March 11, 2022

STERIS Corporation
Carroll Martin
Regulatory Affairs Director
5960 Heisley Road
Mentor, OH 44060

Re: K220395
Trade/Device Name: Endogator Endoscopy Irrigation Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FEQ
Dated: February 11, 2022
Received: February 11, 2022

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, FDA may publish further announcements concerning your device in the Federal Register.

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,

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)*
K220395

Device Name
EndoGator Endoscopy Irrigation Tubing

Indications for Use *(Describe)*
The EndoGator Endoscopy Irrigation Tubing (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).

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 ENDOGATOR Endoscopy Irrigation Tubing

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

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

Submission Date: February 11, 2022

1. Device Name

Trade Name:	ENDOGATOR Endoscopy Irrigation Tubing
Device Class:	Class II
Regulation Name:	Endoscope and Accessories
Common/usual Name:	Irrigation Tubing
Regulation Number:	21 CFR 876.1500
Product Code:	FEQ

2. Predicate Device

EndoGator System, K092429

3. Device Description

The ENDOGATOR Endoscopy Irrigation Tubing is composed of the following:
1) EndoGator™ Irrigation Tubing, and
2) EndoGator™ Irrigation Accessories

The ENDOGATOR Endoscopy Irrigation Tubing is indicated for irrigation during endoscopic procedures by using it in conjunction with an irrigation pump or cautery units, irrigation accessory, endoscope and disposable sterile water bottle. All tubing sets contain a back flow valve at the distal tip that allows irrigation water to travel in one direction, and therefore the risk of cross contamination is significantly reduced. The irrigation tubing sets are for twenty-four hour use and are to be discarded daily. The accessories are single-use devices and are to be discarded between patients. Tubing sets do not come into direct contact with patient tissue.

4. Indications for Use

The ENDOGATOR Endoscopy Irrigation Tubing (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).

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	**Endogator System Predicate Device K092429**	**Modified Device**	**Comparison**
Intended Use	The EndoGator™ system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).	The EndoGator Endoscopy Irrigation Tubing (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).	Identical
Construction	The EndoGator ™ System consists of a bottle cap, tubing set and connector	The EndoGator Endoscopy Irrigation Tubing consists of a bottle cap, tubing set and connector	Identical
Sterile/Non-sterile	Sterile	Sterile	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Sterilization Assurance Level	10^{-6}	10^{-6}	Identical
Accessories	• Single Use Auxiliary Water Jet Connector for Olympus® Endoscopes • Single Use Auxiliary Water Jet Connector for Pentax® Endoscopes • Endogator Channel Adapter • Endogator Backflow Valve • Endogator Y-Connector • Endogator Pump Cartridge • Endogator Extension Tubing • SpyGlass Tube Set	• Single Use Auxiliary Water Jet Connector for Olympus® Endoscopes • Single Use Auxiliary Water Jet Connector for Pentax® Endoscopes • Endogator Channel Adaptor • Endogator Backflow Valve	Similar All of the applicable listed accessories for the modified device are identical to the predicate.
Usage	Single Use: • Single Use Auxiliary Water Jet Connector for Olympus Endoscopes • Single Use Auxiliary Water Jet Connector for Pentax Endoscopes • Endogator Backflow Valve • Endogator Channel Adaptor • Endogator Y-Connector • SpyGlass Tube Set	Single Use: • Single Use Auxiliary Water Jet Connector for Olympus® Endoscopes • Single Use Auxiliary Water Jet Connector for Pentax® Endoscopes • Endogator Backflow Valve • Endogator Channel Adaptor	Identical The usage of the applicable accessories with modified device is identical as the usage for the accessories from the predicate device.
	24 Hour/Multi-patient Use • Endogator Extension Tubing • Auxiliary Water Jet Connector	24 Hour/Multi-patient Use • Endogator for Endostat II, Olympus OFP or Endo Stratus	Identical The usage of the irrigation tubing

Features	Endogator System Predicate Device K092429	Modified Device	Comparison
	for Olympus Endoscopes • Auxiliary Water jet Connector for Pentax Endoscopes • Endogator for Pentax/Meditron Pumps • Endogator for Pentax/Meditron Pumps with Fujinon Endoscope Connectors • Endogator for Endostat II/III Unit or Olympus OFP Unit • Endogator for EGP-100 Irrigation Unit • Endogator for EGP-100 Irrigation Units with Fujinon Endoscope Connectors	Pumps • Endogator for EGP-100, Olympus OFP, Torrent Irrigation Pumps and the gi4000 Electrosurgical Generator (irrigation pump component)	for the modified device is identical to the usage for the predicate device.
	Reusable: • Endogator Pump Cartridge	Reusable: • None	Similar There are no reusable accessories being used with the modified device.
Materials	Acrylonitrile Butadiene (Buna-N) Acrylonitrile Butadiene Styrene (ABS) Cyclohexanone High Impact Polystyrene (HIPS) Isopropyl Alcohol Nickel-plated Brass Polycarbonate Polypropylene Polyvinyl Chloride (PVC) Silicone UV cured Glue	Acrylonitrile Butadiene (Buna-N) Acrylonitrile Butadiene Styrene (ABS) Thermoplastic elastomer Isopropyl Alcohol Nickel-plated Brass Polycarbonate Polypropylene Polyvinyl Chloride (PVC) Silicone UV cured Glue	Similar Cyclohexane and high impact polystyrene were used in components for part numbers that have been discontinued. The acrylonitrile butadiene (Buna-N) in the o-ring of the check valve for the irrigation tubing was replaced by thermoplastic elastomer (Buna-N still exists in other components of the device). Thermoplastic elastomer is a well-known material in the medical device industry.
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Identical
Energy	None	None	Identical

Features	Endogator System Predicate Device K092429	Modified Device	Comparison
Used/Delivered			
Method of Application	Manual	Manual	Identical
Compatible Endoscopes	Olympus, Pentax, Fujinon	Olympus, Pentax, Fujinon	Identical
Compatible Irrigation Pumps	Pentax, Meditron, Endostat II, Endostat III, Olympus OFP	Endostat II, EGP-100, Olympus OFP, Endo Stratus, Torrent Irrigation Pump, gi4000 Electrosurgical Generator (irrigation pump component)	Similar. All compatible pumps are peristaltic pumps.

6. Summary of Non-Clinical Performance Testing

The following testing was conducted to verify the changes:

Test	Purpose	Acceptance Criteria	Results
Tensile Testing	Ensure the modification to the change in connection method between the pump tubing and irrigation tubing sections meet specifications.	Tensile values are to meet design specifications	Pass
Flow Rate Testing	Verify that flowrate was not impacted when using the irrigation tubing with the Torrent Irrigation pump and the gi4000 Electrical Surgical Generator.	Flowrate values are to meet design specifications	Pass
Durability Testing	Verify that the irrigation tubing structural integrity was not impacted when used with the Torrent Irrigation pump and the gi4000 Electrical Surgical Generator.	Device structural integrity must not be compromised when used with the Torrent Irrigation Pump and the gi4000 Electrosurgical Generator	Pass

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well or better than the legally marketed predicate device (K092429).