



October 20, 2023

Steris
Carroll Martin
Director, Regulatory Affairs
5976 Heisley Rd
Mentor, Ohio 44060

Re: K232951

Trade/Device Name: BioShield Biopsy Valve (00711124); BioShield Biopsy Valve (00711125); BioShield Biopsy Valve (00711126); BioShield Biopsy Valve (00711127); BioShield Biopsy Valve (00711129); BioShield Biopsy Valve (00711135); BioShield Biopsy Valve (00711136); BioShield Biopsy Valve - sterile (00711128); BioShield Irrigator (00711133); BioShield Irrigator (00711137); BioShield Irrigating Adaptor (00711131); BioShield Irrigator - extension tubing (00711134)

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and Accessories

Regulatory Class: Class II

Product Code: ODC, OCX

Dated: September 18, 2023

Received: September 21, 2023

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 (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 Gastorenal, ObGyn,
General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K232951

Device Name

BioShield Biopsy Valve (00711127); BioShield Biopsy Valve (00711129); BioShield Biopsy Valve (00711135); BioShield Biopsy Valve (00711136); BioShield Biopsy Valve - sterile (00711128); BioShield Irrigator (00711133); BioShield Irrigator (00711137); BioShield Irrigating Adaptor (00711131); BioShield Irrigator - extension tubing (00711134)

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.

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**510(k) Summary for the
BioShield Biopsy Valve
BioShield Irrigator – extension tubing
BioShield Irrigating Adaptor**

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: September 18, 2023

1. **Device Name**

Trade Name: BioShield Biopsy Valve
BioShield Irrigator – Extension Tubing
BioShield Irrigating Adaptor
Device Class: Class II
Regulation Name: Endoscope channel accessory
Endoscopic irrigation/suction system
Common/usual Name: Biopsy Valve
Regulation Number: 21 CFR 876.1500
Product Code: ODC, OCX

2. **Predicate Device**

BioShield – ERCP Biopsy Valve, K210342
BioShield Irrigator – Extension Tubing, K210342
BioShield Irrigating Adaptor, K210342

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 irrigation option for the user. All valves, with the exception of one version, are supplied non-sterile.

There are two irrigation devices 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 Irrigating Adaptor consists of a luer connection attached to a stainless-steel tip. The Bioshield Irrigating Adaptor 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 devices are provided non-sterile.

BioShield Biopsy Valves and Irrigation Devices

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 Irrigating Adaptor 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 Irrigating Adaptor and its predicate can be found in **Table 1**. There are no modifications to the BioShield Biopsy valves or the BioShield Irrigation Extension Tubing.

Table 1. Technological Characteristics Comparison Table

Features	BioShield Irrigating Adaptor, K210342 (Predicate Device)	Modified BioShield Irrigating Adaptor (Proposed Device)	Comparison
Intended Use	The BioShield Irrigating Adaptor is intended to be used with the biopsy valve to provide access for irrigation.	The BioShield Irrigating Adaptor is intended to be used with the biopsy valve to provide access for irrigation.	Identical
Construction	Hollow metal tube with standard plastic luer lock connector. No colorant.	Hollow metal tube (stainless steel) with standard plastic (polypropylene) luer lock connector. The luer lock has an amber colorant.	Similar. Testing has shown that the addition of the amber colorant has no impact on safety, effectiveness or device performance.

6. Summary of Non-Clinical Performance Testing

Non-clinical testing consisted of the following:

Testing	Acceptance Criteria	Results
Leakage Testing	The BioShield Irrigating Adaptor must not spray or experience geyser type leaks	Pass
Biocompatibility Testing	The BioShield Irrigating Adaptor patient-contacting materials must be non-cytotoxic, a non-sensitizer, a non-irritant and non-pyrogenic.	Pass

7. Conclusion

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