October 11, 2024

STERIS Corporation
Jackie Oliver
Sr. Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K242742
Trade/Device Name: DEFENDO Single Use Valve Kit AW/S Valves - 2pc for OLYMPUS EUS (00711900)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC, FDF
Dated: September 10, 2024
Received: September 11, 2024

Dear Jackie Oliver:

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)*

K242742

Device Name

DEFENDO Single Use Valve Kit AW/S Valves - 2pc for OLYMPUS EUS (00711900)

Indications for Use *(Describe)*

The DEFENDO EUS Air/Water Valve is intended to be used to control the air/water function of an endoscope during an GI Endoscopic procedure.

The DEFENDO EUS Suction Valve is intended to be used to control the suction function of an endoscope during a GI Endoscopic 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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Special 510(K) Summary
For the
DEFENDO Single Use Valve Kit AW/S Valves -2pc for OLYMPUS EUS

1. Company Name and Address

1.1 Sponsor

STERIS Corporation
5960 Heisley Rd.
Mentor, Ohio 44060

Contact: Jackie Oliver
Senior Regulatory Affairs Specialist
Telephone: (440) 358-6289
Email: Jackie_Oliver@steris.com

1.2 Manufacturing Facility

US Endoscopy
5976 Heisley Road
Mentor, Ohio 44060

2. Device Name

Proprietary Name: DEFENDO Single Use Valve Kit AW/S Valves – 2pc for OLYMPUS EUS

Common Usual Name: Endoscope channel accessory

Classification Name: Endoscopic and accessories

3. Establishment Registration Number

STERIS Corporation
5960 Heisley Rd.
Mentor, Ohio 44060
Registration number: 1527821

US Endoscopy
5976 Heisley Road
Mentor, Ohio 44060
Registration number: 1528319

4. Device Classification

Class:	II
Classification Number:	21 CFR 876.1500
Classification Panel:	Gastroenterology/Urology
FDA Review Product Code:	ODC, FDF

5. Predicate Devices

DEFENDO Single Use Valve Kit AW/S Valves – 2pc OLYMPUS EUS
K240098

6. Device Description

The DEFENDO EUS Air/Water Valve and the DEFENDO EUS Suction Valve are accessories to an echoendoscope.

The EUS Air/Water valve allows the end user to control air or CO2 insufflation down the endoscope's accessory channel, control water used to wash the lens of the endoscope and insufflate a balloon at the distal end of the echoendoscope

The DEFENDO EUS Suction valve allows the user to control suction through the echoendoscope's accessory channel and suction to the balloon at the distal end of the echoendoscope.

Both devices are single-use devices, supplied sterile.

7. Intended Use/Indications for Use

The DEFENDO EUS Air/Water Valve is intended to be used to control the air/water function of an endoscope during a GI endoscopic procedure.

The DEFENDO EUS Suction Valve is intended to be used to control the suction function of an endoscope during a GI endoscopic procedure.

8. Device Comparison Table

The DEFENDO Single Use Valve Kit AW/S Valves – 2pc for OLYMPUS EUS are identical in design to the predicate and have the same intended use. The shelf life of the predicate device is 1 year while the subject device has a shelf life of 3 years (see comparison table below).

Features	DEFENDO Single Use Valve Kit AW/S Valves – 2-pc for OLYMPUS EUS K240098 (Predicate Device)	DEFENDO Single Use Valve Kit AW/S Valves – 2-pc for OLYMPUS EUS (Proposed Device)	Comparison
Intended Use	The DEFENDO EUS Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure. The DEFENDO EUS Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	The DEFENDO EUS Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure. The DEFENDO EUS Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	Identical
Construction:	**Air/Water Valve**		
	Stem, Gaskets, Spring Guide, Spring(s), and Endcap with Skirt # of Gaskets: 9 # of Springs: 2	Stem, Gaskets, Spring Guide, Spring(s), and Endcap with Skirt # of Gaskets: 9 # of Springs: 2	Identical
	Suction Valve		
	Stem, Spring Guide, Spring(s), Endcap with Skirt, and Stainless-Steel Collar # of gaskets: 4 # of springs: 2	Stem, Spring Guide, Spring(s), Endcap with Skirt, and Stainless-Steel Collar # of gaskets: 4 # of springs: 2	Identical
Sterile/ Non-sterile	Sterile	Sterile	Identical
Sterilization Method	EtO	EtO	Identical
Sterilization Assurance Level	10^{-6}	10^{-6}	Identical

Usage	Single-Use	Single-Use	Identical
Materials:	**Air/Water Valve**		
	Cap: PC-ABS Spring(s): Stainless-Steel Valve Stem: Top Half – Stainless-Steel / Bottom Half - PC-ABS Spring Guide: PC-ABS Gaskets: TPE Skirt: TPE Endcap: PC-ABS	Cap: PC-ABS Spring(s): Stainless-Steel Valve Stem: Top Half – Stainless-Steel / Bottom Half - PC-ABS Spring Guide: PC-ABS Gaskets: TPE Skirt: TPE Endcap: PC-ABS	Identical
	Suction Valve		
	Cap: PC-ABS Spring(s): Stainless – Steel Center Valve stem: Stainless-Steel Offset Valve Stem: Ultem Plastic Spring Guide: PC-ABS Gaskets: TPE Skirt: TPE Endcap: Ultem Cap Insert: Brass Metal collar: Stainless-Steel	Cap: PC-ABS Spring(s): Stainless – Steel Center Valve stem: Stainless-Steel Offset Valve Stem: Ultem Plastic Spring Guide: PC-ABS Gaskets: TPE Skirt: TPE Endcap: Ultem Cap Insert: Brass Metal collar: Stainless-Steel	Identical
Device Dimensions (lengths/widths)	Air/Water Valve:		
	Overall Length: 46 mm Endcap Overmold Diameter: 11.25 mm	Overall Length: 46 mm Endcap Overmold Diameter: 11.25 mm	Identical
	Suction Valve:		
	Overall Length: 33 mm Stem Diameter: 3.8 mm	Overall Length: 33 mm Stem Diameter: 3.8	Identical
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Identical

Energy Used/Delivered	None	None	Identical
Compatible Endoscopes	Olympus endoscope with a balloon channel	Olympus endoscope with a balloon channel	Identical
Packaging	Sealed thermoform tray	Sealed thermoform tray	Identical
***Shelf Life**	1 year shelf life	3 year shelf life	Similar: The DEFENDO Single Use Valve Kit AW/S Valves – 2pc OLYMPUS EUS has passed 3 year (accelerated) age testing and the device functions as intended.

9. Summary of Non-Clinical Performance Testing

(*Identical testing was conducted on both the predicate (cleared) 1 year version of the device and proposed 3 year shelf life version of the device. The three year shelf life summary is below.)

Non-clinical testing consisted of the following:

Testing	Acceptance Criteria	Results
Air/Water Valve		
Leakage	Valve shall not continuously leak water	Pass
Insertion	No damage shall occur to either the valve or the endoscope during insertion	Pass
Valve - Stationary	Valve shall remain in place on the endoscope after being fully seated	Pass
Flow	Minimum flows of predetermined levels of each air and CO2 shall be demonstrated	Pass
Flow	Minimum flow of predetermined rates of water shall be demonstrated during flow of each air and CO2	Pass
Flow	Minimum flow of predetermined rates of water shall fill the balloon during flow of each air and CO2	Pass
Tensile Strength	Spring compression force shall fall within predetermined range in Stage 1 compression	Pass
Tensile Strength	Spring compression force shall fall within predetermined range in Stage 2 compression	Pass
Cap - Torque	Torque force shall be above a predetermined threshold to ensure no separation of cap from the valve stem occurs.	Pass

Testing	Acceptance Criteria	Results
Suction Valve		
Leakage	Valve shall not continuously leak water	Pass
Insertion	No damage shall occur to either the valve or the endoscope during insertion.	Pass
Insertion	The valve must not be able to be inserted incorrectly into EUS scope suction port.	Pass
Valve - Stationary	Valve shall remain in place on the endoscope after being fully seated	Pass
Tensile Strength	Spring compression force shall fall within predetermined range in Stage 1 compression	Pass
Tensile Strength	Spring compression force shall fall within predetermined range in Stage 2 compression	Pass
Cap - Torque	Torque force shall be above a predetermined threshold to ensure no separation of cap from the valve stem occurs.	Pass

Testing	Acceptance Criteria	Results
Packaging		
Pouch Seal – Tensile Testing	Force to open sealed pouch shall be 0.57 lbs or greater	Pass

10. Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the subject device is as safe, and effective as the predicate. The differences between the proposed and predicate devices include extension of shelf life and additional statements in the Instructions for Use.

The non-clinical testing for the extension in shelf life from one year to three years demonstrates the proposed change is substantially equivalent to the predicate.

The additional statements in the Instructions for Use do not raise any new concerns of safety and effectiveness.