August 14, 2023

Medivators
Disha Kabrawala
Senior Regulatory Affairs Specialist
14605 28th Avenue North
Minneapolis, Minnesota 55447

Re: K231418
Trade/Device Name: ENDOGATOR™ Hybrid Irrigation Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: May 11, 2023
Received: May 16, 2023

Dear Disha Kabrawala:

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 -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
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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)*
K231418

Device Name
ENDOGATOR™ Hybrid Irrigation Tubing

Indications for Use *(Describe)*
The ENDOGATOR™ Hybrid Irrigation Tubing (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO2 (via a CO2 supply) along with sterile water 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
For
ENDOGATOR™ Hybrid Irrigation Tubing

Medivators Inc
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Fax No: 844-348-5637

Contact Person: Disha Kabrawala
Senior Regulatory Affairs Specialist
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Summary Date: May 11, 2023

CANTEL MEDICAL TRADITIONAL PREMARKET NOTIFICATION [510(k)]
ENDOGATOR™ Hybrid Irrigation Tubing

1. Device Name

Trade Name:	ENDOGATOR™ Hybrid Irrigation Tubing
Device Class:	II
Common/usual Name:	ENDOGATOR™ Hybrid Irrigation Tubing
Classification Name:	Endoscope and Accessories
Classification Number:	876.1500
Product Code:	OCX (endoscopic irrigation/suction system)

2. Predicate Devices

The Universal Irrigation Solution Hybrid, K102855

3. Description of Devices

The ENDOGATOR™ HYBRID Irrigation Tubing device contains a threaded cap and tubeset designed to be attached to sterile water bottles. The proximal end of the irrigation tubing includes the threaded bottle cap for attachment to a sterile water bottle. The bottle cap has three tubes attached, one for receiving CO2 (and air in the case of Pentax SKU's), one coaxial tube which has an inner lens rinsing uptake tube surrounded by an air/CO2 delivery tube, and one for delivering water for irrigation which interfaces with an irrigation pump. The water delivery tubes, both irrigation as well as lens rinsing include backflow check valves.

Air/CO2 and Lens Rinse Line Description

The threaded cap uses a coaxial tube to partition water and air/CO2 which is connected to the endoscope-interfacing connector. Pressurized air or CO_2 provided by the endoscope's processor/light source or a CO_2 insufflator is fed into the endoscope (either directly or first through the device & bottle system via luer connection.) The Endogator Hybrid enables the air/CO_2 to pressurize the bottle and flow through the endoscope to the air/water valve. The Endogator Hybrid serves as a passive element in the system, allowing the delivery of pressurized air/CO_2 to endoscopes.

Irrigation Line Description

The irrigation tubing pump section is installed into peristaltic-roller-type irrigation pumps, which transfer water through means of applying force to the external surface of the tubeset via revolving rollers, actuated by a user-controlled foot pedal, causing water to be siphoned from the sterile water bottle and transferred

downstream to the endoscope. The flow rate can be manipulated by user-interaction with the pump interface. The distal end of the irrigation tubing includes a backflow valve which allows water to travel only in one direction to mitigate cross-contamination. The irrigation check valve has a luer connection that enables the irrigation tubing to be connected to the ENDOGATOR™ auxiliary port or biopsy accessory adapters that interface with endoscopes (separate devices).

4. Intended Use / Indications for Use

The ENDOGATOR™ Hybrid Irrigation Tubing (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO2 (via a CO2 supply) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump or cautery unit.

5. Comparison of Technological Characteristics with the Predicate Device

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

Table 1: Physical Description and Technological Properties vs the Predicate Device

Feature	Proposed ENDOGATOR Hybrid Irrigation tubing	Predicate (K102855) The Universal Irrigation Solution Hybrid	Comparison
Intended Use	The ENDOGATOR™ Hybrid Irrigation Tubing (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO2 (via a CO2 supply) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump or cautery unit.	The Universal Irrigation Hybrid™ solution (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO2 (via a CO2 supply) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump or cautery unit.	Identical
Sterile	Sterile	Sterile	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Sterilization Assurance Level	10^{-6}	10^{-6}	Identical

Feature	Proposed ENDOGATOR Hybrid Irrigation tubing	Predicate (K102855) The Universal Irrigation Solution Hybrid	Comparison
Intended Use	24hr/ Multi-patient use	24hr/ Multi-patient use	Identical
Reprocessing	None; Daily disposal	None; Daily disposal	Identical
Compatible Endoscope(s)	Olympus® 140/160/180/190 series GI endoscopes PENTAX™ GI Endoscopes, FUJI 500 series GI Endoscopes FUJI 700 series GI Endoscopes	Olympus® 140/160/180/240/260 series GI endoscopes	Different Additional part numbers implemented to for Pentax, Fuji endoscopes
Patient Contact	No direct contact	No direct contact	Identical
Target Patient Population	Male/Female, Pediatric to Adult - Patients population undergoing GI endoscopic procedure	Male/Female, Pediatric to Adult - Patients population undergoing GI endoscopic procedure	Identical
Materials	Nitrile Butadiene (Buna-N) acrylonitrile-butadiene-styrene Acrylonitrile Butadiene Styrene (ABS) BLACK PEARL C Thermoplastic Elastomer Polycarbonate Non-Phthalate Polyvinyl Chloride (PVC) Polypropylene Buna-N Nitrile Nickel-Plated Brass Silicone Mabs Terflux UV cured Glue	Nitrile Butadiene (Buna-N) acrylonitrile-butadiene-styrene Acrylonitrile Butadiene Styrene (ABS) BLACK PEARL C Thermoplastic Elastomer Polycarbonate Phthalate Polyvinyl Chloride (PVC) Polypropylene Buna-N Nitrile Nickel-Plated Brass Silicone Mabs Terflux	Similar Use of non-phthalate polyvinyl Chloride material for tubing
Usage	Single Use	Single Use	Identical

Feature	Proposed ENDOGATOR Hybrid Irrigation tubing	Predicate (K102855) The Universal Irrigation Solution Hybrid	Comparison
Construction	Threaded Cap, Irrigation Tube set, Coaxial Tube, Backflow Check Valve	Threaded Cap, Irrigation Tube set, Coaxial Tube	Different Backflow check valve is added to prevent the flow in reverse direction. The successful results of testing prove that device is safe and effective
Energy Used / Delivered	None	None	Identical

6. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Table 2: Non-clinical testing

Testing	Requirements	Results
Water Flow Rate	Lensing Flow Rate must be no lower than 10% of Predicate after calling for water for 20 seconds	Pass
Insufflation Air & CO2 Flow	Air & CO2 Flow Rate must be no lower than 10% of the predicate	Pass
Backflow Test	The backflow valve must withstand at least 10 PSI	Pass
Lens Rinsing Flow Rate	Lensing Flow Rate must be no lower than 10% of predicate after calling for water for 20 seconds	Pass
Durability of glue bonded connections	The bonded connections must meet or exceed 10 lbs of axial pull force and must maintain strength and durability requirements after being subjected to 2X EtO sterilization.	Pass

Biocompatibility testing

Biocompatibility of the ENDOGATOR Hybrid™ Irrigation Tubing was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "Surface – Mucosal Membrane" with a contact duration of "Limited (< 24 hours)". The following tests were performed: Cytotoxicity, Irritation, and Sensitization. All evaluation acceptance criteria were met.

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 (K102855), Class II (21 CFR 876.1500), product code OCX.