December 27, 2023

Endosound, Inc.
Patrick Herriman
VP Quality
4640 S. Macadam Ave Unit 200
Portland, OR 97239

Re: K232518
Trade/Device Name: EndoSound Vision System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODG, IYN, IYO, ITX
Dated: November 21, 2023
Received: November 28, 2023

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.

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
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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)*
K232518

Device Name
EndoSound Vision System

Indications for Use *(Describe)*

The EndoSound Vision System (EVS), when affixed to an endoscope, is intended to provide ultrasonic visualization of, and ultrasound guided therapeutic access to the Upper Gastrointestinal Tract including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum and underlying areas. The EVS, mounted on an endoscope, is introduced orally when indications consistent with the requirement for a GI procedure are met.

The EVS is a prescription only device to be used by a qualified physician.

The clinical environments where the system can be used include clinics, hospitals, and ambulatory surgery centers.

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)

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510(K) Summary

Identifying information

Manufacturer: EndoSound, Inc.

Device Trade Name: EndoSound Vision System

Address: 4640 S Macadam Avenue
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Portland, OR 97239

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Contact Person: Patrick Herriman, VP of Quality, EndoSound, Inc., herriman@endosound.com

Date 510(k) Summary Prepared: August 7th, 2023

Class and Predicate Information

Classification Name	Regulation Number	Product Code
Endoscopic Ultrasound System Gastroenterology-Urology	876.1500	ODG
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasonic Transducer	892.1570	ITX

Common Name: Endoscopic Ultrasound System

Proprietary Name: EndoSound Vision System (EVS)

Regulatory Class: Class II

Predicate Devices: Olympus GF Type UCT180, Olympus GF Type UST180, Evis Exera II Ultrasound Gastrovideoscope used with ALOKA SSD-a 10 Ultrasound System (K093395)

PENTAX Medical EG-J10U Endoscopic Ultrasound System with EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type) (used with Hitachi ARIETTA 70 Ultrasound console (K134016))

Reference Predicate Device: Telemed ArtUs Pulsed Doppler ultrasound imaging system (K211248)

LIST OF CONSENSUS STANDARDS

The EndoSound Vision System (EVS) was tested to be in conformance with the following consensus standards, with applicable test certifications included in this submission:

- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment –Part 1-2 General requirements for safety and essential performance –Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance, Collateral Standard: Usability
- IEC 60601-2-18 Medical Electrical Equipment – Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment
- IEC 60601-2-37 Medical electrical equipment –Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- IEC 62304 Medical device software - Software life cycle processes.
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 14971 Medical devices - Application of risk management to medical devices.
- ISO 15223-1 Medical devices - Symbols to be used with medical device labels labelling and information to be supplied - Part 1: General requirements.
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11 Biological evaluation of medical devices - Part 11: Acute Cytotoxicity

Indication for Use

The EndoSound Vision System (EVS), when affixed to an endoscope, is intended to provide ultrasonic visualization of, and ultrasound guided therapeutic access to the Upper Gastrointestinal Tract including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum and underlying areas. The EVS, mounted on an endoscope, is introduced orally when indications consistent with the requirement for a GI procedure are met.

The EVS is a prescription only device to be used by a qualified physician.

The clinical environments where the system can be used include clinics, hospitals, and ambulatory surgery centers.

Device Description

The EndoSound Vision System® (EVS) is an add-on ultrasound system designed to attach externally to an upper gastrointestinal (GI) endoscope (gastroscope/upper (EGD) endoscope). Once attached, it temporarily converts an EGD endoscope to a fully capable EUS endoscope. The EVS consists of:

- an electronic ultrasound beamformer/image analyzer (EVSScanner),
- a reusable transducer assembly (Ultrasound Transducer Module (UTM)),
- a cable/connector to interface the transducer to the beamformer (Transducer Extension Cable (TEC)),
- a sterile, disposable mounting kit with an operator control mechanism (Ultrasound Disposable Kit (UDK-T)) used to externally affix the EVS to a standard gastroscope/upper (EGD) endoscope and to provide needle and transducer angle control.

When attached to an upper GI endoscope, the EVS enables real-time ultrasound imaging, ultrasound guided needle aspiration and other EUS guided procedures within the upper gastrointestinal tract and surrounding organs. Native functions of the gastroscope including video imaging, articulation insufflation and suctioning are available after attachment of the EVS device. The system works in tandem with a PC computer/monitor/tablet connected via a USB 3.0 cable that runs custom software (EVSViewer) and provides the user interface and ultrasound display. The EVS components and technical characteristics are described individually below.

EVSScanner (Beamformer): The EVSScanner is a small, portable, self-contained module that contains the electronics that perform the ultrasound scanning and receiving functions (beamforming). The beamformer is the commercially available ArtUs ultrasonic system (K211248) manufactured by Telemed with a firmware modification that allows the system to recognize the EndoSound transducer. The device produces real-time ultrasound images in combination with the EVS curved linear array transducer and a computer/display running EVSViewer software.

Ultrasound Transducer Module (UTM): The UTM is a 6.4mm radius-of-curvature (ROC) convex, 96-element, curved-linear ultrasound array imaging over a frequency range from 5 to 12 MHz. The array produces a fixed ultrasound field-of-view of 150 degrees. The array is connected to a flat, multi-wire cable to a waterproof connector. The transducer is designed to be high-level disinfected using Cidex OPA as commonly employed for gastroscopes and EUS scopes.

Transducer Extension Cable (TEC)

The TEC consists of a multiwire coax cable with connector interfaces on each end. One end plugs into the EVSScanner and the other end plugs into the UTM. It functions as an extension cable to extend the length of the UTM while in use and the UTM facing connector provides a waterproof seal with the UTM while in use.

EVSViewer Software: The EVSViewer is the software run on a PC/monitor which processes the ultrasound data received from the EVSScanner module and displays the ultrasound image. It also functions to produce the user interface on the computer monitor. The software is equivalent to the Echo Wave II software manufactured by Telemed (K211248) with the following changes:

- EVS Probe Integration: The EVS UTM probe was integrated to work with the base software.
- Probe Recognition Function: The probe recognition function was altered to read a single-wire EEPROM (electronic chip) residing in the EVS UTM.

- UTM Counter in the EVSViewer: A dialog box displays upon bootup requiring the user to press a button to proceed, debiting the number of preprogrammed uses of the UTM attached array until the probe is locked out.

- Ultrasound Field of View (FOV) lock: The EVSViewer removes the ability of the user to change the ultrasound field-of-view (only the full 150-degree field of view is allowed).

- EndoSound Splash Screen: Displays an EndoSound splash screen upon bootup.

- Insert EndoSound Icons: EndoSound branded small icons are displayed on the user interface.

All changes to the software have been verified and validated.

Ultrasound Disposable Kit (UDK-T)

The UDK-T is a disposable, single-use kit provided sterile, that is used to attach the EVS to the compatible endoscope and provide transducer and needle articulation in addition to the native gastroscope controls. Sterility and shelf-life testing for six-month life was conducted and reports may be found in Appendix 4, Clinical Safety & Effectiveness. Silicone sleeves are included to protect the endoscope and help secure it to compatible gastroscopes. The control wire is terminated to a control knob which is affixed to the proximal end of the gastroscope. The control knob allows the transducer assembly as well as any needle inserted through the working channel to be articulated/deflected over a working range.

Comparison Table to Predicate Devices

Table 1	**Proposed Device (this submission)**	**Predicate Device**	**Predicate Device**
Device Name	EndoSound Vision System (EVS)	Evis Exera II Ultrasound Gastrovideoscope (Olympus GF-UCT180) (used with ALOKA SSD-a 10 Ultrasound System)	PENTAX Medical EG-J10U Endoscopic Ultrasound System with EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type) (used with Hitachi ARIETTA 70 Ultrasound console (K134016))
Manufacturer	EndoSound, Inc.	Olympus	Pentax
510(k) Number	K232518	K093395	K200090
Product Code	IYN, IYO, ITX, ODG	IYN, IYO, ITX, ODG, NWB	IYN, IYO, ITX, ODG

Indications for Use	The EndoSound Vision System (EVS), when affixed to an endoscope, is intended to provide ultrasonic visualization of, and ultrasound guided therapeutic access to the Upper Gastrointestinal Tract including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum and underlying areas. The EVS, mounted on an endoscope, is introduced orally when indications consistent with the requirement for a GI procedure are met.	This instrument has been designed to be used with an Olympus universal endoscopic ultrasound center or a diagnostic ultrasound system (ALOKA CO. LTD), video system center, light source, documentation equipment, monitor, EndoTherapy accessories and other ancillary equipment. This instrument is designed for endoscopic real-time ultrasound imaging, ultrasound guided needle aspiration and other endoscopic procedures within the upper gastrointestinal tract and surrounding organs	The PENTAX Medical Endoscopic Ultrasound System is intended to provide optical visualization of ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Track including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.
Endoscope Compatibility	Gastroscopes/endoscopes with bending section diameters from 9.5-11.5mm	NA	NA
Distal Mechanical Dimensions (As attached to compatible endoscope)	Height in attachment region (max): 19.4 mm Width in attachment region (max): 13.5mm	Diameter: 15.5 mm	Diameter 14.65 mm
Working Length	1167 mm	1250 mm	1250 mm
Attachment method	Disposable component	NA	NA
Needle deflection	Disposable component with wire control of transducer assembly and needle deflection	Integral mechanical elevator	Integral mechanical elevator
Ultrasound Transducer Type	Convex Curved Linear	Convex Curved Linear	Convex Curved Linear
Transducer Radius of Curvature	6.4 mm	5 mm	6 mm

Imaging Modes	B, M, Pulse Wave Doppler (PWD), Color Doppler (CFM), Power Doppler (PDI), Directional Power Doppler (DPDI), Combined modes (B+B, B+M, 4B, B+PWD (Duplex), B+CFM/PDI/DPDI+PWD (Triplex)), Tissue Harmonic Imaging (THI) and Inverted Tissue Harmonic Imaging (ITHI)	B, M, Color Doppler, Power Doppler, Pulse Wave Doppler, Combined modes: B/M, B/PWD, M/CD, B/CD/PWD, B/CWD, B/CD/CWD B/CD/PWD	Bmode, Mmode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, Real-Time Tissue Elastography, and Real Time Virtual Sonography.
Scanning Direction	Parallel to insertion direction (adjustable to forward viewing)	Parallel to insertion direction	Parallel to insertion direction
Scanning Frequencies	5, 5.3, 6.7, 8, 9, 11 MHz	5, 6, 7.5, 10, 12 MHz	5.0, 6.5, 7.5, 10.0, 13.0 MHz
Ultrasound Field of View	150 degrees	180 degrees	150 degrees
Contacting Method	Direct	Balloon, Direct	Balloon, Direct
Transducer Articulation Range (using UDK control) (relative to endoscope axis)	5-85 degrees	Fixed	Fixed
Bending portion angulation range	UP 157^0, DOWN 73^0 RIGHT 87^0 LEFT 80^0 (Typical, attached to Pentax 29i10 gastroscope)	UP 130^0, DOWN 90^0 RIGHT 90^0 LEFT 90^0	UP 160^0, DOWN 130^0 RIGHT 120^0 LEFT 120^0
Transducer Surface Temperature (Maximum)	41 degrees C	43 degrees C	43 degrees C
Ingress Protection Rating	IPX7/IPX8	IPX7	IPX7
Electrosurgery compatible	Yes	Yes	Yes
Acoustic Output	Track 3 Compliant	Track 3 Compliant	Track 3 Compliant

Disinfection Compatibility	Liquid Chemical High Level Disinfection	Liquid Chemical High Level Disinfection	Liquid Chemical High Level Disinfection

General Safety and Effectiveness

Ultrasound Scanning

The EVSScanner employs the same basic principles of operation including signal generation, digital acquisition, processing, and display as the predicate device. The transducer is of the same principal design and form and uses similar transduction processes to generate and receive the ultrasound signal. Phantom and *in vivo* study comparison images show similar scanning resolution, image quality and ultrasound image performance. The EVS has no ultrasound characteristics, modes, or features that are not previously evaluated or present in the predicate device, or that are not commonly used in traditional ultrasound systems.

Physical Characteristics

The EVS is placed on an upper GI gastroscope to create a device similar in performance to a dedicated ultrasound endoscope. In the EVS the cabling and control wires are external to the endoscope, whereas in the predicates, the control wires and electronic cabling are interior to the endoscope. For efficient management of the external cabling, the UDK-T control wire is wrapped around the endoscope during attachment, which manages the external electronic cabling to the endoscope. Verification and Validation testing has shown that the external cabling does not impact the performance and safety of the EVS relative to the listed predicates. Once attached, the physical form, ultrasound image, and physical manipulations of the device are substantially equivalent to the listed predicates.

The EVS varies from the predicate in the manner of deflection of the needle The predicate devices use a built-in elevator mechanism to deflect the needle whereas the EVS uses an external, disposable attachable kit (UDK-T) to manipulate the needle to the intended target. The process entails using the UDK-T Control Knob to alter the articulation of the transducer assembly. This allows the needle to be inserted through a built-in slot in the EVS to place the needle in the ultrasound scan plane. Once through the aperture, the directed movement of the transducer assembly deflects the needle. Overall, the physical attribute differences do not impact safety or efficacy of the combined system or performance as compared to the predicate devices as reported in the study data in the body of this submission.

Biocompatibility

A summary of the successfully completed biological safety testing on components of the EVS in contact with the patient is shown in Table 2.

Table 2. Summary of Completed ISO 10993-1 Tests Performed

Ultrasound Disposable kit (UDK-T) PN 18040 Ultrasound Transducer Module (UTM) PN 18010	
Cytotoxicity	ISO 10993-5
Sensitization	ISO 10993-10
Irritation	ISO 10993-23 or ISO 10993-10
Acute systemic toxicity	ISO 10993-11:2017

UTM Reprocessing

Manual Cleaning, High-Level Disinfection and Rinsing Validation studies were performed on the EVS UTM by an outside GLP accredited laboratory with passing results.

UDK Sterilization and Packaging Integrity, ECH and ETO Residual Testing

The UDK-T sterile kit (PN 18040) is sterilized using ETO sterilization. Packaging Verification including sterilization efficacy testing was performed at time T0 (after manufacture) and time T1 (post 6 months accelerated aging).

Animal Testing

A GLP lab study was performed comparing safety and performance of the EVS with a predicate endoscope (PENTAX EG-3870UTK EUS scope) (K130247, K182004). The study was conducted with an expert endoscopist as the user under the supervision of the GLP quality director and the study director. A detailed optical and endoscopic ultrasound regimen was utilized for both the EVS and the control device. The regimen was implemented four times in each of 3 live animal models.

Study results included:

Overall Safety Assessment: Following the completion of six procedures, no clinically relevant damage was identified, either radiologically, endoscopically, or macroscopically.

Optical and EUS imaging: The study incorporated both standard endoscopic (i.e., optical) assessment and complete EUS assessment. The comparison of images obtained from these tests revealed no significant differences from the control, suggesting that the EVS is substantially equivalent to the control device in terms of imaging quality.

Behavior of EVS during Needle Targeting: No issues or remarkable differences were observed when angulating the EVS to the same extent as the predicate device. The clinical behavior of the EVS is substantially equivalent to the control device. The EVS successfully conducted procedures in the evaluated scenarios.

Endoscope and Device Maneuverability: The study evaluated the manipulation of both the endoscope and the EVS device. The findings suggest that mounting the EVS on the endoscope does not have a significant impact on the bending and maneuverability of the endoscope compared to when the EVS is not mounted.

Cable management: No cable trapping of mucosal tissue between the cable and the endoscope occurred during use, or any other damage to the upper GIT occurred throughout the study.

Verification and validation testing for the EVS was completed in accordance with EndoSound's Design and Control process in compliance with 21 CFR Part 820.30. Successful results of testing are included in the body of this submission.

Potential risks of the EVS were identified according to ISO 14971. Mitigations were implemented and tested as part of the performance testing described above, with all mitigations verified and validated as documented in the attached risk management file. Technological differences from the predicate were shown not to result in any new issues of safety or efficacy according to the performance data submitted.

Conclusion

Based on a comparison of physical characteristics, safety testing and animal studies performed, and conformance to consensus standards cited above and information provided in this Premarket notification, EndoSound considers the EVS to be as safe and effective and the performance is substantially equivalent to the predicate devices described herein.