February 9, 2024

Steris Corporation
Jackie Oliver
Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K240098
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
Dated: January 12, 2024
Received: January 12, 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.

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,

Sivakami Venkatachalam -S

for
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)*
K240098

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 endosocpe 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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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 (00711900)

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

5. Predicate Devices

BioGuard EUS Air/Water and Suction Valves K202104

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 similar in design to the predicate and have the same intended use. The differences between the proposed and predicate devices are summarized in the table below.

Table 1. Device Comparison Table for the DEFENDO Single Use Valve Kit AW/S Valves – 2pc for OLYMPUS EUS and predicate device.

Features	BioShield Air/Water Suction Valves EUS K202104 (Predicate Device)	DEFENDO Single Use Valve Kit AW/S Valves – 2-pc for OLYMPUS EUS (Proposed Device)	Comparison
Intended Use	The BioGuard EUS Air/Water Valve is intended to be used to control the air/water function of an endoscope during a GI endoscopic procedure. The BioGuard EUS Suction Valve is intended to be used to control the suction function of 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 (Only a name change)
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), and Endcap with Skirt # of gaskets: 4 # of springs: 2	Stem, Spring Guide, Spring(s), Endcap with Skirt, and Stainless-Steel Collar # of gaskets: 4 # of springs: 2	Similar

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: PC-ABS Cap Insert: Brass	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	Similar
Device Dimensions (lengths/widths)	Air/Water Valve: Overall Length: 46 mm Endcap Overmold Diameter: 11 mm	Air/Water Valve: Overall Length: 46 mm Endcap Overmold Diameter: 11.25 mm	Similar
	Suction Valve: Overall Length: 33 mm Stem Diameter: 3.8 mm	Suction Valve: 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

9. Summary of Non-Clinical Performance Testing

Non-clinical testing consisted of the following:

Testing	Acceptance Criteria	Results
Air/Water Valve		
Leakage Testing	The EUS Air/Water Valve shall not leak.	Pass
Insertion	The valves shall stay seated on the air/water port once placed.	Pass
Suction Valve		
Strength of Suction Valve	The valve shall maintain suction capability and strength.	Pass
Insertion	The valve must not be able to be inserted incorrectly into EUS scope's suction port.	Pass
Valve actuation	The Suction Valve shall withstand repeated actuation.	Pass
Valve usage without sticking	The Suction Valve shall be used without any sticking.	Pass

10. Conclusion

Based on the Construction and materials and non-clinical performance data, the subject device is shown to be substantially equivalent to the predicate and having met the acceptance criteria based on its indications for use.