January 8, 2021

STERIS Corporations
Carroll Martin
Regulatory Affairs Director
5976 Heisley Road
Mentor, OH 44060

Re: K203630
Trade/Device Name: BioGuard 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 9, 2020
Received: December 11, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203630

Device Name
BioGuard Air/Water and Suction Valves

Indications for Use *(Describe)*

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.

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
For
BioGuard 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

Submission Date: December 10, 2020

1. Device Name

Trade Name:	BioGuard Air/Water and Suction Valves
Device Class:	Class II
Regulation Name:	Endoscope and Accessories
Common/usual Name:	Endoscope Air/Water and Suction Valves
Regulation Number:	21 CFR 876.1500
Product Code:	ODC, FDF

2. Predicate Device

BioGuard Air/Water and Suction Valves, K192059

3. Device Description

The BioGuard Air/Water Valve and the BioGuard Suction Valve are accessories to an endoscope. The Air/Water valve allows the end user to control air or CO2 insufflation down the endoscope's accessory channel and also controls water used to wash the lens of the endoscope. The Suction valve allows the user to control suction through the scope's accessory channel. The valves are sterile, single-use, disposable devices.

The Air/Water valve consists of a snap cap, stem, gaskets, spring and valve base (skirt and endcap).

The Suction valve consists of a stem, spring and valve base (skirt and endcap).

4. Indications for Use

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.

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	BioGuard Air/Water and Suction Valves K192059 – Predicate Device	Modified Device	Comparison
Intended Use	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.	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.	Identical
Construction	Air/Water Valve Stem, gaskets, spring and valve base (skirt and endcap) # of gaskets: 4	Air/Water Valve Stem, gaskets, spring and valve base (skirt and endcap) # of gaskets: 4	Identical
Construction	Suction Valve Stem, spring and valve base (skirt and endcap) No ridges at bottom of stem	Suction Valve Stem, spring and valve base (skirt and endcap) No ridges at bottom of stem	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 (by component)	Air/Water Valve Snap Cap: ABS Plastic Spring: Stainless Steel Valve Stem: ABS Plastic Gaskets: Rabalon Skirt: TPE Endcap: ABS plastic or PC-ABS	Air/Water Valve Snap Cap: ABS Plastic Spring: Stainless Steel Valve Stem: ABS Plastic Gaskets: Rabalon Skirt: TPE Endcap: ABS plastic or PC-ABS **Addition of glue (4011 Loctite) to the valve stem.**	**Similar**
Materials (by component)	Suction Valve Suction Stem: ABS Plastic Spring: Stainless Steel Skirt: TPE Endcap: PC-ABS	Suction Valve Suction Stem: ABS Plastic Spring: Stainless Steel Skirt: TPE Endcap: PC-ABS	Identical

Features	BioGuard Air/Water and Suction Valves K192059 – Predicate Device	Modified Device	Comparison
Device Dimensions (lengths/widths)	Air/Water Valve: Length: 45.9 mm	Air/Water Valve: Length: 45.9 mm	Identical
Device Dimensions (lengths/widths)	Suction Valve: Length: 27.4 mm Diameter: 5.6 mm	Suction Valve: Length: 27.4 mm Diameter: 5.6 mm	Identical
Operating Principle	Manual actuation	Manual actuation	Identical
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Identical
Energy Used/Delivered	None	None	Identical
Method of Application	Manual	Manual	Identical

6. Summary of Non-Clinical Performance Testing

The purpose of this Special 510(k) is apply glue (4011 Loctite) to the valve stem of the air/water valve. This change is intended to mitigate loosening of the snap cap from the valve during use. The non-clinical testing involved the following:

- Torque (unscrewing) testing of the air/water valve cap to ensure the glue bond meets a set strength.
- Functional testing that involved repetitive cycling (pushed down and released) of the air/water valve. This simulates actual use testing.

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well or better than the legally marketed predicate device (K192059), Class II (21 CFR 876.1500), product code ODC and FDF.