December 27, 2021

FUJIFILM Sonosite, Inc.
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
SAINT PAUL MN 55114

Re: K213763
Trade/Device Name: Sonosite PX Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OIJ
Dated: November 30, 2021
Received: December 1, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Jessica Lamb, Ph.D.
Assistant Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K213763

Device Name
Sonosite PX Ultrasound System

Indications for Use *(Describe)*
The Sonosite PX 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
Transesophageal (cardiac)
Transrectal
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 PX 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 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 PX 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:	21 CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570
Primary Product Code:	IYN

Secondary Product Codes:	IYO ITX OIJ
Device Class:	Class II
Classification Panel:	Radiology

3) Predicate Device:

Primary Predicate: Sonosite PX Ultrasound System (K200964)

Reference Device: SonoSite Edge II Ultrasound System (K162045)

4) Device Description:

The Sonosite PX 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 (including Simultaneous M-Mode and anatomical M-Mode), Pulsed Wave (PW) Doppler (including Pulsed Wave Tissue Doppler), Continuous Wave (CW) Doppler, Color Power Doppler (including Velocity Color Doppler), Tissue Harmonic Imaging or in a combination of these modes, including Triplex imaging.

The system includes a variety of accessories including optional needle guide starter kits. 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 PX 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
Transesophageal (cardiac)
Transrectal
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 PX 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.

6) Technological Characteristics:

The Sonosite PX Ultrasound System, subject device of this submission, is equivalent to the previously cleared Sonosite PX (K200964) and Edge II (K162045) Ultrasound Systems in terms of both the intended use and technological characteristics. The Sonosite PX (subject device) uses the same fundamental scientific technology as the predicate device.

Feature	Sonosite PX Ultrasound System (This submission)	Sonosite PX Ultrasound System (K200964)	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 PX 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 Small Organ (breast, thyroid, testicle, prostate) Transvaginal Peripheral Vessel Trans-Rectal Trans-esophageal (cardiac) Needle guidance	Abdominal Adult Cephalic Cardiac Adult Cardiac Pediatric Fetal – OB/GYN Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Ophthalmic Pediatric Small Organ (breast, thyroid, testicle, prostate) Peripheral Vessel Transvaginal Needle guidance	Abdominal Adult 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 Neonatal Cephalic Trans-Rectal Trans-esophageal (cardiac) Needle guidance	The Indications for Use are a subset of Sonosite PX Ultrasound system (primary predicate-K200964)) and Sonosite Edge II Ultrasound system (reference device-K162045).

Transducer Types	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal	Linear Array Curved Linear Array Phased Array Intracavitary	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal	Transducer types for Sonosite PX are all a subset of Sonosite PX Ultrasound 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 PX is unchanged and the same as the primary predicate Sonosite PX (K200964)
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 AMM 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 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 Color M-Mode Color Power Doppler Zoom Combination Modes Pulsed Wave (PW) Doppler Continuous Wave (CW) Doppler SonoHD2 Noise Reduction SonoMB/MBe Image Compounding Steered CW Doppler Velocity Color Doppler Tissue Doppler Imaging (TDI)	Modes of operation are a subset of Sonosite PX Ultrasound system (primary predicate) and Sonosite Edge II Ultrasound system (reference device). The AMM imaging frame and transmit sequence is identical to regular simultaneous 2D/M-mode as seen on predicate device Sonosite PX (K200964). The only difference is the AMM line is extracted from the 2D image data based on the AMM line position the user specified and the display in the sweep field of view.
DICOM	DICOM 3.0 Store and Offline Media	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step(PPS), Storage Commitment	DICOM 3.0 Store, Print, Modality Worklist, Perform ProcedureStep (PPS), Storage Commitment	Includes a subset of thisinformation
#Transmit Channels	128 digital channels	128 digital channels	128 digital channels	-

#Receive Channels	128 digital channels	64 digital channels (128 digital channels usingSynthetic Aperture)	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 Polysulfon e UDEL P1700 PolyVinylChloride (PVC)Silicone RTV Adhesive Silicone **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 testedto ISO 10993-1. Materials used in SonositePX have undergone identical biocompatibility and cleaning/disinfection testing to the predicate devices. Bio-compatibility summary test results are provided in D00414, Bio-compatibility Test Report, included in Attachment 6 ofthis submission.
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	AAMI/ANSI ES60601-1:2005 (R2012 IEC 60601-2-37:2007+AMD1:2015 CAN/CSA-C22.2 No. 60601-1:14 JSAJIS T 0601-1:2017, JSA JIS T 0601-2-37 IEC 61157:2007+AMD1:2013	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	-

	IEC 62359:2010+AMD1:2017	NEMA UD 2-2004 (R2009) IEC 62359:2010+AMD1:2017		
EMC Compliance	IEC 60601-1-2:2014 CISPR 11:2015+AMD1:2016 +AMD2:2019 IEC 61000-4-2. IEC 61000-4-3 IEC 61000-4-4. IEC 61000-4-5 IEC 61000-4-6. IEC 61000-4-8 IEC 61000-4-11	IEC 60601-1-2:2014 CISPR 11:2015+AMD1:2016 +AMD2 IEC 61000-4-2. IEC 61000-4-3 IEC 61000-4-4. IEC 61000-4-5 IEC 61000-4-6. IEC 61000-4-8 IEC 61000-4-11	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A	-
DICOM	DICOM PS3.15 2011	NEMA PS3.15 2003	NEMA PS3.15 2003	-
Airborne Equipment Standards	none applied	none applied	RTCA/DO160 (section 21)	Airborne equipment standards have not been applied to the Sonosite PXultrasound system and labeling will not claim to this.

System Characteristics	**Sonosite PX:** Beamformer 128/128 using SA (configurable) 12.1" Capacitive touch screen interface 19" LED LCD HD monitor 256 gray shades on LED LCD 2 USB 3.0 4 USB 2.0 Stand Base Dimensions: 26.4" L x 21.2" W Stand Height (max): 64" (monitor up) Stand Height (min): 42.2" (monitor down) Weight: 149.35 lbs (fully configured w/ 3 transducers and stand base Weight: 32.80 lbs (w/ 1 transducer) System operates via batteryor AC power Battery life: 1 hour imaging - 10 days idle Input: 100 – 240 VAC, 50/60 Hz Output 1: 26.7VDC output, 220 W max System on stand:	**Sonosite PX:** Beamformer 128/128 using SA (configurable) 12.1" Capacitive touch screen interface 19" LED LCD HD monitor 256 gray shades on LED LCD 2 USB 3.0 4 USB 2.0 Stand Base Dimensions: 26.4" L x 21.2" W Stand Height (max): 64" (monitor up) Stand Height (min): 42.2" (monitor down) Weight: 149.35 lbs (fully configured w/ 3 transducers and stand base Weight: 32.80 lbs (w/1 transducer) System operates via battery or AC power Battery life: 1 hour imaging - 10 days idle Input: 100 – 240 VAC, 50/60 Hz Output 1: 26.7VDC output, 220 W max System on stand:	**Edge II:** Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD2 USB ports Dimensions: 12.8"(W) x 12.1" (L) x 2.5"(H) Weight: 9.0 lbs System operates via battery or AC power Battery life: 1.5 - 4 hour operation per charge 100 – 240V options, 50/60Hz, 15VDC output	Sonosite PX 2.0 includes a non-diagnostic ECG module.Like reference device Edge II ultrasound system (K162045), this module provides ECG tracing of the cardiac signal synchronized with the ultrasound image.

	Input: 100 – 240 VAC, 50/60 Hz Output 1: 26.7VDC output, 220 W max Output 2: 100-240VAC, 50-60 Hz (AC Printer) 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) **Additional system features:** Assisted CardiacOutput (ACO) – Available on Sonosite PX system	Input: 100 – 240 VAC, 50/60 Hz Output 1: 26.7VDC output, 220 W max Output 2: 100-240VAC, 50-60 Hz (AC Printer) Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages Wireless 802.11 (a/b/g/n) support for image transfer **Additional system features:** Assisted Cardiac Output (ACO) – Available on Sonosite PX system	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) – Available on Edge II system	
510(k) Track	Track 3	Track 3	Track 3	

7) Determination of Substantial Equivalence:

Summary of Technological Comparison to Predicate Devices:

The Sonosite PX Ultrasound System, subject device of this submission, is enhanced implementation of previous FDA Cleared predicate devices Sonosite PX (K200964) and Sonosite Edge II Ultrasound System (K162045). The technological characteristics and physical design are unchanged from the primary predicate Sonosite PX (K200964) and reference device Edge II (K162045) ultrasound systems. The primary function of Sonosite PX Ultrasound System and the predicate devices is diagnostic ultrasound imaging or fluid flow analysis of the human body. The Sonosite PX Ultrasound System employs the same fundamental scientific characteristics as the currently marketed predicate devices. The Sonosite PX 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 PX Ultrasound System) and its predicates.

- Addition of T8-3 transducer, which is substantially equivalent to the TEExi transducer previously cleared on Edge II (K153626).
- Addition of C10-3 transducer, which is substantially equivalent to the C5-1 and C35x transducers previously cleared on Sonosite PX (K200964) and Edge II (K162045) respectively.
- Addition of two new clinical indications: trans-esophageal and trans-rectal, which are the same indications cleared on Edge II (K162045).
- Addition of non-diagnostic ECG module which provides ECG tracing of the cardiac signal synchronized with the ultrasound image, similar to the module cleared on Edge II (K162045).
- Addition of compatible OEM Needle Guide for use with C10-3 transducer. The needle guidance has been cleared (K093713).
- Addition of PIV exam type (preset) to work with L12-3 transducer. The PIV exam type (preset) is already available on predicated device Sonosite PX (K200964) transducer L19-5.
- Addition of Anatomical M-Mode available on P5-1 and T8-3 probes in cardiac exams. Anatomical M-Mode (AMM) is a display option in simultaneous 2D-Mode, which is available in Sonosite PX (K200964). The AMM uses 2D data instead of M-mode data.
- Addition of Cleaning Mode for device, which locks the user interface touch screen so that user can wipe the screen without accidentally touching or moving controls.
- Addition of carotid exam and measurements. The carotid exam type and measurements have the same imaging optimization as the arterial exam type on predicate Sonosite PX (K200964). The carotid exam type provides carotid blood flow calculations using either the right or left side. This is similar to what is seen in arterial exam for the reference device (K162045). However the subject device provides the user with the ability to evaluate fluid responsiveness for calculating stenosis in the carotid specifically.
- Addition of Qview. The Qview feature provides a communication pathway with QPathE. To access the reporting capability of QPathE, the user can access the product through the Sonosite PX system by opening the Qview feature. Both Qview and QPathE are products of Telexy Healthcare.
- Addition of Customized Exam Setting. This allows for the customer to use the exams

provided to them on the Sonosite PX and customize the settings to have their most preferred or used exams placed in an order based on the use of the system and exam presets. This does not change the function of the device or exam types. Rather allows for preferences for exams to be customized through this settings tool.

The transducer types for the subject device are all a subset of the primary predicate (Sonosite PX - K200964) and reference device (Sonosite Edge II - K162045). The transducer frequency range is unchanged and the same as the primary predicate Sonosite PX (K200964). The transducers have been tested to performance standards and the acoustic output is less than FDA established limits. Similar to the predicates, 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 PX leverage existing technological characteristics and features available on both the primary predicate (K200964) and 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 PX Ultrasound System has been evaluated for electrical, thermal, mechanical, and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated, 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, Clinical Validation. All patient contact materials are biocompatible.
The Sonosite PX 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	5-40	ANSI AAMI ISO 14971:2007/(R) 2010 - Medical devices - Application of risk management to medical devices
IEC 62359	12-316	IEC 62359:2010+AMD1:2017 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 PX Ultrasound System and transducers, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

Conclusion

The Sonosite PX Ultrasound System meets FDA requirements for Track 3 devices, shares indications for use with the primary predicate and reference device. With successful verification and validation testing and conformance to applicable electromedical device safety standards as well as compliance verified through independent evaluation as part of the nonclinical testing summarized above, FUJIFILM Sonosite considers the proposed Sonosite PX Ultrasound System to be as safe, as effective and performance that is substantially equivalent to the primary predicate.