October 7, 2021

Steris Corporation
Carroll Martin
Regulatory Affairs Director
5976 Heisley Road
Mentor, OH 44060

Re: K212860
Trade/Device Name: SmartBand EMR Kit (SB-EMR-K, SB-EMR-K-12, SB-EMR-K-9.4), SmartBand EMR Pack (SB-EMR-P, SB-EMR-P-12, SB-EMR-P-9.4), SmartSnare EMR Hexagonal Snare (SS-230-1 or packaged with kit)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: FDI
Dated: September 7, 2021
Received: September 8, 2021

Dear Carroll Martin:

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 (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 located 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, 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212860

Device Name
SmartBand® EMR Kit (SB-EMR-K, SB-EMR-K-12, SB-EMR-K-9.4)
SmartBand® EMR Pack (SB-EMR-P, SB-EMR-P-12, SB-EMR-P-9.4)
SmartSnare™ EMR Hexagonal Snare (SS-230-1 or packaged with Kit)

Indications for Use *(Describe)*
The SmartBand® EMR Device is intended for endoscopic mucosal resection in the upper GI tract.

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

SmartBand EMR Kit (SB-EMR-K, SB-EMR-K-12, SB-EMR-K-9.4)

SmartBand EMR Pack (SB-EMR-P, SB-EMR-P-12, SB-EMR-P-9.4)

SmartSnare EMR Hexagonal Snare (SS-230-1 or packaged with Kit)

STERIS Corporation
5976 Heisley Road
Mentor, OH 44060

Contact: Carroll Martin
Regulatory Affairs Director
Tel: 440-358-6259
Email: Carroll_Martin@steris.com

Submission Date: September 7, 2021

1. Device Name

Trade Name:	SmartBand EMR Kit (SB-EMR-K, SB-EMR-K-12, SB-EMR-K-9.4) SmartBand EMR Pack (SB-EMR-P, SB-EMR-P-12, SB-EMR-P-9.4) SmartSnare EMR Hexagonal Snare (SS-230-1 or packaged with Kit)
Device Class:	Class II
Regulation Name:	Endoscopic Electrosurgical Unit and Accessories
Common/usual Name:	Ligation Device
Regulation Number:	21 CFR 876.4300
Product Code:	FDI
Review Panel:	Gastroenterology/Urology

2. Predicate Device

SmartBand EMR Kit (SB-EMR-K, SB-EMR-K-12)

SmartBand EMR Pack (SB-EMR-P, SB-EMR-P-12)

SmartSnare EMR Hexagonal Snare (SS-230-1 or packaged with Kit)

All cleared under K190512

3. Device Description

The SmartBand EMR Device is an endoscopic mucosal resection device that is provided as a kit or a pack that is designed for ligation assisted endoscopic mucosal resection (EMR) in the upper gastrointestinal (GI) tract. The SmartBand EMR Kit consists of the SmartBand Ligator Kit, supplied non-sterile and the SmartSnare EMR Hexagonal Snare, supplied sterile. The ligator kit contains a ligation handle, loading device, connector tube and a cylindrical barrel with 5 bands separated by a deployment cord. The SmartBand EMR Pack consists of a cylindrical barrel with 5 bands separated by a deployment cord. The SmartBand EMR Pack can be used when more bands are needed to complete a procedure. The SmartBand EMR Hexagonal Snare consists of a handle, finger slide and a hexagonal snare loop on the distal end.

4. Indications for Use

The SmartBand® EMR Device is intended for endoscopic mucosal resection in the upper GI tract.

5. Technological Characteristics Comparison Table

A comparison of technical characteristics between the proposed and predicate devices is summarized in **Table 1**.

Table 1. Technological Characteristics Comparison Table

Features	SmartBand EMR Device Predicate Device K190512	Modified Device	Comparison
Intended Use	The SmartBand® EMR Device is intended for endoscopic mucosal resection in the upper GI tract.	The SmartBand® EMR Device is intended for endoscopic mucosal resection in the upper GI tract.	Same
Device Components	Ligation Device 5 non-latex bands (4 green and 1 blue) Trigger cord Loading Device Flush Tube Deployment Handle Pentax Adaptor	Ligation Device 5 non-latex bands (4 green and 1 black) Trigger cord Loading Device Flush Tube Deployment Handle Pentax Adaptor Universal Connector Band Lock	Similar. The color change of one band and the addition of the Universal Connector and Band Lock do not affect the intended use or fundamental technology of the device.
	Snare Stainless steel snare loop Shaft Finger Slide Snare Handle Body	Snare Stainless steel snare loop Shaft Finger Rings Snare Handle Body	Same
Materials of Construction	Snare Snare loop – stainless steel (patient contacting) Sheath – Teflon (patient contacting) Core Wire – Nitinol (patient contacting) Stainless steel (snare loop) Strain relief – polyurethane (non-patient contacting) Finger slide – ABS (non-patient contacting) Snare handle body – ABS (non-patient contacting	Snare Snare loop – stainless steel (patient contacting) Sheath – Teflon (patient contacting) Core Wire – Nitinol (patient contacting) Stainless steel (snare loop) Strain relief – polyurethane (non-patient contacting) Finger slide – ABS (non-patient contacting) Snare handle body – ABS (non-patient contacting	Similar. The materials of the Universal Connector and Band Lock do not affect the intended use or fundamental technology of the device.
	Ligation Device Bands - Non-latex synthetic polyisoprene (patient contacting) Barrel - Polycarbonate (patient contacting) Trigger cord - Liquid crystal polymer (patient contacting) Loading device - Stainless steel (non-patient contacting) Flush tube - ABS (non-patient contacting) Handle – ABS (non-patient contacting)	Ligation Device Bands - Non-latex synthetic polyisoprene (patient contacting) Barrel - Polycarbonate (patient contacting) Trigger cord - Liquid crystal polymer (patient contacting) Loading device - Stainless steel (non-patient contacting) Flush tube - ABS (non-patient contacting) Handle – ABS (non-patient contacting) Universal Connector – Silicone (non-patient contacting) Band Lock – Polyurethane (non-patient contacting)	

Features	SmartBand EMR Device Predicate Device K190512	Modified Device	Comparison
# of bands/color	5 non-latex bands (4 green and 1 blue)	5 non-latex bands (4 green and 1 black)	Similar. This change aids the user in determining when they are getting close to using all of the bands, as the black band is the second to last band in line on the barrel. The change in color does not affect the intended use or fundamental technology of the device.
Barrel Dimensions	Inside diameter: 10.75mm and 12.0mm Depth: 7.75mm	Inside diameter 9.4mm, 10.75mm, and12.0mm Depth 7.75mm (10.75mm and 12.0mm sizes) Depth 9.5mm (9.4mm size)	Similar. This change gives the user more options based on the size of the treatment area.
Sterile/Non-sterile	Sterile (snare) and Non-sterile (ligation device)	Sterile (snare) and Non-sterile (ligation device)	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterilization Assurance Level	10^{-6}	10^{-6}	Same
Usage	Single used; snare is used with diathermic energy	Single used; snare is used with diathermic energy	Same
Target Population	Patients undergoing an endoscopic mucosal resection procedure	Patients undergoing an endoscopic mucosal resection procedure	Same
Energy Used/Delivered	Diathermic energy (snare)	Diathermic energy (snare)	Same
Method of Application	Manual	Manual	Same

Features	SmartBand EMR Device Predicate Device K190512	Modified Device	Comparison
Packaging Change	No band lock	Band lock present to secure the bands during shipping	Different. The band lock prevents the bands from dislodging from the barrel during shipping. The additional box is a convenience for the user. These changes have no effect on how the device is used or its fundamental technology.
	No stand-alone box for the snare	Addition of stand-alone box for snare	
Compatible endoscopes	Pentax, Fujinon and Olympus	Pentax, Fujinon and Olympus	Same
Compatible electrical surgical generators	ERBE VIO 300-D	ERBE VIO 300-D US Endoscopy gi4000 Electrosurgical Generator	Similar. The function of the electrical snare of the proposed device remains the same in that it is attached to the electrical surgical generator to allow the flow of electrical energy to the snare loop for the purpose of resecting tissue. The use of the modified device with the US Endoscopy gi4000 Electrosurgical Generator does not change the intended use or fundamental technology of the modified device.
Addition of universal connector	Not present.	Present	Different. The universal connector allows the user to attach the ligation device handle directly to the accessory ports of endoscopes that do not have a luer connection on the accessory port. This change has no effect on how the device is used or its fundamental technology.
Expiration Dating	12 months	24 months	Different. The extended shelf life of the proposed device provides the user greater flexibility related to device use. It has no effect on how the device is used or its fundamental technology.

6. Summary of Non-Clinical Performance Testing

Verification testing consisting of measurements, visual inspection, ship testing and packaging testing.

Biocompatibility testing in accordance with ISO 10993-4, -5, -10 and -11 and USP38-NF33.

Simulated use testing.

7. Conclusion

The minor changes that are the subject of this submission have no impact on the fundamental scientific technology of the device or how it is used. STERIS has determined that the modified device is as safe and effective as the legally marketed predicate device.