1	Identical

The proposed devices have the same intended use as the predicate with the same technological characteristics. Based on the testing in this submission, the minor physical differences do not impact safety, effectiveness, or how the devices are used.

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. Indications for Use

The PADLOCK CLIP™ EFTR Device is a 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 have the same intended use and similar technological characteristics. The minor design differences do not raise different questions of safety and effectiveness as compared to the predicate device. Non-clinical testing consisted of the following:

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
PADLOCK CLIP EFTR Kit

Category	Testing	Acceptance Criteria	Results
Simulated Use	Endoscope Detachment Force	Meets Design Requirements	Pass
	Transparent Housing Verification	Meets Design Requirements	Pass
	Clip and Snare Deployment	Meets Design Requirements	Pass
	Over the Scope Attachment Verification	Meets Design Requirements	Pass
	Safety Cap Verification	Meets Design Requirements	Pass
	Handle Stay Visual Verification	Meets Design Requirements	Pass
	Safety Cap Visual Verification	Meets Design Requirements	Pass
	Snare Proximal to Clip Visual Verification	Meets Design Requirements	Pass
Packaging Requirements	Peel Seal Strength Verification	Meets Design Requirements	Pass
Component Force and Functional Requirements	Clip Deployment Force	Meets Design Requirements	Pass
	MAX Handle Snare Retraction Force	Meets Design Requirements	Pass
	Snare Continuity Test	Meets Design Requirements	Pass
	Pusher Compression Force	Meets Design Requirements	Pass
	Spool Compression Force	Meets Design Requirements	Pass
	Clip Pusher OD Measurement	Meets Design Requirements	Pass
	Device Working Length Measurement	Meets Design Requirements	Pass
	Tissue Chamber Depth Measurement	Meets Design Requirements	Pass
	Tissue Chamber Distal ID Measurement	Meets Design Requirements	Pass
	Active Cord Detachment Force	Meets Design Requirements	Pass
	Catheter (110302) to Housing Force	Meets Design Requirements	Pass
	Catheter (110052) to Housing Force	Meets Design Requirements	Pass
	Catheter (110303) to Pusher Force	Meets Design Requirements	Pass
	Drive Cable to Snare Loop Force	Meets Design Requirements	Pass
	Tissue Retention Force	Meets Design Requirements	Pass
	Clip Closure Force	Meets Design Requirements	Pass
	Actuator to Catheter (110302) Force	Meets Design Requirements	Pass
	Actuator to Catheter (110052) Force	Meets Design Requirements	Pass
	Drive Cable to Connector Force	Meets Design Requirements	Pass
	Scope Attachment to Housing Force	Meets Design Requirements	Pass
	Legibility of Markings	Meets Design Requirements	Pass

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
PADLOCK CLIP EFTR Kit

6. Summary of Validation Testing

Category	Testing	Acceptance Criteria	Result
Validation Testing	Clip Deployment and Snare Resection Validation	Meets Design Requirements	Pass
	Straight and Articulated Endoscope Position Use Validation	Meets Design Requirements	Pass
	Visualization in the Lower GI Tract Validation	Meets Design Requirements	Pass
	Endoscope Compatibility Validation	Meets Design Requirements	Pass
	Safety Feature for Deployment of Clip Validation	Meets Design Requirements	Pass

7. Summary of Animal Test – Design Validation

Testing	Acceptance Criteria	Result
The PADLOCK CLIP™ EFTR Device Clip must facilitate healing after the removal of lesions up to 3cm in the GI tract.	Meets Design Requirements	Pass

8. Summary of additional testing

Testing	Acceptance Criteria	Result
MRI Testing	Meets the Requirements of ASTM F2052-21, ASTM F2182-19, ASTM F2119-2013 (17)	Pass
Electrical testing	Meets the Requirements of IEC 60601-1:2005 Ed.3 + A1; A2, IEC 60601-2-2:2017 Ed.6 and, IEC 60601-2-18:2009 Ed.3	Pass
Biocompatibility	Meets the requirements of ISO 10993-5:2009 Ed.3, 10993-12:2021 Ed.5, 10993-11:2017 Ed.3 & 10993-23:2021 Ed.1, 10993-1:2018, 10993-6 Ed. 3, 10993-18:2020	Pass
Human Factors	Meet Predetermined Critical Tasks	Pass
EMC Testing	Meets the Requirements of 60601-1-2:2014+A1:2020 and 60601-4-2:2016 Meets the Requirements of EMC clauses 201.17/202 of ANSI AAMI IEC 60601-2-2:2017 Meets the Requirements of EMC clauses of 201.17/202 of IEC 60601-2-18 Ed. 3 2009-08	Pass

9. Conclusion

Based on the intended uses, technological characteristics, non-clinical performance data, and additional testing, the subject device is as safe, as effective, and performs at least as well as the legally marketed predicate device K170867, Class II (21 CFR 876.4400), product code PKL and associated codes FDI, KNS, and OCZ**.**