July 10, 2025

FUJIFILM Sonosite, Inc.
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K251830
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: June 13, 2025
Received: June 13, 2025

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.

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251830

Device Name
Sonosite LX Ultrasound System

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
Dermatological
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 Pulsed Wave Tissue Doppler), Continuous Wave Doppler (CWD), Color Power Doppler (including Velocity Color Doppler), Tissue Harmonic Imaging (THI), Tissue Doppler Imaging (TDI), and Combined modes, including 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 Ultrasound 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary
K251830

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 LX Ultrasound System (K233597)

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:	II
Classification Panel:	Radiology

Reference Device: SonoSite Vevo MD Imaging System (K190476)

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:	II
Classification Panel:	Radiology

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.

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
Dermatological
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 Pulsed Wave Tissue Doppler), Continuous Wave Doppler (CWD), Color Power Doppler (including Velocity Color Doppler), Tissue Harmonic Imaging (THI), Tissue Doppler Imaging (TDI), and Combined modes, including 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 Ultrasound 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.

5) Technological Characteristics:

The Sonosite LX Ultrasound System, subject device of this submission, is equivalent to the previously cleared primary predicate Sonosite LX (K233597) and the reference device, Vevo MD Imaging Systems in terms of both the intended use and technological characteristics. The Sonosite LX (subject device) uses the same fundamental scientific technology as the primary predicate device.

Feature	Sonosite LX Ultrasound System (This submission)	Sonosite LX Ultrasound System (K233597)	Sonosite VevoMD Imaging System (K190476)	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	Abdominal Adult Cephalic Neonatal Cephalic Cardiac Adult Cardiac Pediatric Dermatological 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 Peripheral vessel Small Organ (breast, thyroid, testicle, prostate) Transrectal Transvaginal Trans-esophageal (cardiac) Needle Guidance	Abdominal Neonatal Cephalic Dermatological Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Ophthalmic Pediatric Peripheral Vessel Small Organ (breast, thyroid, testicles, prostate)	The Indications for Use are similar as what was cleared on Sonosite LX Ultrasound system (primary predicate- K233597). The dermatological indication introduced with Sonosite LX in this submission is previously cleared on the reference device, Vevo MD Imaging system (K190476). The dermatological indication on UHF46-20 supports vessel and superficial exam types and is an extension of the dermatological indication on UHF48 (K190476).
Transducer Types	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal	Linear Array	Same as the primary predicate (K233597)
Transducer Frequency	1.0 – 46.0 MHz	1.0-19.0 MHz	1.0- 70 MHz	While the introduction of UHF46-20 has increased the frequency range for the Sonosite LX Ultrasound System, it still falls within the range of previously cleared primary predicate, Sonosite LX (K233597) and the reference device, Vevo MD (K190476).
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	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: 455 (UHF48) TI Type: TIS (UHF22) TI Value: 4.15 (UHF22) MI: 1.26 (UHF22) Ipa.3@MI Max:	Acoustic output is within the FDA established limits and same as the primary predicate.

	(L15-4)		580 W/cm^2 (UHF48)	

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 Power Doppler, Combination Modes Pulse Wave Doppler (PWD) Tissue Doppler Imaging (TDI), Continuous Wave Doppler (CWD), Speckle reduction algorithm (formerly branded as SonoHD2 Noise Reduction) SonoMB/MBe Image Compounding CW Doppler Velocity Color Doppler, Simultaneous PWD HPRF	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Simultaneous M-Mode Anatomical M-Mode Color Power Doppler Combination Modes Pulsed Wave Doppler (PWD) Tissue Doppler Imaging (TDI) Continuous Wave Doppler (CWD) Speckle reduction algorithm (formerly branded as SonoHD2 Noise Reduction) SonoMB/MBe Image Compounding CW Doppler Velocity Color Doppler Simultaneous PWD HPRF	M-Mode Pulse Wave Doppler Mode (PWD) 2D: B Mode / 2D Mode Power Doppler Mode Color Doppler Mode	Same as the primary predicate (K233597)
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, Perform Procedure Step (PPS), Storage Commitment	Same as the primary predicate (K233597)
#Transmit Channels	128 digital channels	128 digital channels	64 digital channels	Same as the primary predicate (K233597)
#Receive Channels	128 digital channels	128 digital channels	64 digital channels	Same as the primary predicate (K233597)

Patient Contact Materials	**Transducers:** Silicone Rubber Polysulfone PolyVinylChloride (PVC) Silicone RTV Adhesive Silicone Polymethyl-pentene Epoxy Paste Adhesive Polyurethane FKM rubber Thermoplastic Polyurethane Rexolite Needle Guides: Acetal copolymer Acrylonitrile-butadien- styrene (ABS) Rexolite	**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)	**Transducer:** Silicone Rubber Polysulfone Poly-Vinyl-Chloride (PVC) Spectrally Transparent Epoxy TPX Polymethyl Pentene Rexolite	Rexolite is introduced as lens material for the UHF46-20 on the Sonosite LX system, This UHF48-20 has passed biocompatibility testing per ISO 10993-1. The rexolite material used for the lens is also the same as the one used on Vevo MD's UHF48 and UHF70 transducers (K190476). The rest of the ultrasound material is the same as the material used on the previously cleared transducers under (K233597).
DICOM	DICOM PS3.15	DICOM PS3.15	NEMA PS3.15 2011	Same as the primary predicate (K233597)

System Characteristics	**Sonosite LX (Kiosk form factor)** Beamformer 128/128 21.3" Projected Capacitive (PCAP) touch screen interface 2 USB 2.0 Ports 2 USB 3.0 Ports 1 USB port for optional printer Stand battery **Dimensions:** 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) System operates via battery or AC power. **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) **Ratings:** Stand Input: 100–240 VAC, 50–60 Hz, 6.0–2.5 A Stand Output: 100–240 VAC, 50–60 Hz, 2.5–1.0 A **Stand battery ratings:** 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) 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/ac) support for image transfer	**Sonosite LX (Kiosk form factor)** Beamformer 128/128 21.3" Projected Capacitive (PCAP) touch screen interface 2 USB 2.0 Ports 2 USB 3.0 Ports 1 USB port for optional printer Stand battery. **Dimensions:** 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) System operates via battery or AC power. **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) **Ratings:** Stand Input: 100–240 VAC, 50–60 Hz, 6.0–2.5 A **Stand battery ratings:** 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) 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/ac) support for image transfer	**Sonosite VevoMD** Beamformer 64/64 using SA (configurable) 12.1" touch screen interface Touch panel with the 19" LED clinical monitor 4 USB 3.0 ports **Dimensions:** Stand base Dimensions: 26.4" L x 21.2" W Stand Height (with monitor folded) = 48 in (122 in) **Weight**: 95 kg (209 lbs) Wireless 802.11 (a/b/g/n/ac) support for image transfer System must be plugged in AC power for operation. **Ratings:** 100V, 120V and 240V at 50/60Hz Wireless 802.11 (a/b/g/n/ac) support for image transfer	The system characteristics are the same as the primary predicate device, Sonosite LX system (K233537). The new transducer, UHF46-20 introduced with Sonosite LX in this submission is equivalent to UHF48 transducer in the reference device, Vevo MD system (K190476). The dermatological indication on UHF46-20 supports vessel and superficial exam types and is an extension of the dermatological indication on UHF48 (K190476).

	Additional system features: Added the UHF46-20 ultra-high frequency transducer and associated exam types	**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		The Sonosite LX ultrasound system features are unchanged. The change in this submission is the introduction of the UHF46-20 transducer with the added Dermatological indication. The ultrasound system features are unchanged and already cleared on the Sonosite LX ultrasound system (K233597) and the introduction of UHF460-20 with the dermatological indication is an extension of the dermatological indication on UHF48 cleared on Vevo MD Imaging system (K190476).
510k Track	Track 3	Track 3	Track 3	Same

6) 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 LX (K233597) and Sonosite Vevo MD Imaging System (K190476).

The technological characteristics are unchanged from the primary predicate Sonosite LX (K233597) and reference device, Vevo MD imaging system (K190476). The primary function of Sonosite LX Ultrasound System (this submission) 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 UHF46-20 transducer, which is substantially equivalent to the UHF48 transducer previously cleared on Sonosite Vevo MD Imaging system (K190476).
- Addition of new dermatological indication which is substantially equivalent to the dermatology indication on Vevo MD imaging system (K190476) and supported under the superficial and vessel exam types
- Introduction of new transducer material (Rexolite)
- Updated transducer frequency range for Sonosite LX system which falls within the range of previously cleared primary predicate, Sonosite LX (K233597) and the reference device, Vevo MD (K190476).

The transducer types for the subject device are all a subset of the primary predicate (Sonosite LX - K233597) and reference device (Sonosite Vevo MD – K190476). The transducer frequency range for Sonosite LX in this submission falls within the range of previously cleared primary predicate, Sonosite LX (K233597) and the reference device, Vevo MD Imaging system (K190476).
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 (K233597) and the reference device (K190476). The submission device is substantially equivalent to the predicates with respect to the intended use and technological characteristics.

Summary of Non-Clinical Tests:

The subject ultrasound system Sonosite LX Ultrasound System uses the new transducer UHF46-20, which 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	19-46	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	19-36	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, which uses the new transducer UHF46-20 did not require clinical studies to support the determination of substantial equivalence. The Sonosite LX with new transducer UHF46-20 has been successfully tested in a clinical environment and the device performed as expected.

Conclusion

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. 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 regards to safety and effectiveness to the predicate devices.