January 13, 2021

Steris Corporation
Carroll Martin
Regulatory Affairs Director
5976 Heisley Road
Mentor, OH 44060

Re: K202104
Trade/Device Name: BioGuard EUS Air/Water and Suction Valves
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC, FDF
Dated: December 4, 2020
Received: December 7, 2020

Dear Carroll Martin:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202104

Device Name
BioGuard EUS Air/Water and Suction Valves

Indications for Use *(Describe)*
The BioGuard EUS Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.

The BioGuard EUS Suction Valve is intended to be used to control the suction function on 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
For the
BioGuard EUS Air/Water and Suction Valves

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Carroll Martin
Regulatory Affairs Director
Tel: 440-358-6259
Email: carroll_martin@steris.com

Summary Date: January 4, 2021

STERIS Traditional 510(k) PREMARKET NOTIFICATION
BioGuard EUS Air/Water and Suction Valves

1. Device Name

Device Name:	BioGuard EUS Air/Water and Suction Valves, P/N 00711780
Common Name:	Air/Water and Suction Valves
Regulation Name:	Endoscopic Channel Accessory

2. Device Classification

Regulatory Class:	II
Regulation Number:	21 CFR 876.1500
Device Panel:	Gastroenterology/Urology
Product Code:	ODC and FDF
Product Code Name:	Endoscope Channel Accessory (ODC) Colonoscope and Accessories, Flexible, Rigid (FDF)

3. Predicate Device

K192059	BioGuard Air/Water Valve, BioGuard Suction Valve

4. Description of Device

The BioGuard EUS Air/Water Valve and the BioGuard EUS Suction Valve are accessories to an echoendoscope. The EUS Air/Water valve allows the end user to control air or CO_2 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 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.

5. 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.

6. Technological Characteristic Comparison Table

The BioGuard EUS Air/Water and Suction valves are similar in design to the predicate and have exactly the same intended use. The differences between the proposed and predicate devices are the design of the valves and the particular type of endoscope on which the devices are used. The design is different than the predicate (see table below) because the BioGuard EUS Air/Water and Suction valves are used on echoendoscopes that have different dimensions than the endoscopes that are used with the predicate device. The echoendoscopes also have a balloon channel to allow the inflation and deflation of a balloon with water. These differences do not raise any new concerns of safety and effectiveness when compared to the predicate device.

Table 1 summarizes the similarities/differences between the proposed device and the predicate.

Table 1. Proposed/Predicate Device Technological Characteristics Comparison Table

Feature	BioGuard EUS Air/Water and Suction Valve (Proposed)	BioGuard Air/Water and Suction Valve (Predicate K192059)	Comparison
Intended use	The BioGuard EUS Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure. The BioGuard EUS Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	The BioGuard Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure. The BioGuard Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	Same
Construction	Air/Water Valve: Stem, gaskets, spring guide, spring(s) and endcap with skirt	Air/Water Valve: Stem, gaskets, spring and valve base (skirt and endcap)	Similar
	Suction Valve: Stem, spring guide, spring(s) and endcap with skirt	Suction Valve: Stem, spring and valve base (skirt and endcap)	Similar
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

Feature	BioGuard EUS Air/Water and Suction Valve (Proposed)	BioGuard Air/Water and Suction Valve (Predicate K192059)	Comparison
Materials	Air/Water Valve: PC-ABS, Stainless Steel, TPE	Air/Water Valve: ABS Plastic, Stainless Steel, Thermoplastic styrene (Rabalon), TPE	Similar
	Suction Valve: PC-ABS, Stainless Steel, Ultem Plastic, TPE, Brass	Suction Valve: ABS Plastic, Stainless Steel, TPE, PC-ABS	Similar
Device Dimensions (lengths/widths)	Air/Water Valve: Length: 46 mm Diameter: 11 mm	Air/Water Valve: Length: 45.9 mm Diameter: 10 mm	Similar
	Suction Valve: Length: 33 mm Diameter: 3.8 mm	Suction Valve: Length: 27.4 mm Diameter: 5.6 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	Olympus endoscope with a balloon channel	Olympus endoscope without a balloon channel	Similar
Packaging	Sealed thermoform tray	Sealed thermoform tray	Same

7. Description of Safety and Substantial Equivalence

Functional testing assessing the air/water valves ability to control the supply of air/CO_2 and water to an endoscope was conducted via bench and simulated use testing. Functional testing assessing the suction valves ability to control the evacuation of air/CO_2 and water through the endoscope was conducted via bench and simulated use testing.

8. Conclusion

The proposed device, the BioGuard EUS Air/Water and Suction Valves, is substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.