November 8, 2022

Diversatek Healthcare
Alyssa Roelli
Senior Regulatory Projects Manager
102 E. Keefe Ave.
Milwaukee, WI 53212

Re: K222734
Trade/Device Name: Diversatek Healthcare PureFlo Irrigation System / Water Bottle Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX, FEQ
Dated: September 7, 2022
Received: September 9, 2022

Dear Alyssa Roelli:

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
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)*

K222734

Device Name
Diversatek Healthcare PureFlo™ Irrigation System / Water Bottle Tubing

Indications for Use *(Describe)*

The Diversatek Healthcare PureFlo™ Irrigation System (tubing and accessories to accommodate various gastrointestinal endoscopes and irrigation pumps) is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.

The Diversatek Healthcare PureFlo™ Auxiliary Water Jet Connector is used in conjunction with the PureFlo™ Irrigation Tubing and is intended to provide irrigation via irrigation fluids such as sterile water supplied during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.

The Diversatek Healthcare PureFlo™ Water Bottle Tubing is intended to be used with an air source from an endoscope with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.

The Diversatek Healthcare PureFlo™ Water Bottle Tubing CO2 is intended to be used with an air or carbon dioxide (CO2) source with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.

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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510(k) Summary

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

1. Submission Sponsor and Contact

Submitter's Name:	Diversatek Healthcare
Submitter's Address:	102 E. Keefe Ave. Milwaukee, WI 53212
Establishment Registration No.:	2183446
Contact Person:	Alyssa Roelli Senior Regulatory Projects Manager
Telephone:	414-265-7620 x4814
Fax	414-265-7628
Email:	aroelli@diversatek.com
Date Prepared:	August 10, 2022

2. Device Identification

Trade Device Name:	Diversatek Healthcare PureFlo™ Irrigation System / Water Bottle Tubing
Common Device Name:	Irrigation System / Water Bottle Tubing
FDA Product Codes:	OCX, FEQ
FDA Device Names:	Endoscopic Irrigation / Suction System; Pump, Air, Non-Manual, For Endoscope
Classification Number:	21 CFR 876.1500
Classification Name:	Endoscope and accessories
Regulatory Class:	2

3. Predicate Device Identification

In order to properly cover the entire product range of the application, multiple predicates have been selected.

Primary Predicate Device

Predicate 510(k) No.:	K140405
Predicate Trade Device Name:	Torrent® Irrigation System
Predicate FDA Product Code:	OCX
Predicate FDA Device Name:	Endoscopic Irrigation / Suction System
Predicate Classification Number:	21 CFR 876.1500
Predicate Classification Name:	Endoscope and Accessories
Predicate Regulatory Class:	2

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Secondary Predicate Device

Predicate 510(k) No.:	K101146
Predicate Trade Device Name:	AquaShield® System (Water Bottle Cap System)
Predicate FDA Product Code:	FEQ
Predicate FDA Device Name:	Pump, Air, Non-Manual, For Endoscope
Predicate Classification Number:	21 CFR 876.1500
Predicate Classification Name:	Endoscope and Accessories
Predicate Regulatory Class:	2

Secondary Predicate Device

Predicate 510(k) No.:	K191559
Predicate Trade Device Name:	AquaShield® System CO_2
Predicate FDA Product Code:	FEQ
Predicate FDA Device Name:	Pump, Air, Non-Manual, For Endoscope
Predicate Classification Number:	21 CFR 876.1500
Predicate Classification Name:	Endoscope and Accessories
Predicate Regulatory Class:	2

4. General Device Description

This submission includes the Diversatek Healthcare PureFlo™ Irrigation System and Water Bottle Tubing. All devices within this submission are provided sterile.

The Diversatek Healthcare PureFlo™ Irrigation System (tubing and accessories to accommodate various gastrointestinal endoscopes and irrigation pumps) is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.

The Diversatek Healthcare PureFlo™ Auxiliary Water Jet Connector is used in conjunction with the PureFlo™ Irrigation Tubing and is intended to provide irrigation via irrigation fluids such as sterile water supplied during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.

The irrigation system consists of irrigation tubing and a single-use auxiliary water jet connector. The tubing is inserted into a water bottle and the cap is screwed on the water bottle. The roller pump tubing of the irrigation tubing is then positioned within one of the specified pumps. The tubing is then connected to the auxiliary water jet connector. The auxiliary water jet connector is then connected to the auxiliary water port of the endoscope. To activate the flow of water, the foot pedal of the pump is pressed. The tubing should be primed prior to insertion of the endoscope in the patient.

The auxiliary water jet connector is replaced after each patient. The irrigation tubing can be used for up to 24 hours on multiple patients.

The Diversatek Healthcare PureFlo™ Water Bottle Tubing is intended to be used with an air source from an endoscope with the purpose of supplying sterile water to the

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endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.

With the pinch clip open, the water bottle tubing is inserted into a water bottle and the cap is screwed on the water bottle. The endoscope connector is then connected to the air/water port on the GI endoscope. The tubing is then primed prior to insertion of the endoscope in the patient.

The water bottle tubing can be used for up to 24 hours on multiple patients.

The Diversatek Healthcare PureFlo™ Water Bottle Tubing CO_2 is intended to be used with an air or carbon dioxide (CO_2) source with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.

The PureFlo™ Water Bottle Tubing CO_2 is used with either air or CO_2.

If using with air: With both blue and white pinch clips open, the water bottle tubing is inserted into a water bottle and the cap is screwed on the water bottle. The endoscope connector is then connected to the air/water port on the GI endoscope. The white pinch clamp is then closed. The tubing is then primed prior to insertion of the endoscope in the patient.

If using with CO_2: With both blue and white pinch clips open, the water bottle tubing is inserted into a water bottle and the cap is screwed on the water bottle. The endoscope connector is then connected to the air/water port on the GI endoscope. The CO_2 Connector / Luer Lock is then connected to the luer lock connection on the CO_2 insufflator. The CO_2 source and insufflator is then turned on. Then turn on the light source of the processor. The tubing is then primed prior to insertion of the endoscope in the patient.

The water bottle tubing CO_2 can be used for up to 24 hours on multiple patients.

5. Intended Use

The Diversatek Healthcare PureFlo™ Irrigation System (tubing and accessories to accommodate various gastrointestinal endoscopes and irrigation pumps) is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.

The Diversatek Healthcare PureFlo™ Auxiliary Water Jet Connector is used in conjunction with the PureFlo™ Irrigation Tubing and is intended to provide irrigation via irrigation fluids such as sterile water supplied during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.

The Diversatek Healthcare PureFlo™ Water Bottle Tubing is intended to be used with an air source from an endoscope with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.

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The Diversatek Healthcare PureFlo™ Water Bottle Tubing CO_2 is intended to be used with an air or carbon dioxide (CO_2) source with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.

6. Technological Characteristics

The following three tables include summaries of the Diversatek Healthcare technological characteristics as compared to the predicate devices manufactured by Steris (US Endoscopy).

For the Irrigation System, there is a separate Intended Use for the Auxiliary Water Jet Connector, which is a consumable accessory used within the Irrigation System. The Intended Use is the same as the predicate device manufactured by Steris (US Endoscopy) as listed in their IFU.

Table 5.1 Diversatek Healthcare and the Predicate Steris (US Endoscopy) Irrigation System Technological Characteristics

Characteristic	Diversatek Healthcare Irrigation System	Steris (US Endoscopy) Irrigation System	Comparison
Trade Name	PureFlo™ Irrigation System	Torrent® Irrigation System	N/A
510(k) Number	K222734	K140405	N/A
FDA Product Code	OCX	OCX	Identical
FDA Device Name	Endoscopic Irrigation / Suction System	Endoscopic Irrigation / Suction System	Identical
FDA Classification Number	21 CFR 876.1500	21 CFR 876.1500	Identical
FDA Classification Name	Endoscope and Accessories	Endoscope and Accessories	Identical
Manufacturing Design / Materials	The irrigation system is manufactured using plastic tubing, plastic injection molded connectors and caps, and one-way valves.	The irrigation system is manufactured using plastic tubing, plastic injection molded connectors and caps, and one-way valves.	Similar
Pump Compatibility	• Olympus • Medivators • Boston Scientific • ERBE	• Steris • Olympus • Medivators • ERBE	Similar
Intended Use Irrigation System	The Diversatek Healthcare PureFlo™ Irrigation System (tubing and accessories to accommodate various gastrointestinal endoscopes and irrigation pumps) is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic	The Torrent® irrigation system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in	Similar

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Characteristic	Diversatek Healthcare Irrigation System	Steris (US Endoscopy) Irrigation System	Comparison
	procedures when used in conjunction with an irrigation pump or electrosurgical unit.	conjunction with an irrigation pump or electrosurgical unit.	
Intended Use Auxiliary Water Jet Connector	The Diversatek Healthcare PureFlo™ Auxiliary Water Jet Connector is used in conjunction with the PureFlo™ Irrigation Tubing and is intended to provide irrigation via irrigation fluids such as sterile water supplied during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.	The Torrent® irrigation scope connector is used in conjunction with the Torrent® irrigation tubing (tubing and accessories to accommodate various endoscopes and irrigation pumps) and are intended to provide irrigation via irrigations fluids such as sterile water supplied during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump (or electrosurgical unit).	Similar
Patient Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Identical
Patient Contact Categorization	Indirect, Mucosal Membrane, Limited Duration	Indirect, Mucosal Membrane, Limited Duration	Identical
Sterilization Method	EO Gas	EO Gas	Identical
Duration of Usage	24-Hour, Multi-Patient (Irrigation Tubing)	24-Hour, Multi-Patient (Irrigation Tubing)	Identical
	Single Patient Use (Auxiliary Water Jet Connector)	Single Patient Use (Irrigation Scope Connector)	Identical
Shelf Life	3 Years (Irrigation Tubing)	1 Year (Irrigation Tubing)	Different
	3 Years (Auxiliary Water Jet Connector)	3 Years (Irrigation Scope Connector)	Identical

Table 5.2 Diversatek Healthcare and the Predicate Steris (US Endoscopy) Water Bottle Tubing Technological Characteristics

Characteristic	Diversatek Healthcare Water Bottle Tubing	Steris (US Endoscopy) Water Bottle Tubing	Comparison
Trade Name	PureFlo™ Water Bottle Tubing	AquaShield® System	N/A
510(k) Number	K222734	K101146	N/A
FDA Product Code	FEQ	FEQ	Identical
FDA Device Name	Pump, Air, Non-Manual, For Endoscope	Pump, Air, Non-Manual, For Endoscope	Identical
FDA Classification Number	21 CFR 876.1500	21 CFR 876.1500	Identical

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Characteristic	Diversatek Healthcare Water Bottle Tubing	Steris (US Endoscopy) Water Bottle Tubing	Comparison
FDA Classification Name	Endoscope and Accessories	Endoscope and Accessories	Identical
Manufacturing Design / Materials	The water bottle tubing is manufactured using plastic tubing, plastic injection molded connectors, a plastic cap and a plastic pinch clip.	The water bottle tubing is manufactured using plastic tubing, plastic injection molded connectors, a plastic cap and a plastic pinch clip.	Similar
Scope Compatibility	Olympus	Olympus	Identical
Intended Use	The Diversatek Healthcare PureFlo™ Water Bottle Tubing is intended to be used with an air source from an endoscope with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.	The AquaShield® system is intended to be used with an air source from an endoscope with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.	Similar
Patient Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Identical
Patient Contact Categorization	Indirect, Mucosal Membrane, Limited Duration	Indirect, Mucosal Membrane, Limited Duration	Identical
Sterilization Method	EO Gas	EO Gas	Identical
Duration of Usage	24-Hour, Multi-Patient	24-Hour, Multi-Patient	Identical
Shelf Life	Three Years	One Year	Different

Table 5.3 Diversatek Healthcare and the Predicate Steris (US Endoscopy) Water Bottle Tubing CO_2 Technological Characteristics

Characteristic	Diversatek Healthcare Water Bottle Tubing CO_2	Steris (US Endoscopy) Water Bottle Tubing CO_2	Comparison
Trade Name	PureFlo™ Water Bottle Tubing CO_2	AquaShield® System CO_2	N/A
510(k) Number	K222734	K191559	N/A
FDA Product Code	FEQ	FEQ	Identical
FDA Device Name	Pump, Air, Non-Manual, For Endoscope	Pump, Air, Non-Manual, For Endoscope	Identical
FDA Classification Number	21 CFR 876.1500	21 CFR 876.1500	Identical
FDA Classification Name	Endoscope and Accessories	Endoscope and Accessories	Identical

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Characteristic	Diversatek Healthcare Water Bottle Tubing CO_2	Steris (US Endoscopy) Water Bottle Tubing CO_2	Comparison
Manufacturing Design / Materials	The water bottle tubing CO_2 is manufactured using plastic tubing, plastic injection molded connectors, a plastic cap, a filter housed in a molded plastic part, and plastic pinch clips.	The water bottle tubing CO_2 is manufactured using plastic tubing, plastic injection molded connectors, a plastic cap, a filter housed in a molded plastic part, and plastic pinch clips.	Similar
Scope Compatibility	Olympus	Olympus	Identical
Intended Use	The Diversatek Healthcare PureFlo™ Water Bottle Tubing CO_2 is intended to be used with an air or carbon dioxide (CO_2) source with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.	The AquaShield® system CO_2 is intended to be used with an air or carbon dioxide (CO_2) source with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available sterile water bottles.	Similar
Patient Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Identical
Patient Contact Categorization	Indirect, Mucosal Membrane, Limited Duration	Indirect, Mucosal Membrane, Limited Duration	Identical
Sterilization Method	EO Gas	EO Gas	Identical
Duration of Usage	24-Hour, Multi-Patient	24-Hour, Multi-Patient	Identical
Shelf Life	Three Years	One Year	Different

7. Non-Clinical Performance Testing

Diversatek Healthcare performed bench testing to support substantial equivalence. The following testing was performed on Diversatek Healthcare samples from final, finished devices that were subjected to all manufacturing processes for the “to be marketed” device (including sterilization, environmental conditioning, and transportation). All test results passed, demonstrating that the device is as safe, as effective, and performs as well as or better than the predicate device.

1. Device Specification Conformation
2. Leakage Test
3. Irrigation Tubing Simulated Use Test
4. Pinch Clip Test
5. Water Bottle Tubing Simulated Use Test
6. Backflow Test
7. 24-Hour Simulated Use Test
8. Tensile Test

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8. Sterilization / Shelf Life

All the devices within this submission are sold in a sterile package with a three year shelf life. The devices have been sterilized in a validated EO sterilization cycle. The EO sterilization cycle has a Sterility Assurance Level (SAL) of 10^{-6}. An aging validation was performed on the final, finished devices within this submission to confirm product sterility throughout the life of the product. The devices passed all pre-established acceptance criteria of the validation.

9. Biocompatibility

Biocompatibility testing was performed on the sterile, final, finished devices per FDA Guidance Document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The testing included Cytotoxicity, Sensitization, and Intracutaneous Reactivity. The devices are categorized as surface devices with mucosal membrane contact for a limited duration (≤24 hours). All devices passed pre-established acceptance criteria for the testing.

10. Conclusion

Based on the intended use, technological characteristics and overall performance of the devices in bench testing, Diversatek Healthcare believes the proposed Irrigation System and Water Bottle Tubing and the predicate devices are substantially equivalent.

Through risk assessment and bench testing, Diversatek Healthcare has concluded the Irrigation System and Water Bottle Tubing does not raise any new issues of safety and effectiveness and performs as well as the legally marketed predicate devices.