September 3, 2021

STERIS Corporation
Carroll Martin
Regulatory Affairs Director
5976 Heisley Rd
Mentor, OH 44060

Re: K210342
Trade/Device Name: BioShield- ERCP Biopsy Valve, BioShield Irrigator – Extension Tubing, BioShield Irrigating Adaptor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC, OCX
Dated: August 2, 2021
Received: August 4, 2021

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 control's 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,

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)*
K210342

Device Name
BioShield Biopsy Valve
BioShield Irrigator - Extension Tubing
BioShield Irrigating Adaptor

Indications for Use *(Describe)*
The single-use BioShield biopsy valve is used to cover the opening to the biopsy/suction channel of gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provides access for irrigation.

The BioShield Irrigator – extension tubing is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in conjunction with the BioShield Irrigator.

The BioShield Irrigating Adaptor is intended to be used with the BioShield Biopsy Valve to provide access for irrigation.

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 BioShield Biopsy Valve

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: March 15, 2021

1. Device Name

Trade Name:	BioShield Biopsy Valve
	BioShield Irrigator – Extension Tubing
	BioShield Irrigating Adaptor
Device Class:	Class II
Regulation Name:	Endoscope and Accessories
Common/usual Name:	Biopsy Valve
Regulation Number:	21 CFR 876.1500
Product Code:	OCX, ODC

2. Predicate Device

BioShield – ERCP Biopsy Valve, K070420
Irrigation System, K103239
Medovations BullDog Biopsy Valve Irrigating Adaptor Accessory, K142068

3. Device Description

The BioShield biopsy valve is a single-use disposable cap that is used to cover the biopsy/suction channel of endoscopes during endoscopic procedures and other procedures. It provides access to the endoscope's working channel, minimizes leakage of biomaterial and other fluids during insufflation and instrument exchange and allows for irrigation. The device consists of a valve body and a cap. The device is made from thermoplastic elastomer. There are a total of 10 versions of the BioShield biopsy valve. All 10 versions of the BioShield Biopsy valve are subject to the major change of removing the skirt that aided in maintaining insufflation in the predicate device and two of these 10 versions have had an irrigation line added. Seven versions of the biopsy valve that are compatible with Olympus and Fujinon endoscopes and three versions of the valve that are compatible with Pentax endoscopes. Also, of these 10 versions, there are two versions that have an irrigation line to provide another option to the user to irrigate. All valves, with the exception of one version, are supplied non-sterile.

There are two accessories provided with the BioShield biopsy valve. These devices were not previously cleared under the 510(k) process. Their product code is OCX. They are the BioShield Irrigator and the BioShield Irrigator Extension Tubing. The BioShield Irrigator consists of a luer connection attached to a stainless-steel tip. The Bioshield Irrigator is used for intraprocedural gastrointestinal endoscopic irrigation when attached to a luer-lock or slip-tip syringe directly through the BioShield biopsy valve. The BioShield Irrigator Extension Tubing is a 180 cm long piece of irrigation tubing that has connectors on both ends. The tubing can be connected to a BioShield Irrigator biopsy valve on one end and to an irrigation system (irrigation tubing connected to an irrigation source used with an auxiliary water pump) on the other end in order to provide hands-free foot pedal irrigation control. Both of these irrigation accessories are provided non-sterile.

BioShield Biopsy Valves and Accessories

Product Name	Part Number	Sterility Status
BioShield – biopsy valve	00711124	Non-sterile
BioShield – biopsy valve	00711125	Non-sterile
BioShield – biopsy valve	00711126	Non-sterile
BioShield – biopsy valve	00711127	Non-sterile
BioShield – biopsy valve-sterile	00711128	Sterile
BioShield – biopsy valve	00711129	Non-sterile
BioShield Irrigating Adaptor	00711131	Non-sterile
BioShield – irrigator	00711133	Non-sterile
BioShield Irrigator – extension tubing (180 cm)	00711134	Non-sterile
BioShield – biopsy valve	00711135	Non-sterile
BioShield – biopsy valve	00711136	Non-sterile
BioShield – irrigator	00711137	Non-sterile

4. Indications for Use

The single-use BioShield biopsy valve is used to cover the opening to the biopsy/suction channel of gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provides access for irrigation.

The BioShield Irrigator – extension tubing is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in conjunction with the BioShield Irrigator.

The BioShield Biopsy Valve Irrigating Adaptor Accessory is intended to be used with the biopsy valve to provide access for irrigation.

5. Technological Characteristics Comparison Table

A comparison of technical characteristics between the proposed BioShield Biopsy Valve and its predicate can be found in **Table 1**. A comparison of technical characteristics between the proposed accessory, the BioShield Irrigation Extension Tubing and its predicate can be found in **Table 2**. A comparison of technical characteristics between the proposed accessory, the BioShield Irrigating Adaptor and its predicate can be found in **Table 3**.

Table 1. Technological Characteristics Comparison Table

Features	**BioShield – ERCP Biopsy Valve Predicate Device K070420**	**BioShield Biopsy Device (Proposed Device)**	**Comparison**
Intended Use	The single-use BioShield – ERCP biopsy valve is used to cover the opening to the biopsy/suction channel of Olympus and G5 and newer Fujinon gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provides access for irrigation.	The single-use BioShield biopsy valve is used to cover the opening to the biopsy/suction channel of gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provides access for irrigation.	Similar. This change does not impact how the device is used. The modified device has the same fundamental technology as the predicate. The terms "sufflation" and "insufflation have the same meaning.
Construction	Valve Body Valve Body Insert Valve Cap	Valve Body Valve Cap Irrigation Line	Similar. The valve body insert helped the valve maintain insufflation and mitigate leakage. Testing has shown that removal of the insert did not affect these features of the device. The addition of the irrigation line gives the user another option to irrigate through the valve.
Sterile/Non-sterile	Sterile and Non-sterile	Sterile and Non-sterile (only the 00711128 valve is supplied sterile)	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Sterilization Assurance Level	10^{-6}	10^{-6}	Identical
Usage	Single use	Single use	Identical
Materials (by component)	Valve Body and valve cap Thermoplastic elastomer	Valve Body and valve cap: Thermoplastic elastomer Irrigation Line: Polyvinyl chloride Check valve Housing - Polycarbonate Diaphragm: Silicone Irrigation line: Polyvinyl chloride	The same material for the valve. Different materials for the components. Testing of the components shows no effect on safety or effectiveness of the proposed valves themselves.
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
Compatible Endoscopes	Olympus and G5 and newer Fujinon gastrointestinal endoscopes	Pentax, Olympus and G5 and newer Fujinon gastrointestinal endoscopes	Similar. The addition of using the valve on Pentax endoscopes is similar to the predicate in that the fundamental technology and the use of the valve on Pentax endoscopes is identical to the predicate.
Number of Devices/Box	25	50, 100, 200 depending on SKU	Similar. This change is similar to the predicate in that the packaging of the device has not changed, only the number of devices in a box.
Irrigation Accessories	None	The BioShield Irrigating Adaptor consisting of a polypropylene luer lock connected to a stainless-steel tip. The BioShield Irrigation Extension tubing consists of a 180cm piece of polyvinyl chloride tubing with a female connector made of polycarbonate on one end and a male connector made of ABS plastic on the other end	This is different than the predicate device in that these accessories were not offered for use. But testing has shown that use of these accessories does not impact the safety or effectiveness of the BioShield Biopsy valves.

Table 2. BioShield Irrigator Extension Tubing Technological Characteristics Comparison Table

Features	**US Endoscopy's Irrigation System, K103239**	**BioShield Irrigator – extension tubing, K210342**	**Comparison**
Intended Use	The Irrigation System (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.	The BioShield Irrigator – extension tubing is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in conjunction with the BioShield Irrigator.	Similar. The BioShield Irrigator – extension tubing is not connected directly to an irrigation pump or electrosurgical unit but can be connected to irrigation tubing providing the same exact purpose of US Endoscopy's Irrigation System, that is to provide irrigation fluids to the endoscope. Whereas the intended use of the two devices is not exactly the same, the differences do not alter the intended therapeutic effect of the device. The fundamental technology of attaching to a water source and providing irrigation fluids to an endoscope are exactly the same.
Construction	Irrigation Tubing Set: Consists of 110 in (279.4cm) irrigation tubing that has a connector on one end (to connect to the scope connector) and a vented bottle cap on the other end that goes into a water bottle. Scope Connector: Consists of two connectors, one on each end and a check valve in the middle.	BioShield Irrigator – extension tubing: Consists of a 70.9 in (180cm) piece of irrigation tubing with connectors on both ends that allow for connection to the BioShield Biopsy valve with the built-in irrigation line and to a water source.	Similar. Both devices have irrigation tubing as a component. This irrigation tubing serves the same purpose; to connect a water source to the endoscope for the purpose of providing irrigation fluids. The US Endoscopy Irrigation system has a scope connector with a check valve to protect against backflow. This check valve connects directly to the endoscope. The BioShield Irrigator – extension tubing does not have a check valve, it is connected to the

			BioShield Biopsy valve with irrigation line that does have a check valve. Both devices connect to an irrigation source and to the endoscope.
Materials of Construction	Irrigation tubing: PVC Cap: PVC Scope Connector: Polyetherimide	BioShield Irrigator – extension tubing: PVC Male connector: ABS plastic Female connector: polycarbonate	Similar. The irrigation tubing portion of both devices are made of PVC.
Sterility	Sterile	Non-sterile	Different. The Pure Vu System, K210981 is a similar reference device that is provided in a non-sterile state.

Table 3. BioShield Biopsy Valve Irrigating Adaptor Technological Characteristics Comparison Table

Features	**Medovations BullDog Biopsy Valve Irrigating Adaptor Accessory, K142068**	**BioShield Biopsy Valve Irrigating Adaptor Accessory, K210342**	**Comparison**
Intended Use	The BullDog Biopsy Valve Irrigating Adaptor Accessory is intended to be used with the biopsy valve to provide access for irrigation.	The BioShield Biopsy Valve Irrigating Adaptor Accessory is intended to be used with the biopsy valve to provide access for irrigation.	Same
Construction	Hollow metal tube with standard plastic luer lock connector	Hollow metal tube with standard plastic luer lock connector	Same

6. Summary of Non-Clinical Performance Testing

Non-clinical testing consisted of the following:

Testing	Acceptance Criteria	Results
Retention Force Testing	The retention force of the BioShield Biopsy valves must be equal to or greater than the predicate device as documented in K070420 (3.2 lbs.).	Pass
Leakage Testing	The BioShield biopsy valves must not spray or experience geyser type leaks while the endoscope is pressurized	Pass
Device Exchange Testing	The BioShield Biopsy valves should allow device passage and should not become detached during instrument usage and exchange.	Pass
Backflow testing (through check valve attached to irrigation line)	The BioShield Biopsy Valve Irrigator Olympus/Fuji and Pentax must not leak through the check valve located on the irrigation line while the endoscope is pressurized.	Pass
Irrigation Testing using the BioShield Irrigating Adaptor	During irrigation, the biopsy valve should not experience spraying geyser type leaks.	Pass
Irrigation Testing Using the Irrigation Extension Tubing (Flow Rate Testing)	The average amount of water displaced when using the BioShield Irrigation Extension tubing must be equal to ± 15% of the average amount of water displaced when the BioShield Irrigation tubing was not used. Also, water flow should not occur when the pinch clamp is closed.	Pass

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data (bench and simulated use testing), the subject device has shown to be substantially equivalent to the predicate and having met the acceptance criteria based on its indications for use.