March 6, 2024

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

Re: K232004
Trade/Device Name: Defendo Pentax Single Use Biopsy Valve, Defendo Pentax Single Use Air/Water Valve, Defendo Pentax Single Use Suction Valve, Endogator Pentax Single Use Connector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: February 2, 2024
Received: February 2, 2024

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
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)*
K232004

Device Name
Defendo Pentax Single Use Biopsy Valve, Defendo Pentax Single Use Air/Water Valve, Defendo Pentax Single Use Suction Valve, Endogator Pentax Single Use Connector

Indications for Use *(Describe)*
The Defendo Pentax 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 Pentax Single Use Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

The Defendo Pentax 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, help maintain sufflation, and minimize leakage of biomaterial from the biopsy port throughout the endoscopic procedure.

The Endogator Pentax Single Use 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).

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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STERIS®

510(k) Summary

Defendo Pentax 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: 29 February 2024

STERIS®

1. Device Name

Trade Name:	Defendo Pentax Single Use Valves Set
Device Classification:	Class II
Common/usual Name:	Defendo Pentax Single Use Biopsy Valve, Defendo Pentax Single Use Air/Water Valve, Defendo Pentax Single Use Suction Valve, Endogator Pentax Single Use Connector
Classification Name:	Endoscope and Accessories
Classification Number:	21 CFR 876.1500
Product Code:	ODC

2. Predicate Device(s)

Primary predicate is listed first:

K102409 - Defendo Disposable Air/Water Valve Model 100304

K102581 - Defendo Disposable Suction Valve Model 100305

K090851 - Defendo Biopsy Valves

K220395 - Endogator Endoscopy Irrigation Tubing

3. Description of Device

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

- The Air/Water valve allows the end-user to control and maintain air or CO2 insufflation down the endoscope's accessory channel 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 tubset 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.

These valves are supplied in various kits. The kits are combinations of two or more of the different valves listed above.

4. Intended Use

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

The Defendo Pentax 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, help maintain sufflation, and minimize leakage of biomaterial from the biopsy port throughout the endoscopic procedure.

The Endogator Pentax Single Use 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).

5. Technological Characteristic Comparison Table

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

Feature	Defendo Pentax Single Use Air/Water Valve (Subject Device)	Defendo Disposable Air/Water Valve (Predicate K102409)	Comparison
Intended use	The Defendo Pentax 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

STERIS Traditional 510(k) PREMARKET NOTIFICATION
Defendo Pentax Single Use Valves Set

Feature	Defendo Pentax Single Use Air/Water Valve (Subject Device)	Defendo Disposable Air/Water Valve (Predicate K102409)	Comparison
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: ~41 mm Diameter: ~17mm	Air/Water Valve: Length: ~46 mm Diameter: ~17 mm	Similar
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	Pentax 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 Pentax Single Use Suction Valve (Subject Device)	Defendo Disposable Suction Valve (Predicate K102581)	Comparison
Intended Use	The Defendo Pentax Single Use Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	The Defendo Disposable Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	Same
Sterile/Non-sterile	Sterile	Sterile	Same

Feature	Defendo Pentax Single Use Suction Valve (Subject Device)	Defendo Disposable Suction Valve (Predicate K102581)	Comparison
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: ~35 mm Diameter: ~17 mm	Suction Valve: Length: ~27 mm Diameter: ~18 mm	Similar
Materials	Polycarbonate, Stainless Steel, Thermoplastic Elastomer, Colorant, and Rubber	Polycarbonate, Stainless Steel, and Thermoplastic Elastomer	Similar
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	Pentax 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 3. Proposed/Predicate Device Technological Characteristics Comparison Table – Biopsy Valve

Feature	Defendo Pentax Single Use Biopsy Valve (Subject Device)	Defendo Biopsy Valve for Pentax Valves (Predicate K090851)	Comparison
Intended Use	The Defendo Pentax Biopsy Valve is intended for covering the endoscope biopsy port during an endoscopy procedure. The single use Biopsy Valve provides access	The Defendo Biopsy Valve is intended for covering the endoscope biopsy port during an endoscopy procedure. The valve provides	Same

STERIS Traditional 510(k) PREMARKET NOTIFICATION
Defendo Pentax Single Use Valves Set

Feature	Defendo Pentax Single Use Biopsy Valve (Subject Device)	Defendo Biopsy Valve for Pentax Valves (Predicate K090851)	Comparison
	for endoscopic device passage and exchange, help maintain sufflation, and minimize leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	access for endoscopic device passage and exchange, help maintain sufflation, and minimize leakage of biomaterial from the biopsy port throughout the 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)	Length: ~18 mm Diameter: ~16 mm	Length: ~17 mm Diameter: ~17 mm	Similar
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Same
Energy Used/ Delivered	None	None	Same
Compatible Endoscopes	Pentax endoscope	Pentax endoscopes	Same
Packaging	Supplied as a kit in PETG Tray with Tyvek Lid	Supplied individually in Tyvek Pouch	Package systems all maintain sterile barrier

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

Feature	Endogator Pentax Single Use Connector (Subject Device)	Endogator Connector (K092429)	Comparison
Intended Use	The Endogator Pentax Connector is intended to be used in	The Endogator system is intended	Similar

Feature	Endogator Pentax Single Use Connector (Subject Device)	Endogator Connector (K092429)	Comparison
	conjunction with Endogator Irrigation Tubing (not included) to provide irrigation via sterile water during GI endoscopic procedures when used with an irrigation pump (or cautery unit).	to provide irrigation via sterile water supply during GI endoscopic procedure when sued in conjunction with an irrigation pump (or cautery unit).	(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: ~32 mm Diameter: ~15 mm	Length: ~32 mm Diameter: ~15 mm	Same
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Same
Energy Used/Delivered	None	None	Same
Compatible Endoscopes	Pentax endoscope	Pentax endoscopes	Same
Packaging	Supplied as a kit inPETG Tray with Tyvek Lid	Supplied individually in Tyvek Pouch	Package systems all maintain sterile barrier

4. <u>Non-Clinical Performance Testing</u>

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
    - Sonic Weld Break Testing
- Valve Operation / Procedure Duration Test

Suction Valve

- Suction Bypass
- Suction Rate (water and soil)
- Mechanical testing
    - Depression Force
    - Valve Application Force
    - Valve Removal Force
    - Sonic Weld Break Testing
- Valve Operation / Procedure Duration Test

Biopsy Valve

- Leak Testing
- Insufflation Testing

Auxiliary Waterjet Valve (Connector)

- Flow Durability Testing
- Check Valve Functionality Testing (Back Flow Prevention Test)
- Mechanical Strength 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. <u>Biocompatibility</u>

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.