February 20, 2025

STERIS Corparation
Gregory Land
Lead Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K250140
Trade/Device Name: 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
Dated: January 16, 2025
Received: January 17, 2025

Dear Gregory Land:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250140

Device Name

Defendo Fujifilm 700 Single Use Cleaning Adapter

Indications for Use *(Describe)*

The Defendo Fujifilm 700 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.

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

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1. Device Name

Trade Name:	Defendo Fujifilm 700 Single Use Cleaning Adaptor for Olympus Endoscopes
Device Class:	Class II
Regulation Name:	Endoscope And Accessories
Common/usual Name:	Cleaning Adaptor
Regulation Number:	21 CFR 876.1500
Product Code:	ODC

2. Predicate Device

Defendo Fujifilm 700 Single Use Cleaning Adaptor, K232329

3. Device Description

This device 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 Defendo Fujifilm 700 Single Use Cleaning Adapter is a single use, non-sterile disposable valve that fits onto the air/water cylinder of Fujifilm endoscopes (that do not contain a balloon channel). It allows air and water to be flushed through the endoscope’s air/water channels after an endoscopic procedure is completed to remove debris. The adapter is not intended to be used with patients and a warning tag comes with the device providing this information. The materials of the valve are non-patient contacting. The Defendo Fujifilm 700 Single Use Cleaning Adapter assembly consists of a cap, a spring, a spring cup, an overmolded boot, the cleaning valve stem, the valve stem backflow umbrella valve, and valve stem sealing gaskets and a warning label.

4. Indications for Use

The Defendo Fujifilm 700 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 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	Defendo Fujifilm 700 Single Use Cleaning Adaptor, K232329 – Predicate Device	Defendo Fujifilm 700 Single Use Cleaning Adaptor - Modified Device	Comparison
Indications for Use	The Defendo Fujifilm 700 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 Defendo Fujifilm 700 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.	Same
Construction	Cap Cap Colorant - Yellow Spring Spring cup (substrate) Boot (overmold) Cleaning Valve stem Valve stem sealing gaskets (5) Gaskets Colorant – Black	Cap Cap Colorant - Yellow Spring Spring cup (substrate) Boot (overmold) Cleaning Valve stem Valve stem sealing gaskets (5) Gaskets Colorant – Black	Same
Sterile/Non-sterile	Sterile	Non-Sterile	Different
Sterilization Method	EtO	None	Different
Sterilization Assurance Level	10^{-6}	None	Different.
Usage	Single use	Single use	Same
Materials (by component)	Cap – Polycarbonate Cap Colorant - Avient PC Yellow #3 HC CC10312800WE Spring – Stainless steel Spring cup (substrate) - Polycarbonate Boot (overmold) - Thermoplastic elastomer Valve stem – Polycarbonate Valve Stem Colorant - Avient PC Yellow #3	Cap – Polycarbonate Cap Colorant - Avient PC Yellow #3 HC CC10312800WE Spring – Stainless steel Spring cup (substrate) - Polycarbonate Boot (overmold) - Thermoplastic elastomer Valve stem – Polycarbonate Valve Stem Colorant - Avient PC Yellow #3	Same

Features	Defendo Fujifilm 700 Single Use Cleaning Adaptor, K232329 – Predicate Device	Defendo Fujifilm 700 Single Use Cleaning Adaptor - Modified Device	Comparison
	HC CC10312800WE Valve stem sealing gaskets – Thermoplastic elastomer Gasket colorant - Clariant Mevopur PE9SAA17700 PE 2% Black	HC CC10312800WE Valve stem sealing gaskets – Thermoplastic elastomer Gasket colorant - Clariant Mevopur PE9SAA17700 PE 2% Black	
Device Dimensions (lengths/widths)	Length: 1.800 inches Width: 0.748 inches	Length: 1.800 inches Width: 0.748 inches	Same
Operating Principle	Manual actuation	Manual actuation	Same
Energy Used/Delivered	None	None	Same
Applicable Endoscopes	Fuji	Fuji	Same
Packaging	PETG Tray with Tyvek Lid	Poly bag	Different

6. Summary of Non-Clinical Performance Testing

The purpose of this Special 510(k) is to obtain clearance for a non-sterile version of the Defendo Fujifilm 700 Single Use Cleaning Adaptor. The non-clinical testing involved the following:

Testing Conducted	Acceptance Criteria	Results
Button cycling/external leak	Meet acceptance criteria	Pass
Water Flow Rate	Meet acceptance criteria	Pass
Air Flow Rate	Meet acceptance criteria	Pass
Cap breakage strength	Meet acceptance criteria	Pass
Force to depress	Meet acceptance criteria	Pass
Backpressure Hold Test	Meet acceptance criteria	Pass
Force to Attach	Meet acceptance criteria	Pass
ASTM D4169 Ship Test	Meet acceptance criteria	Pass

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, Defendo Fujifilm 700 Single Use Cleaning Adaptor, K232329, Class II (21 CFR 876.1500), product code ODC.