November 6, 2020

Steris Corporation
Jacqueline Oliver
Regulatory Affairs Specialist
5976 Heisley Rd
Mentor, OH 44060

Re: K202583
Trade/Device Name: BioShield biopsy valve EUS - Linear
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODD
Dated: September 3, 2020
Received: September 8, 2020

Dear Jacqueline 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 (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)*
K202583

Device Name
BioShield® biopsy valve EUS - Linear

Indications for Use *(Describe)*
The single use BioShield® biopsy valve EUS is used to cover the opening to the biopsy/suction channel of flexible echoendoscopes. 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.

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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510(k) Summary
For the
BioShield® biopsy valve EUS - Linear

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Jackie Oliver
Regulatory Affairs Specialist
Tel: 440-358-6289
Email: Jackie_oliver@steris.com

Summary Date: September 1, 2020

1. Device Name

Trade/Device Name:	BioShield biopsy valve EUS - Linear
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and accessories
Regulatory Class:	Class II
Product Code:	ODD

2. Predicate Device

K070420	BioShield ERCP Biopsy Valve

3. Description of Device

The BioShield® biopsy valve EUS - Linear is an accessory to a linear echoendoscope. The EUS biopsy valve allows the end user to cover the accessory port of a linear echoendoscope. The BioShield® biopsy valve EUS - Linear consists of tether and cap. The biopsy valves' cap can be removed from the accessory port while being held on the echoendoscope via the tether to the cap.

The biopsy valve is a single-use, disposable device that is supplied sterile or non-sterile.

4. Indications for Use

The single use BioShield® biopsy valve EUS is used to cover the opening to the biopsy/suction channel of flexible echoendoscopes. 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.

5. Technological Characteristic Comparison Table

The BioShield® biopsy valve EUS - Linear is similar in design to the predicate and has similar intended uses. 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 BioShield® biopsy valve EUS - Linear is used on linear echoendoscopes that have different dimensions than the endoscopes that are used with the predicate device. 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	BioShield® biopsy valve EUS - Linear (Proposed)	BioShield ERCP Valve (Predicate K070420)	Comparison
Indications for use	The single use BioShield® biopsy valve EUS is used to cover the opening to the biopsy/suction channel of flexible echoendoscopes. 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 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.	Similar
Construction	Valve Body Valve Cap	Valve Body Valve Body Insert Valve Cap	Similar
Sterile/Non-sterile	Sterile & Non-sterile	Sterile & Non-sterile	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterilization Assurance Level	10^{-6}	10^{-6}	Same
Usage	Single use	Single use	Same
Materials	Thermoplastic Elastomer	Thermoplastic Elastomer	Same

Feature	BioShield® biopsy valve EUS - Linear (Proposed)	BioShield ERCP Valve (Predicate K070420)	Comparison
Device Dimensions	Length: 0.52” Width: 0.52” Height: 0.77”	Length: 0.87” Width w/side-tabs 0.88” Height: 0.86”	Similar
Target Population	GI Endoscopic procedures	GI Endoscopic procedures	Same
Energy Used/Delivered	None	None	Same
Method of Application	Manual application	Manual application	Same
Compatible Endoscopes	Linear Echoendoscopes	Olympus & G5 and newer Fujinon gastrointestinal endoscopes	Similar
Packaging	Polybag (non-sterile) Peel Pouch (sterile)	Polybag (non-sterile) Peel Pouch (sterile)	Same

6. Description of Safety and Substantial Equivalence

Testing for the proposed biopsy valves, both sterile and non-sterile showed they were comparable to the predicate devices in maintaining insufflation, allowing for device exchange and minimizing leakage from the biopsy port. The proposed devices met all acceptance criteria of the verification testing.
Performance testing includes:

Bench Testing Summary

Performance testing was conducted to demonstrate that the proposed BioShield biopsy valve EUS are comparable to the predicate K070402 devices.

A summary of the testing conducted is provided in the table below:

Summary of Tests Conducted for the BioShield biopsy valve EUS - Linear

Testing	Acceptance Criteria
Retention Force Testing	The retention force of the BioShield EUS biopsy valve - Linear (sterile & non-sterile) must be equal to or greater than the predicate device.
Leakage Testing	The BioShield biopsy valve EUS - Linear (sterile & non-sterile) must be comparable to or better than the predicate device. The device(s) shall not spray or experience geyser type leaks while pressurized.
Device Exchange Testing	The BioShield biopsy valve EUS - Linear should allow device passage and should not become detached during instrument usage and exchange.
Shelf Life Testing	The proposed devices were accelerated aged for a period equal to one year of real-time aging prior to conducting the testing provided in this submission.

Provided below is a detailed summary of the testing activities.

Retention Force Testing
Objective: This test was intended to determine the force required to remove the proposed devices, the BioShield Biopsy Valves EUS - Linear (sterile & non-sterile) from the echoendoscope and compare those results to the predicate device.

Sample: Fifteen BioShield biopsy valves EUS - Linear (non-sterile) from 3 different lots (5 from each lot) and 15 BioShield biopsy valves EUS - Linear (sterile) from 3 different lots (5 from each lot) were used for testing.

Procedure: The testing procedure included the use of a calibrated force gauge to measure tensile force in pounds. The BioShield biopsy valve EUS - Linear (non-sterile) was attached to the inlet port of an echoendoscope. The valve was pulled off the endoscope and the force required to remove the biopsy valve from the linear echoendoscope was measured. This procedure was repeated for the remaining non-sterile valves and the sterile valves.

Standards utilized: None

Leakage Testing
Objective: To establish that the proposed devices, the BioShield Biopsy Valves EUS – Linear (sterile & non-sterile), do not leak when attached to a pressurized echoendoscope.

Sample: Fifteen BioShield biopsy valves EUS - Linear (non-sterile) from 3 different lots (5 from each lot) and 15 BioShield biopsy valves EUS - Linear (sterile) from 3 different lots (5 from each lot) were used for testing.

Procedure: Attach the BioShield biopsy valve EUS – Linear (non-sterile) to the inlet port of the echoendoscope. Affix a pressure tube assembly at the end of the linear echoendoscope and introduce 5 psi of water pressure up the accessory channel. Verify that leaks do not occur at the biopsy valve cap while the accessory channel is pressurized. Repeat this procedure for the remaining non-sterile valves and the sterile valves.

Standards Utilized: None

Device Exchange Testing
Objective: To establish that the proposed devices, the BioShield Biopsy Valves EUS – Linear (sterile & non-sterile), allow for the passage of endoscopic devices of varying sizes.

Sample: Fifteen BioShield biopsy valves EUS - Linear (non-sterile) from 3 different lots (5 from each lot) and 15 BioShield biopsy valves EUS - Linear (sterile) from 3 different lots (5 from each lot) were used for testing.

Procedure: Secure a linear echoendoscope to the lab bench in a tortuous configuration. Attach the BioShield Biopsy Valve EUS – Linear (non-sterile) to the inlet port of the echoendoscope. Insert and remove the below listed devices. Test insertion and removal of the following device types: biopsy forceps and injection needles.

Standards Utilized: None

Shelf Life Testing (Accelerated aging)
Tested in accordance with Standard: ASTM F1980-16 - Standard Guide For Accelerated Aging Of Sterile Barrier Systems for Medical devices.

Biocompatibility Testing:
Cytotoxicity: Tested in accordance with ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity

Irritation: Tested in accordance with ISO 10993-10: 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization

Sensitization: Tested in accordance with ISO 10993- 10: 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization

Sterilization

Tested in accordance with AAMI/ANSI/ISO 11135-1:2014, Sterilization of health care products - Ethylene Oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical device