FUJIFILM SonoSite Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive Suite 510k
SAINT PAUL MN 55114

December 6, 2023

Re: K233597
Trade/Device Name: Sonosite LX Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 8, 2023
Received: November 8, 2023

Dear Prithul Bom:

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,

Yanna S. Kang -S

Yanna Kang
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
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)*
K233597

Device Name
FUJIFILM Sonosite LX Ultrasound System (Sonosite LX)

Indications for Use *(Describe)*
The Sonosite LX ultrasound system is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Abdominal
Adult Cephalic
Neonatal Cephalic
Cardiac Adult
Cardiac Pediatric
Fetal – OB/GYN
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Ophthalmic
Pediatric
Peripheral vessel
Small Organ (breast, thyroid, testicles, prostate)
Transesophageal (cardiac)
Transrectal
Transvaginal
Needle Guidance

Modes of operation include: B Mode (B), M-Mode (M) (including simultaneous M-mode and anatomical M-Mode), PW Doppler (PWD) (including High Pulse Repetition Frequency (HPRF) and simultaneous PWD for certain exam types), Tissue Doppler Imaging (TDI), Continuous Wave Doppler (CWD), Color Power Doppler, Velocity Color Doppler, Color Variance, Tissue Harmonic Imaging (THI), Multi-beam imaging, Steep Needle Profiling, Trapezoid, and combined modes, including duplex and triplex imaging: B+M, B+PWD, B+CWD, B+C, (B+C)+PWD, (B+C)+CWD.

This device is indicated for Prescription Use Only.

The Sonosite LX system is intended to be used in medical practices, clinical environments, including Healthcare facilities, Hospitals, Clinics and clinical point-of-care for diagnosis of patients.

The system is used with a transducer attached and is powered either by battery or by AC electrical power. The clinician is positioned next to the patient and places the transducer onto the patient's body where needed to obtain the desired ultrasound image.

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 **K233597**

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter:

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2) Device

Trade Name:	Sonosite LX Ultrasound System
Common Name:	Diagnostic Ultrasound System and Transducers with Accessories
Regulation Name:	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer
Regulation Number:	892.1550 892.1560 892.1570

Primary Product Code:	IYN
Secondary Product Codes:	IYO ITX
Device Class:	Class II
Classification Panel:	Radiology

3) Predicate Device:

Primary Predicate: Sonosite PX Ultrasound System (K213763)

Reference Device: SonoSite Edge II Ultrasound System (K162045)

4) Device Description:

The Sonosite LX Ultrasound System is a full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data in 2D, M Mode, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, Color Power Doppler (CPD), and color Doppler (Color) or in a combination of these modes. The Sonosite LX is designed as an integrated unit with its kiosk-style stand.

The system includes a variety of accessories including needle guide starter kits. The system includes USB host support for peripherals such as input devices, storage devices, and an Ethernet port. Input devices include wired and wireless devices. The system also includes an ECG-specific port to support the ECG feature. The non-diagnostic ECG module provides ECG tracing of the cardiac signal synchronized with the ultrasound image.

5) Intended Use/Indications for Use:

The Sonosite LX ultrasound system is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Abdominal
Adult Cephalic
Neonatal Cephalic
Cardiac Adult
Cardiac Pediatric
Fetal – OB/GYN
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Ophthalmic
Pediatric
Peripheral vessel
Small Organ (breast, thyroid, testicles, prostate)
Transesophageal (cardiac)
Transrectal
Transvaginal
Needle Guidance

Modes of operation include: B Mode (B), M-Mode (M) (including simultaneous M-mode and anatomical M-Mode), PW Doppler (PWD) (including High Pulse Repetition Frequency (HPRF) and simultaneous PWD for certain exam types), Tissue Doppler Imaging (TDI), Continuous Wave Doppler (CWD), Color Power Doppler, Velocity Color Doppler, Color Variance, Tissue Harmonic Imaging (THI), Multi-beam imaging, Steep Needle Profiling, Trapezoid, and combined modes, including duplex and triplex imaging: B+M, B+PWD, B+CWD, B+C, (B+C)+PWD, (B+C)+CWD.

This device is indicated for Prescription Use Only.

The Sonosite LX system is intended to be used in medical practices, clinical environments, including Healthcare facilities, Hospitals, Clinics and clinical point-of-care for diagnosis of patients.

The system is used with a transducer attached and is powered either by battery or by AC electrical power. The clinician is positioned next to the patient and places the transducer onto the patient's body where needed to obtain the desired ultrasound image.

6) Technological Characteristics:

The Sonosite LX Ultrasound System, subject device of this submission, is equivalent to the previously cleared Sonosite PX (K213763) and Edge II (K162045) Ultrasound Systems in terms of both the intended use and technological characteristics. The Sonosite LX (subject device) uses the same fundamental scientific technology as the predicate device.

Feature	Sonosite LX Ultrasound System (K233597)	Sonosite PX Ultrasound System (K213763)	Sonosite Edge II Ultrasound System (K162045)	Evaluation of Differences
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	The intended use of the Sonosite LX is identical to the predicate and reference devices.
Indications for Use	AbdominalAdult Cephalic Neonatal Cephalic Cardiac Adult Cardiac Pediatric Fetal – OB/GYN Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Ophthalmic Pediatric Peripheral vessel Small Organ (breast, thyroid, testicle, prostate) Transrectal Transvaginal Trans-esophageal (cardiac) Needle Guidance	Abdominal Adult Cephalic Cardiac Adult Cardiac Pediatric Fetal – OB/GYN Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Ophthalmic Pediatric Peripheral Vessel Small Organ (breast, thyroid, testicle, prostate) Transrectal Transvaginal Trans-esophageal (cardiac) Needle guidance	Abdominal Adult Cephalic Neonatal Cephalic Cardiac Adult Cardiac Pediatric Fetal – OB/GYN Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Ophthalmic Pediatric Small Organ (breast, thyroid, testicle, prostate) Transvaginal Peripheral Vessel Needle guidance Trans-Rectal Trans-esophageal (cardiac) Needle guidance	The Indications for Use are a subset of Sonosite PX Ultrasound system (primary predicate-K213763) and Sonosite Edge II Ultrasound system (reference device-K162045).
Transducer Types	Linear Array Curved Linear Array Phased Array	Linear Array Curved Linear Array Phased Array	Linear Array Curved Linear Array Phased	Transducer types for Sonosite LX are all a subset of Sonosite PX Ultrasound

	Intracavitary Trans-esophageal	Intracavitary Trans-esophageal	Array Intracavitary Trans-esophageal	system (primary predicate) and Sonosite Edge II Ultrasound system (reference device)
Transducer Frequency	1.0-19.0 MHz	1.0-19.0 MHz	1.0 – 15.0 MHz	The frequency range for Sonosite LX is unchanged and the same as the primary predicate Sonosite PX (K213763)
Global Maximum Outputs/Worst Case Setting	Ispta.3: 607 mW/cm^2 (L12-3) TI Type: TIB (P5-1) TI Value: 4.87 (P5-1) MI: 1.72 (L12-3) Ipa.3@MI Max: 793 mW/cm^2 (L15-4)	Ispta.3: 607 mW/cm^2 (L12-3) TI Type: TIB (P5-1) TI Value: 4.87 (P5-1) MI: 1.72 (L12-3) Ipa.3@MI Max: 793 mW/cm^2 (L15-4)	Ispta.3: 598.9 (HFL50x) TI Type: TIB (rP19x) TI Value: 4.98 (rP19x) MI: 1.7 (rP19x) Ipa.3@MI Max: 776 (L38xi)	Acoustic output is less than FDA established limits.
Acoustic Output Display & FDA Limits	Display Feature for Higher Outputs MI Output Display TI Output Display	Display Feature for Higher Outputs MI Output Display TI Output Display	Display Feature for Higher Outputs MI Output Display TI Output Display	MI & TI are always displayed and a power management system ensures that they never exceed the derated FDA limits.
Modes of Operation	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Simultaneous M-Mode Anatomical M-Mode Color Doppler (C) Color Power Doppler (CPD) Zoom Color Velocity Doppler (CVD) Color Variance (Var)	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Simultaneous M-Mode Anatomical M-Mode Color Doppler (C) Color Power Doppler (CPD) Zoom Color Velocity Doppler (CVD) Color Variance (Var)	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Color M-Mode	Modes of operation are a subset of Sonosite PX Ultrasound system (primary predicate) and Sonosite Edge II Ultrasound system (reference device).

	Combination Modes Pulsed Wave (PW) Doppler Continuous Wave (CW) Doppler Speckle reduction algorithm (formerly branded as SonoHD2 Noise Reduction) SonoMB/MBe Image Compounding CW Doppler Tissue Doppler Imaging (TDI)	Combination Modes Pulsed Wave (PW) Doppler Continuous Wave (CW) Doppler Speckle reduction algorithm (formerly branded as SonoHD2 Noise Reduction) SonoMB/MBe Image Compounding CW Doppler Tissue Doppler Imaging (TDI)		

DICOM	DICOM 3.0 Store, Modality Worklist, Modality Perform Procedure Step (MPPS), Storage Commitment, Structured reports, offline media	DICOM 3.0 Store, Modality Worklist, Modality Perform Procedure Step (MPPS), Storage Commitment, Structured reports, offline media	DICOM 3.0 Store, Print, Modality Worklist, Modality Perform Procedure Step (MPPS), Storage Commitment, offline media	Includes a subset of this information
#Transmit Channels	128 digital channels	128 digital channels	128 digital channels	-
#Receive Channels	128 digital channels	128 digital channels	64 digital channels (128 digital channels using Synthetic Aperture)	-

Patient Contact Materials	**Transducers:** Silicone Rubber Polysulfone PolyVinylChloride (PVC) Silicone RTV Adhesive Silicone Polymethyl-pentene Epoxy Paste Adhesive Polyurethane FKM rubber Thermoplastic polyurethane Needle Guides: Acetal copolymer Acrylonitrile-butadien- styrene (ABS)	**Transducers:** Silicone Rubber Polysulfone PolyVinylChloride (PVC) Silicone RTV Adhesive Silicone Polymethyl-pentene Epoxy Paste Adhesive Polyurethane FKM rubber Thermoplastic polyurethane Needle Guides: Acetal copolymer Acrylonitrile-butadien- styrene (ABS)	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL Polyurethane PolyVinylChloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane Needle Guides: Acetal copolymer Acrylonitrile-butadien- styrene (ABS)	All patient contact materials have been tested to ISO 10993-1. Materials used in Sonosite LX have undergone identical biocompatibility and cleaning/disinfection testing to the predicate devices.
Product Safety Certification	AAMI/ANSI ES60601- 1:2005 (R2012) IEC 60601-2- 37:2007+AMD1:2015 CAN/CSA-C22.2 No. 60601-1:14 JSA JIS T 0601-1:2017, JSA JIS T 0601-2-37 IEC 61157:2007+AMD1:2013 IEC 62359:2010+AMD1:2017	AAMI/ANSI ES60601- 1:2005 (R2012) IEC 60601-2- 37:2007+AMD1:2015 CAN/CSA-C22.2 No. 60601-1:14 JSA JIS T 0601-1:2017, JSA JIS T 0601-2-37 IEC 61157:2007+AMD1:2013 IEC 62359:2010+AMD1:2017	AAMI/ANSI ES60601- 1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 60601- 1:08 NEMA UD2-2004 IEC 62359:2010	

EMC Compliance	IEC 60601-1-2:2014 (Edition 4.0) IEC 60601-1-2:2014+A1:2020 (Edition 4.1) CISPR 11:2015+AMD1:2016 +A2:2019 IEC 61000-3-2:2018 IEC 61000-3-3:2013+A1:2017 IEC 61000-4-2:2008 IEC 61000-4-3:2020 IEC 61000-4-3:2020 IEC 61000-4-4::2012 IEC 61000-4-5:2014+A1:2017 IEC 61000-4-6:2013 IEC 61000-4-11:2020+AC:2020+AC:2022 IEC 61000-4-8:2009 IEC 61000-4-39:2017	IEC 60601-1-2:2014 (Edition 4.0) CISPR 11:2015+AMD1:2016 IEC 61000-3-2:2018 IEC 61000-3-3:2013+A1:2017 IEC 61000-4-2:2008 IEC 61000-4-3:2010 IEC 61000-4-3:2010 IEC 61000-4-4::2012 IEC 61000-4-5:2014+A1:2017 IEC 61000-4-6:2013 IEC 61000-4-11:2004+A1:2017 IEC 61000-4-8:2009	AAMI / ANSI / IEC 60601- 1-2:2007(R)2012 CISPR 11, Group 1, Class A	The changes in the standards did not affect the EMC testing performed for the subject device, Sonosite LX and the primary predicate, Sonosite PX (K213763).
DICOM	DICOM PS3.15	DICOM PS3.15	DICOM PS3.15	
Airborne Equipment Standards	None applied	None applied	RTCA/DO160 (section 21)	Airborne equipment standards have not been applied to the Sonosite LX Ultrasound System.

System Characteristics	**Sonosite LX:** Beamformer 128/128 21.3" Projected Capacitive (PCAP) touch screen interface Storage bin capacity: 11 lbs. (5 kg) Stand depth: 25.4 in. (64.5 cm) Stand width: 23.0 in. (58.4 cm) Height range: max with monitor up 68 in. (172.7 cm); min with monitor down 49 in. (124.5 cm) Weight (system and accessories including safe working load): 151.68 lbs. (68.8 kg) 2 USB 2.0 Ports 2 USB 3.0 Ports 1 USB port for optional printer	**Sonosite PX:** Beamformer 128/128 15.6" capacitive screen interface Storage bin capacity: 11 lbs Stand depth: 25.4 in (64.5 cm) Stand width: 23.0 in. (58.4) Height: 45 in. (114.3 cm) maximum, 33 in. (83.8 cm) minimum Weight: 17.92 lbs (8.13 kg) with the L15-4 transducer and battery installed Total Stand weight with systems and peripherals: 118 lbs (53.6 kg) maximum 2 USB 3.0 ports 4 USB 2.0 ports	**Edge II:** Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD Dimensions: 12.8"(W) x 12.1" (L) x 2.5"(H) Weight: 9.0 lbs 2 USB ports	The features introduced are equivalent to Sonosite PX Ultrasound system (K213763) and Sonosite Edge II Ultrasound system (K162045). The variation in the system characteristics is due to the changes in the form factor between Sonosite LX and the primary predicate, Sonosite PX (K213763). The configuration of Sonosite LX as a kiosk-style system has 5 USB ports, while the Sonosite PX (K213763) has 6 USB ports. The USB port types are all the same as the ones available on Sonosite
	Stand battery Length: 19 in. (48.26 cm) Width: 4 in. (10.16 cm) Depth: 2.2 in. (5.59 cm) Weight: 6 lbs (2.72 kg) Battery Life: 3 hours	**Stand battery** Length: 19 in. (48.26 cm) Width: 4 in. (10.16 cm) Depth: 2.2 in. (5.59 cm) Weight: 6 lbs (2.72 kg) Battery life: 1 hour imaging - 10 days idle	System operates via battery or AC power Battery life: 1.5 - 4-hour operation per charge	PX (K213763). HPRF included in Sonosite LX is a setting for PW Doppler that allows measurement of higher velocities by adding multiple sample gates. Trapezoid imaging feature on

	Ratings: Stand Input: 100–240 VAC, 50–60 Hz, 6.0–2.5 A Stand battery 21.6 VDC, 12000mAh, 259.2Wh Input: 26.7 VDC, 8.24 A (max 220 W) Output: 26.7 VDC, 8.24 A (max 220 W) from power supply or 21.6 VDC, 12000 mAh, 259.2 Wh from battery	**Ratings:** Portable power supply Input: 100–240 VAC, 50–60 Hz, 3.4–1.3 A Output: 26.7 VDC, 8.24 A, 220 W max; Class I, continuous use. Stand rating Input: 100–240 VAC, 50–60 Hz, 6.0–2.5 A Output: 100–240 VAC, 50–60 Hz, 2.5–1.0 A Stand battery rating	**Ratings:** 100 – 240V options, 50/60 Hz, 15VDC output	Sonosite LX expands the field of view of both linear and curved transducers to assist in the measurement and assessment of large structures. Cardiac triplex is an imaging feature for scanning in simultaneous PW Doppler mode, and is equivalent to the triplex feature on arterial and venous exam types already cleared on Sonosite PX (K213763).

		21.6 VDC, 12000 mAh, 259.2 Wh Input: 26.7 VDC, 8.24 A (max 220 W) Output: 26.7 VDC, 8.24 A (max 220 W) from power supply or 21.6 VDC, 12000 mAh, 259.2 Wh from battery		Label and Measure in Review (LMiR) feature provides the user with the ability to label and make measurements and calculations on saved images. The feature is substantially equivalent to the analysis (measurement and calculations) and annotations features already cleared on Sonosite PX (K213763). The Voice assist feature on Sonosite LX is intended for hands-free system control, which includes specific commands that allow the most common interactions. The interactions included with Voice assist are the same that can be performed by using the tactile control panel on previously cleared Sonosite PX (K213763).
	Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages Non-diagnostic ECG tracing Wireless 802.11 (a/b/g/n) support for image transfer	Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages Non-diagnostic ECG tracing Wireless 802.11 (a/b/g/n) support for image transfer	Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages Non-diagnostic ECG tracing, CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Wireless 802.11 (b/g/n) support for image transfer	
	Additional system features: Assisted Cardiac Output (ACO), Anatomical M-Mode, Trapezoid imaging, Label and Measurement in Review (LiMR), High Pulse Repetition Frequency (HPRF), Cardiac Triplex, Voice Assist.	Additional system features: Assisted Cardiac Output (ACO), Anatomical M-Mode, SonoMB, Pulse Repetition Frequency (PRF), Measurement and Calculations, Triplex.	Additional system features: Assisted Cardiac Output (ACO) – Available on Edge II system	

510k Track	Track 3	Track 3	Track 3	

7) Determination of Substantial Equivalence:

Summary of Technological Comparison to Predicate Devices:

The Sonosite LX Ultrasound System, subject device of this submission, is enhanced implementation of previous FDA Cleared predicate devices Sonosite PX (K213763) and Sonosite Edge II Ultrasound System (K162045).

The technological characteristics are unchanged from the primary predicate Sonosite PX (K213763) and reference device, Edge II (K162045) ultrasound systems. The primary function of Sonosite LX Ultrasound System and the predicate device is diagnostic ultrasound imaging or fluid flow analysis of the human body. The Sonosite LX Ultrasound System employs the same fundamental scientific characteristics as the currently marketed predicate devices. The Sonosite LX Ultrasound device and predicates share indications for use, share modes of operation and have biosafety equivalence.

The following lists an overview of differences between the proposed subject device (Sonosite LX Ultrasound System) and its predicates.

- Addition of L13-6 transducer, which is substantially equivalent to the L19-5 transducer and HSL25x transducer, previously cleared on Sonosite PX (K213763) and Edge II (K162045), respectively.
- Addition of P11-3 transducer, which is substantially equivalent to the P10x transducer previously cleared on Edge II (K162045).
- Addition of a new clinical indication: Neonatal cephalic, which is the same indication cleared on P10x transducer with Edge II (K162045).
- Addition of High Pulse Repetition Frequency (HPRF), which is based on the same PRF functionality available for PW mode on Sonosite PX (K213763).
- Addition of Trapezoidal imaging feature to assist with the measurement by using large field of view of both linear and curved transducers. The images captured with the trapezoid feature is the same as Sonosite PX (K213763), but it allows for an expanded image base.
- Addition of Cardiac Triplex which is an imaging feature for scanning in simultaneous PW and Doppler mode, and is equivalent to the triplex feature on arterial and venous exam types already cleared on Sonosite PX (K213763).
- Addition of Label and Measure in Review (LMiR) feature to provide the user with the ability to label and make measurements and calculations on saved images. The feature is substantially equivalent to the analysis (measurement and calculations) and annotations features already cleared on Sonosite PX (K213763).
- Addition of Voice Assist feature that is intended for hands-free system control and includes specific commands that allow the most common interactions. The interactions included with Voice assist are the same that can be performed by using the tactile control panel on previously cleared Sonosite PX (K213763).

The transducer types for the subject device are all a subset of the primary predicate (Sonosite PX - K213763) and reference device (Sonosite Edge II - K162045). The transducer frequency range is unchanged and the same as the primary predicate Sonosite PX (K213763). The transducers have been tested to performance standards and the acoustic output is less than FDA established limits.

Similar to both predicate and the reference devices, MI and TI values are always displayed, and a power management system ensures that they never exceed the derated FDA limits.

The changes implemented on the Sonosite LX leverage existing technological characteristics and features available on both the primary predicate (K213763) and the reference device (K162045). The submission device is substantially equivalent to the predicates with respect to the intended use and technological characteristics.

Summary of Non-Clinical Tests:

The Sonosite LX Ultrasound System has been evaluated for electrical, thermal, mechanical, and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated for Sonosite LX, and the device has been found to conform to applicable medical device safety standards.

Assurance of quality was established by employing the following elements of product development: Design Phase Reviews, Risk Assessment, Requirements Development, System and Software Verification, Hardware Verification, Safety Compliance Verification, and Clinical Validation. All patient contact materials are biocompatible.

The Sonosite LX Ultrasound System is designed to comply with the following FDA recognized standards.

Reference No.	Recognition No.	Title
ISO 10993-1	2-258	ISO 10993-1:2018, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
IEC 60601-1	19-4	AAMI / ANSI ES60601- 1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	19-8	ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
IEC 60601-1-6	5-89	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-37	12-293	IEC 60601-2-37 Edition 2.1 2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	13-79	ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)
ISO 14971	5-125	ANSI AAMI ISO 14971:2019 Medical devices - Application of risk management to medical devices

IEC 62359	12-316	IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION - Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

Summary of Clinical Tests:

The Sonosite LX Ultrasound System and transducers, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

Conclusion

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance entitled “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers”, issued February 2023. The Sonosite LX Ultrasound device and predicates conform to applicable electromedical device safety standards with compliance verified through independent evaluation. The Sonosite LX Ultrasound device and predicates meet FDA requirements for Track 3 devices, share indications for use, have biosafety equivalence and are manufactured using the same ISO 13485 and 21 CFR 820 quality system. FUJIFILM SonoSite, Inc. believes that the Sonosite LX Ultrasound System is substantially equivalent with regard to safety and effectiveness to the primary predicate device.