November 8, 2024

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

Re: K243075
Trade/Device Name: Defendo Single Use Cleaning Adapter for Olympus Endoscopes (100322, 100323, 4000096, 4003269, 4003280)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: September 27, 2024
Received: September 27, 2024

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 (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)*

K243075

Device Name

Defendo Single Use Cleaning Adapter for Olympus Endoscopes (100322, 100323,4000096,4003269, 4003280)

Indications for Use *(Describe)*

The Single Use Cleaning Adapter is intended to be used only to pre-clean an 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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STERIS®

510(k) Summary
For
Defendo Single Use Cleaning Adapter for Olympus Endoscopes

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Disha Kabrawala
Senior Regulatory Affairs Specialist
Tel: 732-319-7766
Email: disha_kabrawala@steris.com

Submission Date: November 6, 2024

1. Device Name

Trade Name:	Defendo Olympus Single Use Cleaning Adapter for Olympus Endoscopes (100322, 100323, 4000096, 4003269, 4003280)
Device Class:	Class II
Regulation Name:	Endoscope and Accessories
Common/usual Name:	Cleaning Adapter
Regulation Number:	21 CFR 876.1500
Product Code:	ODC

2. Predicate Device

Defendo Single Use Cleaning Adapter for Olympus Endoscopes, K240352.

3. Device Description

This device is intended as part of the pre-cleaning process, to help clear the air/water channel of Olympus GI endoscopes post procedure.

The Defendo Single Use Cleaning Adapter for Olympus Endoscopes is a single use, sterile disposable valve that fits onto the air/water cylinder of Olympus 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 adapter is used post-procedure to pre-clean the endoscope before it goes through high-level disinfection and/or sterilization. The adapter is attached to the air/water channel of an endoscope. When the adapter is attached to the endoscope, air can flow down the channel of the endoscope. If water is desired to flow down the channel, the device is depressed. When released, air will once again flow down the endoscope channel. The Defendo Single Use Cleaning Adapter for Olympus Endoscopes 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 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 Olympus Single Use Cleaning Adaptor, K240352 – Predicate Device	Defendo Cleaning Adaptor for Olympus Endoscopes-Modified Device	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 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.	Identical
Construction	Cap Cap Colorant - Orange Spring Spring cup (substrate) Boot (overmold) Cleaning Valve stem Valve stem backflow umbrella valve Valve stem sealing gaskets (4) Gaskets Colorant – Black	Cap Cap Colorant – Orange Spring Spring cup (substrate) Boot (overmold) Cleaning Valve Stem Valve stem backflow umbrella valve Valve stem sealing gaskets (4) Gaskets Colorant - Black	Identical
Sterile/Non-sterile	Non-Sterile	Sterile	Different Although the predicate device is non-sterile and the proposed is sterile, the testing provided in this submission shows that this change does not impact safety, effectiveness or how the device is used.
Sterilization Method	None	EtO	Different Ethylene oxide sterilization is a commonly used sterilization method and the testing provide in this submission shows that sterilization does not impact the safety or effectiveness of the device or how it's used. packaging as the procedural valves.
Sterilization Assurance Level	None	10^{-6}	Different The testing provide in this submission shows that sterilization does not impact the safety or effectiveness of the device or how it's used.

Usage	Single use	Single use	Identical
Materials (by component)	Cap – Polycarbonate Cap Colorant – Mevopur Orange NC2M820004-ZN Spring – Stainless steel Spring Cup (substrate) - Polycarbonate Boot (overmold) – Thermoplastic elastomer Valve Stem – Polycarbonate Valve Stem Colorant - Mevopur Orange NC2M820004-ZN Valve stem sealing gaskets – Thermoplastic elastomer Valve stem backflow umbrella valve – Thermoplastic elastomer Gasket colorant - Clariant Mevopur PE9SAA17700 PE 2% Black	Cap – Polycarbonate Cap Colorant – Mevopur Orange NC2M820004-ZN Spring – Stainless steel Spring Cup (substrate) - Polycarbonate Boot (overmold) – Thermoplastic elastomer Valve Stem – Polycarbonate Valve Stem Colorant - Mevopur Orange NC2M820004-ZN Valve stem sealing gaskets – Thermoplastic elastomer Valve stem backflow umbrella valve – Thermoplastic elastomer Gasket colorant - Clariant Mevopur PE9SAA17700 PE 2% Black	Identical

6. Summary of Non-Clinical Performance Testing

The purpose of this Special 510(k) is to obtain clearance for a sterile version of the Defendo Cleaning Adapter that is used on Olympus endoscopes. The non-clinical testing involved the following:

Non-clinical testing consisted of the following:

Testing Conducted	Acceptance Criteria	Results
Button cycling/leak test	Meet acceptance criteria	Pass
Fluid Flow Path	Meet acceptance criteria	Pass
Air Flow Rate	Meet acceptance criteria	Pass
CO2 Flow Rate	Meet acceptance criteria	Pass
Water Flow Rate	Meet acceptance criteria	Pass
Backpressure Hold Test	Meet acceptance criteria	Pass
Valve to Port Attachment Force	Meet acceptance criteria	Pass
Valve to Port Removal Force	Meet acceptance criteria	Pass
Valve Depression Force	Meet acceptance criteria	Pass
Cap breakage strength	Meet acceptance criteria	Pass

Packaging Testing:

Testing Conducted	Acceptance Criteria	Results
Sterile Barrier: Visual Inspection	Meet acceptance criteria	Pass
Sterile Barrier: Dye Penetration	Meet acceptance criteria	Pass

Sterile Barrier: Seal Strength	Meet acceptance criteria	Pass
Functional Testing: Cleaning Valve	Meet acceptance criteria	Pass

Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is substantially equivalent to the legally marketed predicate device, Defendo Single Use Cleaning Adapter for Olympus Endoscopes, K240352, Class II (21 CFR 876.1500), product code ODC.