November 3, 2025

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

Re: K253448
Trade/Device Name: Sonosite MT 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: October 2, 2025
Received: October 2, 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

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.

K253448

Please provide the device trade name(s).

Sonosite MT Ultrasound System

Please provide your Indications for Use below.

The Sonosite MT 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
Cardiac Adult
Cardiac Pediatric
Fetal-OB/GYN
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Ophthalmic
Pediatric
Peripheral Vessel
Small Organ (breast, thyroid, testicles, prostate)
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 MT 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.

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.

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

K253448

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:

Manufacturer Name:	FUJIFILM SonoSite, Inc.
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Date prepared:	August 31, 2025
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2) Device

Trade Name:	Sonosite MT 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) <u>Predicate Device:</u>

Primary Predicate: Sonosite LX Ultrasound System (K251830)

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 Code: IYO, ITX
Device Class: II
Classification Panel: Radiology

Reference Device: 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 Code: IYO, ITX
Device Class: II
Classification Panel: Radiology

4) Device Description:

The Sonosite MT is a high-resolution, portable and versatile ultrasound system designed for use on a stand and easy grab-and-go deployment. It is a fully featured, general purpose, software controlled, diagnostic ultrasound system using all digital architecture.

The system is used to acquire and display high-resolution, real-time ultrasound data in 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.

The system includes a variety of accessories including needle guide starter kits (optional). 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. ECG is available only with cardiac exam types with the P5-1 transducer. Sonosite MT also features a Triple Transducer Connect (TTC) that allows simultaneous connection of three transducers to the system. The system also includes an I/O hub to facilitate connection to a network using an Ethernet connection. The I/O hub includes three USB 2.0 ports to connect with the accessories and one USB 3.0 plug to connect the module with the system. Sonosite MT system features a battery charge indicator presented by four LED lights and a scan time remaining display that indicates the battery charge level.

Intended Use/Indications for Use:

The Sonosite MT 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
Cardiac Adult
Cardiac Pediatric
Fetal – OB/GYN
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Ophthalmic
Pediatric
Peripheral vessel
Small Organ (breast, thyroid, testicles, prostate)
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 MT 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.

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.

5) Technological Characteristics:

The Sonosite MT Ultrasound System, subject device of this submission, is equivalent to the previously cleared primary predicate Sonosite LX (K251830) and the reference device, Sonosite LX Ultrasound System (K233597) in terms of both the intended use and technological characteristics. The Sonosite MT (subject device) uses the same fundamental scientific technology as the primary predicate device.

Feature	Sonosite MT Ultrasound System (This submission)	Sonosite LX Ultrasound System (K251830)	Sonosite LX Ultrasound System (K233597)	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 MT is identical to the predicate and reference devices.
Indications for Use	Abdominal Adult Cephalic Cardiac Adult Cardiac Pediatric Fetal-OB/GYN Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Ophthalmic Pediatric Peripheral vessel Small Organ (breast, thyroid, testicles, prostate) Transvaginal Needle Guidance	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	There are no new indication introduced with this submission. The indication for use include the subset of indications previously cleared on the primary predicate, Sonosite LX (K251830) and reference device, Sonosite LX (K233597).
Transducer Types	Linear Array Curved Linear Array Phased Array Intracavitary	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal	The Sonosite MT has the same transducer types as the primary predicate Sonosite LX (K251830) and reference device, Sonosite LX (K233597), except for trans-esophageal transducer type, which is not available with Sonosite MT in this release.

Transducer Frequency	1.0-19.0 MHz	1.0 – 46.0 MHz	1.0-19.0 MHz	The transducer frequency range is same as the reference device, Sonosite LX (K233597) and is within the range available on the primary predicate device Sonosite LX, (K251830). The transducer frequency range for primary predicate, Sonosite LX (K251830) is attributed to an ultra-high frequency probe which is not available on Sonosite MT.
Global Maximum Outputs/Worst Case Setting	Ispta.3: 621 mW/cm^2 (L19-5) TI Type: TIC (C5-1) TI Value: 4.18 (C5-1) MI: 1.72 (L19-5) Ipa.3@MI Max: 604 W/cm^2 (L12-3)	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 is within the 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 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 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 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)	Same as the primary predicate Sonosite LX (K251830)

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, Modality Worklist, Modality Perform Procedure Step (MPPS), Storage Commitment, Structured reports, offline media	Same as the primary predicate Sonosite LX (K251830) and the reference device Sonosite LX (K233597)
#Transmit Channels	128 digital channels	128 digital channels	128 digital channels	Same as the primary predicate Sonosite LX (K251830) and the reference device Sonosite LX (K233597)
#Receive Channels	64 digital channels	128 digital channels	128 digital channels	The number of receive channels for 2D and PW imaging is limited to 64 channels in Sonosite MT as compared to 128 channels in primary predicate, Sonosite LX (K251830) and reference device, Sonosite LX (K233597). This results in subtle adjustment in lateral resolution in far-field imaging, but it does not alter the image quality. Previously cleared primary predicate Sonosite LX (K251830) and reference Sonosite LX (K233597) offer 64-receiving channel mode on existing probes P5-1 and IC10-3.

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 Rexolite 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)	Same as the reference device, Sonosite LX (K233597).
DICOM	DICOM PS3.15	DICOM PS3.15	DICOM PS3.15	Same as the primary predicate Sonosite LX(K251830) and reference device Sonosite LX (K233597)

System Characteristics	**Sonosite MT (This submission)** Sonosite MT provides an all touch-user interface with two 13.5” LCDs with a 3:2 aspect ratio. **Dimensions** **System** • Length: 12.9 in. (32.7 cm) • Width: 12.9 in. (32.7 cm) • Height: 12.5 in. (31.8 cm with lid raised) • Weight: 13.0 lbs (5.6 kg) with battery installed **Stand** • Depth: 27.3 in. (69.2 cm) • Width: 27.2 in. (69 cm) • Height: 48.7 in. (123,7 cm) maximum, 41 in. (104.1 cm) minimum • Height range: 6.1 in. (15.5 cm) • Weight: 41 lbs. (18.6 kg) •Storage bin capacity: 11 lbs. (5 kg) •Total stand weight with system and peripherals: 96.12 lbs. (43.6 kg) maximum Stand Battery Lite •Length: 13.2 in. (33.9 cm) •Width: 5.0 in. (12.6 cm) •Depth: 2.5 in. (6.3 cm) •Weight: 5.5 lbs (2.5 kg with both batteries installed) Display •Width: 11.2 in. (28.5 cm) •Height: 7.5 in. (20 cm) •Diagonal: 13.5 in. (34.2 cm) •Resolution: 1920 x 1280 px	**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	**Sonosite LX (Kiosk form factor):** 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 MT is a clamshell system that can be used in a mobile configuration (on the stand) and portably (off the stand). The Sonosite MT allows users to interact with the system using one of two touch screens (either the clinical monitor or the control panel), similar to the predicate and reference device, Sonosite LX (K251830 and K233597), which has touch screen monitor and control panel functionality. Sonosite MT, subject of this submission, features a triple transducer connect (TTC) accessory to simultaneously connect three transducers to the system. This is similar to the Sonosite LX (K251830 and K233597), which also have TTC functionality. Like the primary predicate and reference device, Sonosite LX (K251830 and K233597), Sonosite MT also includes an I/O hub to facilitate connection to a network using an Ethernet connection and includes USB ports to connect accessories. The system portal feature previously cleared on Sonosite LX (K251830) is

	Electrical rating **Stand** •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 Lite** •Contains two battery packs: 22.2 VDC, 4250 mAh, 94.35 Wh (each) •Input: 28 VDC, 6.42 A (max 180 W) •Output: 18–28 VDC, 10 A (max 180 W)	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		also available with Sonosite MT.
	Power supply •Input: 100–240 VAC, 50–60 Hz, 2.5 A max •Output: 28 VDC, 6.42 A, 180 W max 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/ax support for image transfer **Additional system features:** System Portal for remote monitoring and management Triple Transducer connect I/O hub	**Additional system features:** Added the UHF46-20 ultra-high frequency transducer and associated exam types	**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 **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	
510k Track	Track 3	Track 3	Track 3	Same

6) Determination of Substantial Equivalence:

Summary of Technological Comparison to Predicate Devices:

The Sonosite MT Ultrasound System, subject device of this submission, is enhanced implementation of previous FDA cleared predicate devices Sonosite LX (K251830) and reference device, Sonosite LX Ultrasound System (K233597).

The primary function of Sonosite MT Ultrasound System (this submission) and the predicate device is diagnostic ultrasound imaging or fluid flow analysis of the human body. The Sonosite MT Ultrasound System employs the same fundamental scientific characteristics as the currently marketed predicate devices. The Sonosite MT 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.

- Sonosite MT has all touch user interface with two 13.5'' LCDs for clinical monitor and control panel. Touch user interface is also available on the previously cleared primary predicate Sonosite LX (K251830), but on a larger clinical monitor and control panel.
- The number of receiving channels for 2D and PW imaging is limited to 64 channels in Sonosite MT. Previously cleared primary predicate Sonosite LX (K251830) and reference Sonosite LX (K233597) offer 64-channel mode on existing probes P5-1 and IC10-3.
- Commercialization of System portal feature for remote monitoring and management to allow remote software updates and system monitoring by connection to a cloud service that allows remote software updates and system monitoring for remote service personnel to troubleshoot issue. The system portal feature was previously cleared on the predicate device Sonosite LX (K251830).
- The Sonosite MT includes an I/O hub to facilitate connection to a network using an Ethernet connection. The primary predicate Sonosite LX (K251830) includes similar capability to facilitate network connection via USB ports.
- The Sonosite MT features a Triple Transducer Connect (TTC) that allows simultaneous connection of three transducers to the system, similar to the triple transducer connection (TTC) available on primary predicate device Sonosite LX (K251830).

The transducers C5-1, L19-5, L12-3, L15-4, P5-1, IC10-3 which are available with the subject device (Sonosite MT) were previously cleared on 510(k) submissions, including for primary predicate Sonosite LX (K251830) and reference device Sonosite LX (K233597). No changes have been made to the transducers. The transducer frequency range for Sonosite MT in this submission falls within the range of previously cleared primary predicate, Sonosite LX (K251830) and the reference device, Sonosite LX (K233597).

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 MT leverage existing technological characteristics and features available on both the primary predicate (K51830) and the reference device (K233597). 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 MT Ultrasound System uses an all-touch user interface, is configured with 64 receiving channels for 2D and PW imaging, uses the previously cleared system portal feature for remote monitoring and management to allow for software updates and system monitoring, has an I/O hub and TTC connection similar to previously cleared reference device (K233597). The Sonosite MT has been evaluated for electrical, thermal, mechanical, and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated for Sonosite MT, 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 MT 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	5-132	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 MT Ultrasound System and transducers, subject of this submission, which uses an all-touch user interface, is configured with 64 receiving channels for 2D and PW imaging, uses the previously cleared system portal feature for remote monitoring and management to allow for software updates and system monitoring, has an I/O hub and TTC connection similar to previously cleared reference device (K233597), did not require clinical studies to support the determination of substantial equivalence. The Sonosite MT 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 MT Ultrasound System and both predicate and reference devices conform to applicable electromedical device safety standards with compliance verified through independent evaluation. The Sonosite MT Ultrasound System and both predicate and referenced devices 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 MT Ultrasound System is substantially equivalent with regards to safety and effectiveness to the predicate devices.