August 29, 2025

Fujifilm Sonosite, Inc.
Anoush Frankian
Director, Regulatory Affairs
21919, 30th Drive SE
BOTHELL WA 98012

Re: K251106
Trade/Device Name: Sonosite LX and Sonosite PX Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: July 30, 2025
Received: July 30, 2025

Dear Anoush Frankian:

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,

MARJAN NABILI -S for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251106

Please provide the device trade name(s).

Sonosite LX and Sonosite PX Ultrasound Systems

Please provide your Indications for Use below.

The Sonosite LX and Sonosite PX ultrasound systems are general purpose ultrasound systems 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 and Sonosite PX ultrasound systems are intended to be used in medical practices, clinical environments, including healthcare facilities, hospitals, clinics, and clinical point-of-care for diagnosis of patients.

The systems are used with a transducers attached and they are 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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K251106

This summary of safety and effectiveness is provided as part of this Premarket Notification in accordance with 21CFR807.92.

1) Date Prepared: April 10, 2025
2) Submitter:

Manufacturer Name:	FUJIFILM SonoSite, Inc.
Address:	21919 30th Drive SE Bothell, WA 98021-3904
Corresponding Official:	Anoush Frankian Director, Regulatory Affairs
Email:	anoush.frankian@fujifilm.com
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Secondary Contact:	Anjana Varier Senior Regulatory Affairs Specialist anjana.varier@fujifilm.com
Telephone:	425-686-6519

3) **Proposed Device:**

Trade Name:	Sonosite LX and Sonosite PX Ultrasound Systems
Common Name:	Diagnostic System and Transducers with Accessories
Regulation Name:	Ultrasonic Pulsed Doppler Imaging System
Regulation Number:	21 CFR 892.1550, 892.1560. 892.1570, 892.2050
Product Code:	IYN, IYO, ITX, QIH
Device Classification:	Class II
Classification Panel:	Radiology

4) Predicate Device:

Primary Predicate:	Sonosite LX Ultrasound System (K233597)
Reference:	Sonosite PX Ultrasound System (K213763)

5) Device Description:

The Sonosite LX and Sonosite PX Ultrasound Systems are full featured, general purpose, software controlled diagnostic ultrasound systems 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 systems include a variety of accessories including needle guide starter kits. The systems include USB host support for peripherals such as input devices, storage devices and Ethernet port. Input devices include wired and wireless devices. The systems also include 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.

6) Intended Use/Indication for Use:

The Sonosite LX and Sonosite PX Ultrasound Systems are general purpose ultrasound systems 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
Feta-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 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 and Sonosite PX Ultrasound Systems are intended to be used in medical practices, clinical environments, including Healthcare facilities, Hospitals, Clinics, and clinical point-of-care for diagnosis of patients.

The systems are used with transducers attached and they are 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.

7) Technological characteristics:

The Sonosite LX and Sonosite PX Ultrasound Systems employ the same fundamental scientific technological characteristics as the predicate devices Sonosite LX Ultrasound System (K233597) and Sonosite PX Ultrasound System (K213763).

Table 1: Technological characteristics

Feature	PIV Assist validated on Sonosite LX and Sonosite PX Ultrasound System (This submission)	Sonosite LX Ultrasound System (K233597) Predicate device	Sonosite PX Ultrasound System (K213763) Reference device
Intended Use	Same as predicate and reference device	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indications for Use	Same as predicate and reference device	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 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
Transducer Types	Same as predicate and reference device	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal
Transducer Frequency	Same as predicate and reference device	1.0-19.0 MHz	1.0-19.0 MHz

Global Maximum Outputs/ Worst Case Setting	Same as predicate and reference device	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)
Acoustic Output Display & FDA Limits	Same as predicate and reference device	Display Feature for Higher Outputs MI Output Display TI Output Display	Display Feature for Higher Outputs MI Output Display TI Output Display
Modes of Operation	Same Same as predicate and reference device	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Simultaneous M-Mode Anatomical M-Mode Color Power Doppler Zoom 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 Velocity Color Doppler Tissue Doppler Imaging (TDI)	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Simultaneous M-Mode Anatomical M-Mode Color Power Doppler Zoom 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 Velocity Color Doppler Tissue Doppler Imaging (TDI)
DICOM	Same as predicate and reference device	DICOM 3.0 Store, Modality Worklist, Modality Perform Procedure Step (MPPS), Storage Commitment,	DICOM 3.0 Store, Modality Worklist, Modality Perform Procedure Step (MPPS), Storage Commitment, Structured reports, offline media

		Structured reports, offline media	
#Transmit Channels	Same as predicate and reference device	128 digital channels	128 digital channels
#Receive Channels	Same as predicate and reference device	128 digital channels	128 digital channels
Patient Contact Materials	Same as predicate and reference device	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)
System Characteristics	PIV Assist is validated on both Sonosite PX and Sonosite LX Ultrasound Systems. No hardware changes were made to either of these devices to include PIV Assist. New features include - • L12-3 PIV Assist feature added to Peripheral IntraVenous Exam Type • L19-5 PIV Assist feature added to Peripheral IntraVenous and Vascular Access Exam Types	**Sonosite LX:** 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	**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

		2 USB 3.0 Ports 1 USB port for optional printer **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 System Rating Input: 100–240 VAC, 50–60 Hz, 6.0–2.5 A Power Output: (for optional printer): 100-240 VAC, 50-60 Hz, 2.5-1.0 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 Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages that include CVR Non-diagnostic ECG tracing	peripherals: 118 lbs (53.6 kg) maximum 2 USB 3.0 ports 4 USB 2.0 ports **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 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 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 Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages that include

		Wireless 802.11 (a/b/g/n) support for image transfer	CVR Non-diagnostic ECG tracing Wireless 802.11 (a/b/g/n/ac) support for image transfer
Track	Track 3	Track 3	Track 3

8) Determination of Substantial Equivalence:

Summary of Technological Comparison to Predicate Devices:

The PIV Assist feature on Sonosite LX and Sonosite PX Ultrasound Systems is an enhanced implementation of previously cleared predicates Sonosite LX (K233597) and Sonosite PX (K213763).

The PIV Assist feature is based on existing features that similarly help clinical users localize and classify veins and arteries through manual compression and the use of color doppler, which are present features and techniques on both Sonosite LX (K233597) and Sonosite PX (K213763). The PIV Assist automates the localization of vein and artery in 2D Mode. Both Sonosite LX (K233597) and Sonosite PX (K213763) provide functions that offer imaging assistance to the operator for vein sizing and depth when the vein is centered. The PIV Assist is an automation of the Catheter to Vein Ratio (CVR) feature cleared with Sonosite PX (K213763). When a candidate vein is centered, the PIV Assist can automatically detect both diameter and depth measurements, which are existing manual functionality that has been cleared on Sonosite LX (K233597) and Sonosite PX (K213763). The user enabling PIV Assist may revert to manual measurements for confirmation. These differences do not raise any new questions of safety or effectiveness.

9) Summary of Non-Clinical Testing

The proposed modification, the addition of PIV Assist feature to the Sonosite LX and Sonosite PX Ultrasound Systems, was tested in accordance with FUJIFILM Sonosite's design and development procedures. The subject devices were tested to the following FDA recognized standards to ensure continued safety and performance.

Table 2: FDA Recognized standards

Reference Number	Recognition Number	Title
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

Assurance of quality was established by employing the following elements of product development: Design Phase Reviews, Risk Assessment, Requirements Development and Review, and System and Software Verification.

Non-Clinical testing also included Performance Validation, for the proposed PIV Assist feature.

Summary of PIV Assist AI Algorithm Performance Testing:

Results (including subgroup performance):

Vessel Precision for the L19-5 transducer when used on both Sonosite LX and Sonosite PX Ultrasound Systems is 97.32% (95% CI:97%- 98%), Vessel Recall is 97.07% (95% CI: 96%-98%), Vessel Classification for Veins is 96.01% (95% CI:95%-97%) and Vessel Classification for Arteries is 89.71% (95% CI: 87%-92%).

For the L12-3 transducer when used on both Sonosite LX and Sonosite PX Ultrasound Systems the results for Vessel Precision is 95.58% (95% CI: 95%-96%), Vessel Recall is 94.49% (95% CI: 93%-95%), Vessel Classification for Veins is 94.54% (95% CI: 93%-96%) and Vessel Classification for Arteries is 86.06% (95% CI: 83%-89%).

Average Depth Error for L19-5 Transducer when used on both Sonosite LX and Sonosite PX Ultrasound Systems is 0.065mm (95% CI: 0.062-0.068mm). The Average Diameter Error for the L19-5 Transducer when used on both Sonosite LX and Sonosite PX Ultrasound Systems is 6.2% (95% CI: 5.5-7.1%), 0.203mm (95% CI: 0.186-0.219mm).

Average Depth Error for L12-3 Transducer when used on both Sonosite LX and Sonosite PX Ultrasound Systems is 0.105mm (95% CI: 0.103-0.108mm). Average Diameter Error for the L12-3 Transducer when used on both LX and PX is 5.6% (95% CI: 5.0-6.2%), 0.19mm (95% CI: 0.18-0.21mm).

Table 3: Subgroup Performance of PIV Assist Performance for L19-5 Transducer on both PX and LX Systems

Demographic Type	Demographic Group	Detection Precision (%)	Detection Recall (%)	Vein Classification Accuracy (%)	Artery Classification Accuracy (%)
Age Range	18-39	95.97% (95% CI: 94%-98%)	97.00% (95% CI: 95%-98%)	97.24% (95% CI: 95%-99%)	90.00% (95% CI: 82%-95%)
	40-65	96.85% (95% CI: 95%-98%)	96.56% (95% CI: 95%-98%)	96.10% (95% CI: 94%-98%)	89.27% (95% CI: 84%-93%)
	65 and over	98.45% (95% CI: 97%-99%)	97.52% (95% CI: 96%-98%)	95.16% (95% CI: 93%-97%)	89.89% (95% CI: 86%-93%)

Sex	F	96.99% (95% CI: 96%-98%)	96.70% (95% CI: 95%-98%)	95.24% (95% CI: 93%-97%)	88.11% (95% CI: 84%-92%)
	M	97.65% (95% CI: 96%-99%)	97.45% (95% CI: 96%-98%)	96.77% (95% CI: 95%-98%)	91.42% (95% CI: 87%-94%)
Ethnicity	African American/Black	95.94% (95% CI: 93%-98%)	96.24% (95% CI: 94%-98%)	90.38% (95% CI: 86%-94%)	83.19% (95% CI: 75%-89%)
	Asian	91.38% (95% CI: 81%-97%)	96.36% (95% CI: 87%-100%)	97.30% (95% CI: 86%-100%)	94.12% (95% CI: 71%-100%)
	Caucasian/White	97.73% (95% CI: 97%-99%)	97.11% (95% CI: 96%-98%)	96.76% (95% CI: 95%-98%)	91.25% (95% CI: 87%-94%)
	Hispanic	97.39% (95% CI: 95%-99%)	97.39% (95% CI: 95%-99%)	98.65% (95% CI: 96%-100%)	96.20% (95% CI: 89%-99%)
	Mixed/Multiracial	100.00% (95% CI: 86%-100%)	100.00% (95% CI: 86%-100%)	100.00% (95% CI: 77%-100%)	100.00% (95% CI: 69%-100%)
	Native American	98.82% (95% CI: 96%-100%)	97.67% (95% CI: 94%-99%)	95.10% (95% CI: 90%-98%)	78.13% (95% CI: 60%-91%)

BMI Range	Below 25	97.06% (95% CI: 95%-98%)	96.35% (95% CI: 94%-98%)	96.13% (95% CI: 94%-98%)	92.22% (95% CI: 87%-96%)
	25-29.9	98.24% (95% CI: 97%-99%)	96.54% (95% CI: 95%-98%)	97.05% (95% CI: 95%-98%)	92.97% (95% CI: 88%-96%)
	30 and above	96.79% (95% CI: 95%-98%)	98.00% (95% CI: 97%-99%)	95.19% (95% CI: 93%-97%)	84.13% (95% CI: 78%-89%)

Table 4: Subgroup Performance of PIV Assist Performance for L12-3 Transducer on both PX and LX Systems

Demographic Type	Demographic Group	Detection Precision (%)	Detection Recall (%)	Vein Classification Accuracy (%)	Artery Classification Accuracy (%)
Age Range	18-39	94.00% (95% CI: 91.68%-95.83%)	93.15% (95% CI: 91%-95%)	94.20% (95% CI: 91%-96%)	81.10% (95% CI: 73%-88%)
	40-65	94.95% (95% CI: 93%-96%)	94.37% (95% CI: 93%-96%)	94.76% (95% CI: 93%-96%)	85.24% (95% CI: 80%-90%)
	65 and over	97.01% (95% CI: 96%-98%)	95.33% (95% CI: 94%-97%)	94.55% (95% CI: 93%-96%)	88.61% (95% CI: 85%-92%)
Sex	F	95.05% (95% CI: 94%-96%)	93.78% (95% CI: 92%-95%)	93.36% (95% CI: 91%-95%)	82.96% (95% CI: 78%-87%)
	M	96.07% (95% CI: 95%-97%)	95.13% (95% CI: 94%-96%)	95.62% (95% CI: 94%-97%)	88.89% (95% CI: 85%-92%)

Ethnicity	African American/ Black	94.40% (95% CI: 91%-97%)	94.96% (95% CI: 92%-97%)	91.36% (95% CI: 87%-95%)	84.03% (95% CI: 76%-90%)
	Asian	100% (95% CI: 95%-100%)	95.71% (95% CI: 88%-99%)	90.91% (95% CI: 78%-97%)	85.19% (95% CI: 66%-96%)
	Caucasian/ White	95.71% (95% CI: 94%-97%)	95.05% (95% CI: 94%-96%)	94.77% (95% CI: 93%-96%)	84.47% (95% CI: 80%-88%)
	Hispanic	94.23% (95% CI: 92%-96%)	92.52% (95% CI: 90%-95%)	97.58% (95% CI: 95%-99%)	94.44% (95% CI: 89%-98%)
	Mixed/Multiracial	100.00% (95% CI: 88%-100%)	93.75% (95% CI: 79%-99%)	89.47% (95% CI: 67%-99%)	84.62% (95% CI: 55%-98%)
	Native American	97.77% (95% CI: 94%-99%)	94.09% (95% CI: 90%-97%)	93.48% (95% CI: 88%-97%)	80.43% (95% CI: 66%-91%)
BMI Range	Below 25	93.98% (95% CI: 92%-96%)	95.12% (95% CI: 93%-97%)	93.64% (95% CI: 91%-96%)	89.21% (95% CI: 85%-93%)
	25-29.9	95.27% (95% CI: 94%-97%)	93.19% (95% CI: 91%-95%)	93.45% (95% CI: 91%-95%)	84.51% (95% CI: 79%-89%)
	30 and above	97.02% (95% CI: 96%-98%)	95.13 % (95% CI: 94%-96%)	95.85% (95% CI: 94%-97%)	83.87% (95% CI: 78%-89%)

Data Collection:

Validation Dataset:

A total of 584 clips were collected from 292 subjects at 3 hospitals within the United States. Three sites were selected to ensure that data collected included a representative U.S. population. To maintain complete independence of the validation dataset, the validation dataset was collected at a much later timeframe and at different sites from the training and tuning data.

Truthing Process:
Images were collected prospectively from 3 hospitals within the United States. Each ultrasound clip was divided into frames for labeling by certified Clinical Sonographers, who independently labeled the data to establish the ground truth. In cases where there was disagreement between the images, an adjudication process took place with an Interventional Radiologist evaluating the labeled data to establish the final ground truth.

10) Clinical Testing:
The proposed modification, the addition of PIV Assist feature to Sonosite LX and Sonosite PX Ultrasound Systems, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

11) Conclusion drawn from clinical and non-clinical testing:
The intended uses and other key features are consistent with traditional clinical practice and the FDA guidance titled "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," issued February 2023. The Sonosite LX and Sonosite PX Ultrasound Systems, with the addition of the PIV Assist feature, and their predicates conform to applicable electromedical device safety standards, with compliance verified through independent evaluation. The Sonosite LX and Sonosite PX Ultrasound Systems, including the proposed modification adding the PIV Assist feature, and the predicates meet FDA requirements for Track 3 devices, share indications for use, demonstrate biosafety equivalence, and are manufactured under the same ISO 13485 and 21 CFR 820 quality systems. FUJIFILM SonoSite, Inc. believes that the Sonosite LX and Sonosite PX Ultrasound Systems, with the proposed modification adding the PIV Assist feature, are substantially equivalent in safety and effectiveness to the primary predicate device.