October 17, 2025

EndoSound, Inc.
Patrick Herriman
VP Quality
4640 S Macadam Ave, Suite 200
Portland, Oregon 97239

Re: K250145
Trade/Device Name: Biopsy Port Adapter
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: September 16, 2025
Received: September 16, 2025

Dear Patrick Herriman:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) #: K250145

# 510(k) Summary

Prepared on: 2025-10-17

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | EndoSound, Inc. |
| Applicant Address | 4640 S Macadam Ave, Suite 200 Portland OR 97239 United States |
| Applicant Contact Telephone | 425-985-8666 |
| Applicant Contact | Mr. Patrick Herriman |
| Applicant Contact Email | herriman@endosound.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Biopsy Port Adapter |
| Common Name | Endoscope and accessories |
| Classification Name | Endoscope Channel Accessory |
| Regulation Number | 876.1500 |
| Product Code(s) | ODC |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K210342 | BioShield Biopsy Valve | ODC |
| K163248 | Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle kit | EOQ |

## Device Description Summary

21 CFR 807.92(a)(4)

The Biopsy Port Adapter (BPA) converts the non-luer-lock biopsy/working channel port of an upper gastrointestinal endoscope into a luer-lock connector port to support Fine Needle Biopsy (FNB) and Fine Needle Aspiration (FNA) endoscopic procedures using luer-lock-type needles. The adapter also seals the port during use and maintains the ability of the scope to provide suction throughout the procedure. The BPA works in tandem with the EndoSound Vision System™ when performing ultrasound-guided FNA and FNB procedures.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The single-use Biopsy Port Adapter (BPA) converts the biopsy/working channel port of an upper gastrointestinal endoscope into a luer-lock connector port. This adapter supports luer-lock-connector fine needle biopsy (FNB) and fine needle aspiration (FNA) devices used during an EndoSound EVS endoscopic procedure, while maintaining scope suction.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The BPA and the predicate accessory adapter have the same intended use. Specifically, both devices are intended to provide a luer-lock for an endoscope connector port and seal the biopsy/working channel port.

The indications for use are slightly different in that the predicate device (the needle and the accessory adapter component) is indicated for use with a bronchoscope while the subject device is indicated for use with an upper GI endoscope.

Both indications fall under the broader intended use of providing a luer-lock for an endoscope connector port and sealing the biopsy/working channel port. The differences in indications do not introduce a new intended use, alter the device's fundamental purpose or raise new safety or effectiveness concerns, as demonstrated through comparative performance data and risk analysis.

## Technological Comparison 21 CFR 807.92(a)(6)

The Biopsy Port Adapter (BPA) shares similar technological characteristics with the listed predicate devices. The currently cleared BioShield Biopsy Valve (K210342), manufactured by Steris, serves a similar function as the EndoSound BPA by attaching to an endoscope connector port and providing sealing and device passage. The BioShield provides sealing and device passage but does not provide luer-lock conversion while the EndoSound BPA provides luer-lock port conversion, device sealing and device passage for upper GI endoscopes while maintaining suction during an endoscopic procedure.

The currently cleared Expect™ Pulmonary adaptor (a component of the Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle kit), (K163248), manufactured by Boston Scientific, serves a similar function as the EndoSound BPA in adapting a non-luer port of a bronchoscope into a luer-type port.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical performance testing was conducted on the proposed Biopsy Port Adapter (BPA) device per the EndoSound Quality Management System design controls in compliance with 21 CFR Part 820.30. Testing successfully demonstrated the BPA device and packaging met all specifications (verified design inputs and validated user needs) and shelf-life requirements at nominal and accelerated age time points.

The following bench tests were performed:

1. BPA to Scope Lock Force
2. BPA to Scope Unlock Force
3. BPA to Scope Suction
4. Needle to BPA to Scope Suction
5. Needle to BPA to Scope Tensile Strength
6. Needle to BPA to Scope Side Load Strength
7. Needle to BPA Unscrew Torque
8. Needle to BPA to Scope Over Torque
9. BPA Durability Cycling
10. Packaging (Package Integrity & Transportation Simulation)

Clinical Testing: N/A

EndoSound has demonstrated the proposed Biopsy Port Adapter is substantially equivalent to the predicate.

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