December 21, 2023

Medivators (A Subsidiary of STERIS Corporation)
Nick Wang
Senior Manager, Regulatory Affairs
3150 Pollok Drive
Conroe, Texas 77303

Re: K232329
Trade/Device Name: Defendo Fujifilm 700 Single Use Biopsy Valve; Defendo Fujifilm 700 Single Use Air/Water Valve; Defendo Fujifilm 700 Single Use Suction Valve; ENDOGATOR Fujifilm 700 Single Use Connector; Defendo Fujifilm 700 Single Use Cleaning Adapter
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC, FDF, OCX, FEQ
Dated: November 21, 2023
Received: November 21, 2023

Dear Nick Wang:

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.

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232329

Device Name
Defendo Fujifilm 700 Single Use Biopsy Valve; Defendo Fujifilm 700 Single Use Air/Water Valve; Defendo Fujifilm 700 Single Use Suction Valve; ENDOGATOR Fujifilm 700 Single Use Connector; Defendo Fujifilm 700 Single Use Cleaning Adapter

Indications for Use *(Describe)*

The Single Use Biopsy Valve is intended for covering the endoscope biopsy port during an endoscopy procedure. The Single Use Biopsy Valve provides access for endoscopic device passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.

The Single Use Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.

The Single Use Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

The Single Use ENDOGATOR™ Connector is intended to be used in conjunction with ENDOGATOR™ Irrigation Tubing to provide irrigation via sterile water during GI endoscopic procedures when used with an irrigation pump (or cautery unit).

The Single Use Cleaning Adapter is intended to be used only to pre-clean the endoscope's air/water channel post-procedure, and not to be used during a patient procedure.

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

Defendo Fujifilm 700 Single-Use Valves Set

Manufacturer: Medivators
3150 Pollok Drive
Conroe, TX 77303

Submitter: Nick Wang, Ph.D. RAC
Senior Manager, Regulatory Affairs
Phone: 440-392-7482

Summary Date: 06 Dec 2023

1. Device Name

Trade Name:	Defendo Fujifilm 700 Single-Use Valves Set
Device Classification:	Class II
Common/usual Name:	Defendo Fujifilm 700 Single Use Biopsy Valve; Defendo Fujifilm 700 Single Use Air/Water Valve; Defendo Fujifilm 700 Single Use Suction Valve; ENDOGATOR Fujifilm 700 Single Use Connector; Defendo Fujifilm 700 Single Use Cleaning Adapter
Classification Name:	Endoscope and accessories
Classification Number:	21 CFR 876.1500
Product Code:	ODC, FDF, OCX, and FEQ

2. Predicate Device(s)

Primary predicate is listed first:

K102409 - Defendo Disposable Air/Water Valve Model 100304

K102581 - Defendo Disposable Suction Valve Model 100305

K210342 - BioShield- Biopsy Valve

K220395 - Endogator Endoscopy Irrigation Tubing

K172916 - FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L and EC-760ZP-V/L, and FUJIFILM Water Tank Model WT-603 (Air/Water Cleaning Adapter)

3. Description of Device

The Defendo Fujifilm 700 Single-Use Valves Set consists of a family of ready-to-use, sterile, single-use valves designed to be used on the Fujifilm 700 series GI endoscopes as accessories. The specific valves that are the subject of this 510(k) include the Defendo Fujifilm 700 Single-Use Air/Water Valve, the Defendo Fujifilm 700 Single-Use Suction Valve, the Defendo Fujifilm 700 Single Use Biopsy Valve, the Endogator Fujifilm 700 Connector, and the Defendo Fujifilm 700 Cleaning Adapter.

- The Air/Water valve allows the end-user to control and maintain air or CO_2 insufflation down the endoscope's air/water feed channels and control the water used to wash the lens of the endoscope during an endoscopic procedure.
- The Suction valve allows the user to control suction through the endoscope's accessory channel and serves as a fluid-removal conduit to aspirate fluids from the patient. This allows the clinician to remove fluids/soil from the GI tract during an endoscopic procedure.

- The Biopsy valve allows instruments/devices to be passed through it while maintaining insufflation, allowing suction, and guiding instruments through the biopsy channel during endoscopic procedures.
- The Connector allows attachment between the irrigation tube set via its luer connection and the compatible endoscope at its dedicated auxiliary water connection. This is sometimes also referred to as the auxiliary water jet valve.
- The Cleaning Adapter allows the user to pre-clean the air and water channels at the bedside prior to endoscope reprocessing.

These valves are supplied in various sets. Each set may include combinations of two or more of the valves listed above.

4. Intended Use

The Single Use Biopsy Valve is intended for covering the endoscope biopsy port during an endoscopy procedure. The Single Use Biopsy Valve provides access for endoscopic device passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.

The Single Use Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.

The Single Use Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

The Single Use ENDOGATOR™ Connector is intended to be used in conjunction with ENDOGATOR™ Irrigation Tubing to provide irrigation via sterile water during GI endoscopic procedures when used with an irrigation pump (or cautery unit).

The Single Use Cleaning Adapter is intended to be used only to pre-clean the endoscope’s air/water channel post-procedure, and not to be used during a patient procedure.

5. Technological Characteristic Comparison Table

Table 1. Proposed/Predicate Device Technological Characteristics Comparison Table – Air / Water Valve

Feature	Defendo Fujifilm 700 Single-Use Air/Water Valve (Subject Device)	Defendo Disposable Air/Water Valve (Predicate K102409)	Comparison
Intended use	The Single Use Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.	The Defendo Disposable Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.	Same
Sterile/Non-sterile	Sterile	Sterile	Same
Sterilization Method	EtO	EtO	Same
Sterilization Assurance Level	10^{-6}	10^{-6}	Same
Usage	Single-Use	Single-Use	Same
Main Device Dimensions (lengths/widths)	Air/Water Valve: Length: ~43.5 mm Diameter: ~19.2 mm	Air/Water Valve: Length: ~46 mm Diameter: ~17 mm	Similar, the slight differences are due to the differences in the endoscope port.
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Same
Energy Used/Delivered	None	None	Same
Method of Application	Manual actuation	Manual actuation	Same
Compatible Endoscopes	Fujifilm 700 series GI endoscope	Olympus endoscope	Reason for this 510(k)
Packaging	Supplied as a kit in PETG Tray with Tyvek Lid	Supplied individually in Tyvek Pouch	Package systems all maintain sterile barrier

Table 2. Proposed/Predicate Device Technological Characteristics Comparison Table – Suction Valve

Feature	Defendo Fujifilm 700 Single-Use Suction Valve (Subject Device)	Defendo Disposable Suction Valve (Predicate K102581)	Comparison
Intended Use	The Single Use Suction Valve is	The Defendo Disposable Suction	Same

Feature	Defendo Fujifilm 700 Single-Use Suction Valve (Subject Device)	Defendo Disposable Suction Valve (Predicate K102581)	Comparison
	intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	
Sterile/Non-sterile	Sterile	Sterile	Same
Sterilization Method	EtO	EtO	Same
Sterilization Assurance Level	10^{-6}	10^{-6}	Same
Usage	Single-Use	Single-Use	Same
Main Device Dimensions (lengths/widths)	Suction Valve: Length: ~28.0 mm Diameter: ~17.2 mm	Suction Valve: Length: ~27 mm Diameter: ~18 mm	Similar, the slight differences are due to the differences in the endoscope port.
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Same
Energy Used/Delivered	None	None	Same
Method of Application	Manual actuation	Manual actuation	Same
Compatible Endoscopes	Fujifilm 700 series GI endoscope	Olympus endoscope	Reason for this 510(k)
Packaging	Supplied as a kit in PETG Tray with Tyvek Lid	Supplied individually in Tyvek Pouch	Package systems all maintain sterile barrier

Table 5-3. Proposed/Predicate Device Technological Characteristics Comparison Table – Biopsy Valve

Feature	Defendo Single-Use Fujifilm 700 Biopsy Valves (Subject Device)	BioShield Biopsy Valve (for Fujifilm Endoscopes) (Predicate K210342)	Comparison
Intended Use	The Single Use Biopsy Valve is intended for covering the endoscope biopsy port during an endoscopy procedure. The single use Biopsy Valve provides access for endoscopic device	The single-use BioShield biopsy valve is used to cover the opening to the biopsy/suction channel of gastrointestinal endoscopes. It	Similar The intended use for the subject device biopsy valve is identical to that of other Defendo Biopsy Valves

Feature	Defendo Single-Use Fujifilm 700 Biopsy Valves (Subject Device)	BioShield Biopsy Valve (for Fujifilm Endoscopes) (Predicate K210342)	Comparison
	passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provides access for irrigation.	currently marketed by Medivators. The minor differences in language between the BioShield and Defendo valves are mainly editorial in nature and do not represent a different intended use.
Sterile/Non-sterile	Sterile	Sterile and Non-Sterile	See note below
Sterilization Method	EtO	EtO	Same
Sterilization Assurance Level	10^{-6}	10^{-6}	Same
Usage	Single-Use	Single-Use	Same
Main Device Dimensions (lengths/widths)	Length: ~16.8 mm Width (handle to tip): ~32.4 mm	Length: ~16.8 mm Width (handle to tip): ~32.4 mm	Same
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Same
Energy Used/ Delivered	None	None	Same
Compatible Endoscopes	Fujifilm 700 series GI endoscope	Fuji Gen 5 or later endoscopes	Same
Packaging	Continue to be supplied individually in Tyvek Pouch (predicate) and supplied as a set in PETG Tray with Tyvek Lid (new).	Supplied individually in Tyvek Pouch	Package systems all maintain sterile barrier

Note: Defendo Fujifilm 700 Single Use Biopsy Valve, the subject valve, is identical to the black non-sterile BioShield Biopsy Valve from K210342, with the only difference is that the subject device is EO sterilized in the valves set. Device testing included in K210342 on both the sterile and non-sterile blue BioShield Biopsy Valves provides evidence that EO sterilization does not negatively affect device performance and both the sterile and non-sterile versions of the device met the performance requirements and performed as expected as the biopsy valve. In this submission, STERIS performed additional confirmatory testing to ensure the biopsy valve included in the subject device (black sterile) continued to perform as intended.

Table 5-4. Proposed/Predicate Device Technological Characteristics Comparison Table – Connector

Feature	Endogator Fujifilm 700 Connector (Subject Device)	Endogator Connector (Predicate K220395)	Comparison
Intended Use	The Single Use ENDOGATOR™ Connector is intended to be used in conjunction with ENDOGATOR™ Irrigation Tubing to provide irrigation via sterile water during GI endoscopic procedures when used with an irrigation pump (or cautery unit).	The Endogator system is intended to provide irrigation via sterile water supply during GI endoscopic procedure when sued in conjunction with an irrigation pump (or cautery unit).	Similar (Language modified for the subject device to reflect the connector provided does not include the Endogator tubing)
Sterile/Non-sterile	Sterile	Sterile	Same
Sterilization Method	EtO	EtO	Same
Sterilization Assurance Level	10^{-6}	10^{-6}	Same
Usage	Single-Use	Single-Use	Same
Main Device Dimensions (lengths/widths)	Length: ~22 mm Diameter: ~12.7 mm	Length: ~22 mm Diameter: ~12.7 mm	Same
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Same
Energy Used/Delivered	None	None	Same
Compatible Endoscopes	Fujifilm 700 series GI endoscope	None specified (commonly used with Fujifilm endoscopes)	Same
Packaging	Continue to be supplied individually in Tyvek Pouch (predicate) and supplied as a set in PETG Tray with Tyvek Lid (new).	Supplied individually in Tyvek Pouch	Package systems all maintain sterile barrier

Note: Endogator Fujifilm 700 Connector (subject device) is the same as the Endogator Backflow Valve in the Endogator system (predicate device). The backflow valve is commonly used as the Auxiliary Water Jet Connector for the Fujifilm 700 Series endoscopes. Testing has been performed to provide evidence that the valve is compatible with and functions as intended when used with the Fujifilm 700 series GI endoscopes

Table 5-5. Proposed/Predicate Device Technological Characteristics Comparison Table – Cleaning Adapter

Feature	Defendo Fujifilm 700 Single-Use Cleaning Adapter (Subject Device)	FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L and EC-760ZP-V/L, and FUJIFILM Water Tank Model WT-603 (Predicate K172916)	Comparison
Intended use	The Single Use Cleaning Adapter is intended to be used only to pre-clean the endoscope's air/water channel post-procedure, and not to be used during a patient procedure.	The predicate reusable air/water channel cleaning adapter is an accessory to Fujifilm 700 endoscopes. While no indications for use for the accessory is directly stated. The adapter's intended purpose is to pre-clean the endoscope's air/water channel post-procedure. The cleared indications for use statement provide in the predicate 510(k) is the indications for use statement of the entire endoscope, not just the cleaning adapter accessory.[#]	Same, the intended purposes of the predicate and subject cleaning adapters are the same.
Sterility	Sterile	Non-Sterile	While sterility is not critical for the adapter application, the subject adapter is provided sterile as it is in the same packaging configuration as the other valves in the set.
Usage	Single-Use	Reprocessed	Reason for this 510k, subject adapter is a single-use adapter, whereas the predicate is reusable and requires reprocessing. Single-use configuration mitigates the risk of cross contamination.

Feature	Defendo Fujifilm 700 Single-Use Cleaning Adapter (Subject Device)	FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L and EC-760ZP-V/L, and FUJIFILM Water Tank Model WT-603 (Predicate K172916)	Comparison
Main Device Dimensions (lengths/widths)	Length: ~45.7 mm Diameter: ~19.2 mm	Length: ~45.8 mm Diameter: ~18.7 mm	Similar, the minor difference do not affect device performance.
Target Population	Patients undergoing an endoscopic procedure. The cleaning adapter does not have any patient contact as it is used post-procedure.	Patients undergoing an endoscopic procedure. The cleaning adapter does not have any patient contact as it is used post-procedure.	Same
Energy Used/Delivered	None	None	Same
Method of Application	Manual actuation	Manual actuation	Same
Compatible Endoscopes	Fujifilm 700 Series GI endoscope	Fujifilm 700 Series GI endoscope	Same
Packaging	Supplied as a set in PETG Tray with Tyvek Lid	Supplied with endoscope or individually	Subject device package system maintains sterile barrier

The indications for use listed in the predicate 510k summary is the following:
FUJIFILM Endoscope Models EG-760R, EG-760Z, EC-760R-V/L, and EC-760ZP-V/L have following indications for use.
FUJIFILM Endoscope Models EG-760R and EG-760Z are upper gastrointestinal endoscopes intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.
FUJIFILM Endoscope Models EC-760R-V/L and EC-760ZP-V/L are lower gastrointestinal endoscopes intended for the visualization of the lower digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the rectum and large intestine.
FUJIFILM Water Tank Model WT-603 has following indications for use. The Water Tank Model WT-603 is intended for use in combination with FUJIFILM 700 system scopes to deliver air and water through the endoscope under the management of a physician in medical facilities. Do not use this product for any other purpose.

4. Non-Clinical Performance Testing

Non-clinical performance testing was performed on the subject device to support the substantial equivalence determination. The following tests were performed:

Air / Water Valve

- Gas (Air and CO_2) flow rate testing
- Water flow rate testing
- Backflow prevention testing

- Mechanical testing
    - Depression Force
    - Valve Application Force
    - Valve Removal Force
    - Force to Disassemble via Axial Pull
- Valve Operation / Procedure Duration Test

Suction Valve

- Suction Bypass
- Suction Rate (water and soil)
- Mechanical testing
    - Depression Force
    - Valve Application Force
    - Valve Removal Force
    - Force to Disassemble via Axial Pull
- Valve Operation / Procedure Duration Test

Biopsy Valve

- Workability / Instrument Access Testing
- Slit Length / Dimensional Stability

Auxiliary Waterjet Valve (Connector)

- Flow Rate / Durability Testing
- Backflow Prevention Test

Cleaning Adapter

- Gas Flow Rate
- Water Flow Rate
- Mechanical Testing
    - Depression Force
    - Adapter Application Force
    - Adapter Removal Force
- Button Cycling / Durability Testing

In addition to performance testing, ISO 11607/ASTM 4169 testing was completed to ensure the packaging of the subject device kit maintained sterile barrier after shipping/transit.

5. Biocompatibility

The biocompatibility of the subject devices was assessed in accordance with the FDA guideline “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”. Biocompatibility testing conducted on the patient-contacting portions of the subject device in accordance with the ISO 10993 standard. The test result shows that the subject devices are biocompatible.

6. Conclusion

Based on the intended use, technological characteristics, non-clinical performance testing, and biocompatibility assessment, the subject device has shown to be substantially equivalent to the predicate and having met the acceptance criteria based on its indications for use.