September 18, 2024

EdgeLife Technologies LLC
% Quinn Place
Chief Operating Officer
485 Brickell Avenue
Suite 4802
Miami, Florida 33031

Re: K234153
Trade/Device Name: EdgeLife Handheld Wireless Ultrasound System (E8200); EdgeLife Handheld Wireless Ultrasound System (E8220)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 13, 2023
Received: August 23, 2024

Dear Quinn Place:

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234153

Device Name
EdgeLife Handheld Wireless Ultrasound System (E8200);
EdgeLife Handheld Wireless Ultrasound System (E8220)

Indications for Use *(Describe)*
The EdgeLife Handheld Wireless Ultrasound System is a general-purpose, handheld, wireless, portable software-controlled ultrasonic diagnostic system that uses pulsed-echo technology to acquire and display ultrasound data in B-Mode, M-Mode, Color Doppler, and Pulse-Wave Doppler (PW) modes. The EdgeLife Handheld Wireless Ultrasound System is intended for diagnostic ultrasound echo imaging, measurement, and fluid flow analysis of the human body for the following clinical applications.

The specific clinical applications and exam types for the linear transducer include vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, abdominal, intraoperative (excluding neurological, central nervous system, non-central cardiovascular system), urology, gynecology, pediatric, fetal, peripheral vessel, carotid, interventional and procedure guidance of needles into the body.

The specific clinical applications and exam types for the convex transducer include: abdominal, pulmonary, thoracic, intra-operative (abdominal organs & vascular), pediatric, small organ, urology, gynecology, obstetrics, musculoskeletal (conventional and superficial), vascular, carotid, and cardiac (adult and pediatric).

The specific clinical applications and exam types for the Endocavitary transducer include gynecology, obstetrics, urology, transvaginal, transrectal, and interventional procedures.

The system is a portable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

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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K234153

EdgeLife Handheld Wireless Ultrasound System - 510(k) Summary

The following 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR § 807.92.

Subject Device Trade Name:	EdgeLife Handheld Wireless Ultrasound System
Subject Device Model Numbers:	E8200, E8220
Common Name:	Diagnostic Ultrasound System and Accessories

1.1 Regulation Number, Name and Product Codes

Regulation Number	Regulation Name	Product Code
21 CFR § 892.1550	Ultrasonic Pulsed Doppler Imaging System	IYN
21 CFR § 892.1560	Ultrasonic Pulsed Doppler Imaging System	IYO
21 CFR § 892.1570	Diagnostic Ultrasonic Transducer	ITX

FDA 510(k) Review Panel:	Radiology
Classification:	Class II
Manufacturer:	Edge Life Technologies 485 Brickell Avenue, Suite 4802 Miami, Florida 33031 U.S.A.
Contact Name:	Quinn Place, Chief Operating Officer qplace@edgelifetech.com
Date 510(k) Summary Prepared:	December 20, 2023
Predicate Device:	Vscan Air K202035
Reference Device:	Clarius Ultrasound Scanner K192107

1.2 Device Description

The EdgeLife Handheld Wireless Ultrasound System, including Scanners, follows Track 3.

The EdgeLife Handheld Wireless Ultrasound System is a general-purpose, handheld, wireless, portable software-controlled ultrasonic diagnostic system that uses pulsed-echo technology to acquire and display ultrasound data in B-Mode, M-Mode, Color Doppler, and Pulse-Wave Doppler (PW) modes.

The EdgeLife Ultrasound Scanner receives instructions from and transmits images to the EdgeLife Ultrasound App running on a paired mobile device that utilizes the iOS operating system via wireless Wi-Fi communication.

The system is a transportable ultrasound system intended for use in environments where healthcare is provided.

The EdgeLife Handheld Wireless Ultrasound System consists of:

- EdgeLife Handheld Ultrasound Scanner:
    - Model E8200 with convex and linear transducers
    - Model E8220 with convex and endocavitary transducers
- EdgeLife Ultrasound App
- Standard off-the-shelf Wireless Qi charger (not a medical device)

1.2.1 Indications for Use

The EdgeLife Handheld Wireless Ultrasound System is a general-purpose, handheld, wireless, portable software-controlled ultrasonic diagnostic system that uses pulsed-echo technology to acquire and display ultrasound data in B-Mode, M-Mode, Color Doppler, and Pulse-Wave Doppler (PW) modes. The EdgeLife Handheld Wireless Ultrasound System is intended for diagnostic ultrasound echo imaging, measurement, and fluid flow analysis of the human body for the following clinical applications.

The specific clinical applications and exam types for the linear transducer include vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, abdominal, intraoperative (excluding neurological, central nervous system,

non-central cardiovascular system), urology, gynecology, pediatric, fetal, peripheral vessel, carotid, interventional and procedure guidance of needles into the body.

The specific clinical applications and exam types for the convex transducer include: abdominal, pulmonary, thoracic, intra-operative (abdominal organs & vascular), pediatric, small organ, urology, gynecology, obstetrics, musculoskeletal (conventional and superficial), vascular, carotid, and cardiac (adult and pediatric).

The specific clinical applications and exam types for the Endocavitary transducer include gynecology, obstetrics, urology, transvaginal, transrectal, and interventional procedures.

The system is a portable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

1.2.2 Comparison of Subject Device and Predicate Device

Comparison of intended use and technological characteristics between EdgeLife Handheld Wireless Ultrasound Scanner and the predicate device, Vscan Air, is presented in the following table.

	EdgeLife Handheld Wireless Ultrasound System	**Vscan Air (K202035)**	**Substantial Equivalence Comparison**
Scanner Type	Dual-Headed	Dual-Headed	Same
Transducer	Convex and Linear (E8200) Convex and Endocavitary (E8220)	Convex and Linear	Similar The subject and predicate have the same convex and linear transducers. The subject device also includes an endocavitary transducer on one of the dual headed probes. Endocavitary transducers are commonly found in current ultrasound systems including the predicate device. Performance test results support that this

	EdgeLife Handheld Wireless Ultrasound System	Vscan Air (K202035)	Substantial Equivalence Comparison
			difference does not raise new questions of safety and effectiveness.
Classification	Class II	Class II	Same
Product Codes	IYN, IYO, ITX	ITX, IYN, IYO	Same
Clinical Settings	Hospitals, clinics and other professional healthcare facility settings	Hospitals, clinics and medical office settings, home, emergency environments	Similar. The only difference is that the subject device is not intended for use in home health or road/air ambulance environments. This difference does not raise new questions of safety and effectiveness.
Users	Trained Healthcare professionals	Trained Healthcare professionals	Same
Patient Population	adult and pediatric	adult and pediatric	Same
Intended Use	Diagnostic ultrasound imaging and fluid flow analysis.	Diagnostic ultrasound imaging and fluid flow analysis	Same
Indications for Use	The EdgeLife Handheld Wireless Ultrasound System is a general-purpose, handheld, wireless, portable software-controlled ultrasonic diagnostic system that uses pulsed-echo technology to acquire and display ultrasound data in B-Mode, M-Mode, Color Doppler, and Pulse-Wave Doppler (PW) modes. The EdgeLife Handheld Wireless Ultrasound System is intended for diagnostic ultrasound echo	Refer to K202035 510(k) Summary.	Similar. Both subject and predicate devices are intended for diagnostic ultrasound echo imaging, measurement and analysis of the human body for the same applications. The subject device also includes an endocavitary transducer that allows for clinical applications including gynecology, obstetrics, urology, transvaginal, transrectal, and interventional procedures. These standard clinical

	EdgeLife Handheld Wireless Ultrasound System	Vscan Air (K202035)	Substantial Equivalence Comparison
	imaging, measurement, and fluid flow analysis of the human body for the following clinical applications. The specific clinical applications and exam types for the linear transducer include vascular/peripheral vascular, musculoskeletal (conventional and superficial), small organs, thoracic/lung, abdominal, intraoperative (excluding neurological, central nervous system, non-central cardiovascular system), urology, gynecology, pediatric, fetal, peripheral vessel, carotid, interventional and procedure guidance of needles into the body. The specific clinical applications and exam types for the convex transducer include: abdominal, pulmonary, thoracic, intra-operative (abdominal organs & vascular), pediatric, small organ, urology, gynecology, obstetrics, musculoskeletal (conventional and superficial), vascular, carotid, and cardiac (adult and pediatric).		application types are found in other legally marketed ultrasound systems including the Reference Device and are not novel. Performance data support the indications for use. Therefore, these differences do not raise new questions of safety and effectiveness.

	EdgeLife Handheld Wireless Ultrasound System	Vscan Air (K202035)	Substantial Equivalence Comparison
	The specific clinical applications and exam types for the Endocavitary transducer include gynecology, obstetrics, urology, transvaginal, transrectal, and interventional procedures. The system is a portable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.		
Portability	Handheld portable	Handheld portable	Same
System Components	Dual-headed probes Mobile app Charger	Dual-headed probe Mobile app Charger	Same.
Frequency	Convex:2-5 MHz with center frequency of 3.2 Mhz Linear 4-12 MHz, with center frequency of 7.5 MHz Endocavitary: 4-9 MHz with the center frequency of 6.5 MHz	Convex: from 2 - 5 MHz with center frequency of 3.3 MHz Linear: From 3 - 12 MHz with center frequency of 7.7 MHz	Similar. The differences don't raise any issues about safety and effectiveness of the device.
Elements	All transducers have 128 elements	GE: Linear 192, convex: 192	Similar. The differences don't raise any issues about safety and effectiveness of the device.
Display	iOS device	iOS or Android device	Similar. This difference does not raise new questions of safety or effectiveness.

	EdgeLife Handheld Wireless Ultrasound System	Vscan Air (K202035)	Substantial Equivalence Comparison
Software	Mobile app downloads on iOS viewing device	Mobile app downloads on iOS and Android viewing device	Similar. This difference does not raise new questions of safety or effectiveness.
Image Format	JPG and DICOM, DICOM transfer to PACS or imaging archive systems	JPG and DICOM, DICOM transfer to PACS or imaging archive systems	Same
Penetration depth	Convex up to 30 cm Linear < 8 cm Endocavity < 12 cm	Convex up to 24 cm and linear up to 8 cm	Similar. The linear end has the same maximum penetration depth. Performance data support that the penetration depths of the Subject devices don't raise any issues about safety and effectiveness of the device.
Principle of Operation	Piezoelectric transducer elements.	Piezoelectric transducer elements	Same.
Power Source	Built in lithium-ion Battery	Built in lithium-ion Battery	Same
Charging Plate	Anker and other off-the shelf charging plates.	Anker	Similar. The performance doesn't raise any issues about safety and effectiveness of the device.
Battery And Charging	Rechargeable internal battery	Rechargeable internal battery	Same
Wireless Capability	Wi-Fi directly communicates between the probe and mobile device	Wi-Fi directly communicates between the	Same

	EdgeLife Handheld Wireless Ultrasound System	Vscan Air (K202035)	Substantial Equivalence Comparison
		probe and mobile device	
Connectivity Requirements	IEEE 802.11n/5GHz	IEEE 802.11n Peer-to-peer connectivity (Android only) Bluetooth BLE 4.0	Similar. Differences do not raise questions of safety and effectiveness.
Security Protocols	The scanner's Wi-Fi uses WPA2 security and requires a password when first connecting to the Mobile Device.	Enterprise-grade wireless encryption standards including EAP and WPA2 (PSK).	Similar. Differences do not raise questions of safety and effectiveness.
Modes of Operation	B-Mode M-Mode Color Doppler Pulsed Wave Doppler (PW)	B-mode Color Doppler B+Color Doppler Harmonic imaging	Similar. Both devices incorporate well-established ultrasound modes and the subject device does not introduce novel modes of operation. Therefore, this difference does not raise questions of safety and effectiveness.
Acoustic Output	Track 3	Track 3	Same
Electrical Safety and EMC, Acoustic Output	Track 3 ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 62359 IEC 60601-2-37	Track 3 ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-2-37 IEC 60601-1-11 IEC 62359	Similar. The only exception is the subject device has not undergone EMC testing for the home use environment.
Biocompatibility	ISO 10993-1	ISO 10993-1	Same

The subject device shares the same intended use, principle of operation and similar technological characteristics as the predicate device. Similarities include portability, wireless handheld

dual-headed transducer probes, mobile app, convex and linear transducers. The main differences from the predicate are the endocavitary transducer head and inclusion of Pulsed Wave Doppler (PW) mode. The PW mode is a well-established mode of operation. The endocavitary transducer also does not represent novel technology and has been cleared in several legally marketed ultrasound systems including the Reference Device, Clarius Ultrasound System K192017. Performance testing including IEC 60601-2-37 demonstrate that these differences do not raise new questions of safety and effectiveness.

1.2.3 Non-Clinical Performance Testing

The following performance data are provided in support of the substantial equivalence determination between the subject device and predicate device.

Table 4: Summary of Non-Clinical Performance Testing

Test	Title/Test Method Summary	Results
Biocompatibility		
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Irritation	ISO 10993-23 Skin Irritation	Non-irritating
	ISO 10993-23 Vaginal Irritation	Non-irritating
Sensitization	ISO 10993-10	Non-sensitizing
Thermal, Electrical, and Mechanical Safety		
Electrical Safety	ANSI AAMI ES 60601-1	Pass
Battery Safety	IEC 62133-2 UN38.3	Pass
Electromagnetic Compatibility	IEC 60601-1-2	Pass
Wireless Coexistence	ANSI C63.27 AAMI TIR69	Pass
FCC Certification	FCC 15, FCC 18	Certified
Acoustic Output	IEC 60601-2-37 IEC 62359	Pass, Track 3
Cleaning and Disinfection		
Model E8200	AAMI TIR30, AAMI TIR12	Pass
Model E8220	AAMI TIR30, AAMI TIR12	Pass
Non-Clinical Verification Testing		
Measurement Accuracy	Internal test methods	Pass
Software Verification and Validation		
Software verification and validation		Pass