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

May 8, 2020

Re: K200964
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: April 9, 2020
Received: April 10, 2020

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 and Part 809); 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

Thalia T. Mills, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/03/2020
See PRA Statement below.

510(k) Number *(if known)*
K200964

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
Needle Guidance

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

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1.3 INDICATIONS FOR USE

The indications for use are listed in the FDA defined tables on the following pages.

Table 1.3-1: Diagnostic Ultrasound Indications for Use Form – Sonosite PX Ultrasound System

System:	Sonosite PX Ultrasound System						
Transducer:	N/A						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler (C)	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	c, e, f
Fetal – OB/GYN	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	c, e, f, h
Abdominal	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD;	c, e, f
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD;	b, c, e, f, h
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f, h
Neonatal Cephalic							
Adult Cephalic	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	f
Trans-rectal							
Trans-vaginal	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	c, e, f, h
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f, h
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f, h
Intra-luminal							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+C; (B+C)+PWD; (B+C)+CWD	c, d, g, f
Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+C; (B+C)+PWD; (B+C)+CWD	c, d, g, f
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f, h
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

a. B = B Mode; M= M Mode including simultaneous; PWD = Pulse Wave Doppler; CWD= Continuous Wave Doppler; C = Color Doppler (Velocity Color Doppler or CVD, Color Power Doppler or CPD, Variance or Var)
b. Steep Needle Profiling (SNP) = Needle enhancement in B mode
c. Tissue Harmonic Imaging (THI)
d. Tissue Doppler Imaging (TDI)
e. Multi-beam Imaging (SonoMB) in B-Mode
f. Color Doppler includes Power/Velocity
g. Color Doppler includes Velocity/Variance
h. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures

Prescription Use (Per 21 CFR 801.109)

Table 1.3-2: Diagnostic Ultrasound Indications for Use Form – L19-5 MHz Transducer

System:	Sonosite PX Ultrasound System						
Transducer:	L19-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler (C)	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	e, f
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD;	b, c, e, f, h
Small Organ (breast, thyroid, testicles. prostate)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f, h
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f, h
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f, h
Intra-luminal							
Cardiac Adult	N	N	N		N	B+M;B+PWD;B+C;(B+C)+PWD	f
Cardiac Pediatric	N	N	N		N	B+M;B+PWD;B+C;(B+C)+PWD	f
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f, h
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

a. 2D = B Mode; M= M Mode including simultaneous; PWD = Pulse Wave Doppler; CWD= Continuous Wave Doppler; C = Color Doppler (Velocity Color Doppler or CVD, Color Power Doppler or CPD, Variance or Var)
b. Steep Needle Profiling (SNP) = Needle enhancement in B mode
c. Tissue Harmonic Imaging (THI)
d. Tissue Doppler Imaging (TDI)
e. Multi-beam Imaging (SonoMB) in B-Mode
f. Color Doppler includes Power/Velocity
g. Color Doppler includes Velocity/Variance
h. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures

Prescription Use (Per 21 CFR 801.109)

Table 1.3-3: Diagnostic Ultrasound Indications for Use Form – L15-4 MHz Transducer

System:	Sonosite PX Ultrasound System						
Transducer:	L15-4 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler (C)	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD;	b, c, e, f
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

a. 2D = B Mode; M= M Mode including simultaneous; PWD = Pulse Wave Doppler; CWD= Continuous Wave Doppler; C = Color Doppler (Velocity Color Doppler or CVD, Color Power Doppler or CPD, Variance or Var)
b. Steep Needle Profiling (SNP) = Needle enhancement in B mode
c. Tissue Harmonic Imaging (THI)
d. Tissue Doppler Imaging (TDI)
e. Multi-beam Imaging (SonoMB) in B-Mode
f. Color Doppler includes Power/Velocity
g. Color Doppler includes Velocity/Variance
h. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures

Prescription Use (Per 21 CFR 801.109)

Table 1.3-4: Diagnostic Ultrasound Indications for Use Form – L12-3 MHz Transducer

System:	Sonosite PX Ultrasound System						
Transducer:	L12-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler (C)	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD, B+C; (B+C)+PWD	e, f
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD;	b, c, e, f
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Intra-luminal							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

a. 2D = B Mode; M= M Mode including simultaneous; PWD = Pulse Wave Doppler; CWD= Continuous Wave Doppler; C = Color Doppler (Velocity Color Doppler or CVD, Color Power Doppler or CPD, Variance or Var)
b. Steep Needle Profiling (SNP) = Needle enhancement in B mode
c. Tissue Harmonic Imaging (THI)
d. Tissue Doppler Imaging (TDI)
e. Multi-beam Imaging (SonoMB) in B-Mode
f. Color Doppler includes Power/Velocity
g. Color Doppler includes Velocity/Variance
h. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures

Prescription Use (Per 21 CFR 801.109)

Table 1.3-5: Diagnostic Ultrasound Indications for Use Form – C5-1 MHz Transducer

System:	Sonosite PX Ultrasound System						
Transducer:	C5-1 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler (C)	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal – OB/GYN	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	c, e, f
Abdominal	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	c, e, f
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Small Organ (breast, thyroid, testicles. prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Musculo-skel. (Superfic.)							
Intra-luminal							
Cardiac Adult	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	f
Cardiac Pediatric	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	f
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	b, c, e, f
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

a. 2D = B Mode; M= M Mode including simultaneous; PWD = Pulse Wave Doppler; CWD= Continuous Wave Doppler; C = Color Doppler (Velocity Color Doppler or CVD, Color Power Doppler or CPD, Variance or Var)
b. Steep Needle Profiling (SNP) = Needle enhancement in B mode
c. Tissue Harmonic Imaging (THI)
d. Tissue Doppler Imaging (TDI)
e. Multi-beam Imaging (SonoMB) in B-Mode
f. Color Doppler includes Power/Velocity
g. Color Doppler includes Velocity/Variance
h. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures

Prescription Use (Per 21 CFR 801.109)

Table 1.3-6: Diagnostic Ultrasound Indications for Use Form – P5-1 MHz Transducer

System:	Sonosite PX Ultrasound System						
Transducer:	P5-1 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler (C)	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal – OB/GYN	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	c, g
Abdominal	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD;	c, e, f
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles. prostate)							
Neonatal Cephalic							
Adult Cephalic	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	f
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+C; (B+C)+PWD; (B+C)+CWD	c, d, g, f
Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+C; (B+C)+PWD; (B+C)+CWD	c, d, g, f
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

a. 2D = B Mode; M= M Mode including simultaneous; PWD = Pulse Wave Doppler; CWD= Continuous Wave Doppler; C = Color Doppler (Velocity Color Doppler or CVD, Color Power Doppler or CPD, Variance or Var)
b. Steep Needle Profiling (SNP) = Needle enhancement in B mode
c. Tissue Harmonic Imaging (THI)
d. Tissue Doppler Imaging (TDI)
e. Multi-beam Imaging (SonoMB) in B-Mode
f. Color Doppler includes Power/Velocity
g. Color Doppler includes Velocity/Variance
h. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures

Prescription Use (Per 21 CFR 801.109)

Table 1.3-7: Diagnostic Ultrasound Indications for Use Form – IC10-3 MHz Transducer

System:	Sonosite PX Ultrasound System						
Transducer:	IC10-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler (C)	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal – OB/GYN	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	c, e, f, h
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles. prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal	N	N	N		N	B+M; B+PWD; B+C; (B+C)+PWD	c, e, f, h
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under this appendix

Additional Comments:

a. 2D = B Mode; M= M Mode including simultaneous; PWD = Pulse Wave Doppler; CWD= Continuous Wave Doppler; C = Color Doppler (Velocity Color Doppler or CVD, Color Power Doppler or CPD, Variance or Var)
b. Steep Needle Profiling (SNP) = Needle enhancement in B mode
c. Tissue Harmonic Imaging (THI)
d. Tissue Doppler Imaging (TDI)
e. Multi-beam Imaging (SonoMB) in B-Mode
f. Color Doppler includes Power/Velocity
g. Color Doppler includes Velocity/Variance
h. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures

Prescription Use (Per 21 CFR 801.109)

ATTACHMENT 1 – Summary of Safety and Effectiveness

Summary of Safety and Effectiveness

In accordance with the requirements addressed by the Safe Medical Devices Act of 1990 and FDA's *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*, this Attachment provides the "510(k) Summary" of safety and effectiveness information to support the determination of substantial equivalence to currently-marketed predicate devices.

A "Certification" is also included herein.

510(k) Summary/Statement Certification

Re: 510(k) Premarket Notification
Sonosite PX Ultrasound System

CHECK ONLY ONE:

_X_ 1. 510(k) Summary. Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

____ 2. 510(k) Statement I certify that, in my capacity as

_____
of_____(company),

I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Sudipta Chakrabarti
_____

02/18/2020

Sudipta Chakrabarti
Sr. Regulatory Affairs Specialist
FUJIFILM SonoSite, Inc.

Date

510(K) Summary

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's name, address, telephone number, contact person:

FUJIFILM SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official:	Sudipta Chakrabarti Sr. Regulatory Affairs Specialist
E-mail:	sudipta.chakrabarti@fujifilm.com
Telephone:	(425) 951-1371
Facsimile:	(425) 951-1201
Date prepared:	August 30, 2019
Alternate Contact:	Anoush Frankian Sr. Manager, Regulatory Affairs
E-mail:	anoush.frankian@fujifilm.com
Telephone:	(425) 951-6824
Facsimile:	(425) 951-1201

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

Sonosite PX Ultrasound System

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX
Ultrasonic Pulsed Echo Imaging System	892.1560	OIJ

3) Identification of the predicate or legally marketed device:

Primary Predicate: SonoSite Edge II Ultrasound System (K162045)

Secondary Predicate: SonoSite X-Porte Ultrasound System (K171437)

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), 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. The Sonosite PX Ultrasound System also includes needle guidance capability. The system is capable of working with two different types of needle guide brackets available, including 1) Fixed-angle, in-plane brackets where a pair of guidelines are generated that represent the path of the needle and 2) Transverse-angle, out-of-plane brackets (adjustable depths) where the guidelines appear down the center of the image. Each Sonosite PX transducer has an appropriate needle guide bracket kit to support needle guidance with the system.

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
Needle Guidance

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:

Sonosite PX, Edge II, and X-Porte Ultrasound Systems are Track 3 devices that employ the same fundamental scientific technology. A comparison table is provided below.

Feature	Sonosite PX Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K162045)	SonoSite X-Porte Ultrasound System (K171437)
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
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 Cardiac Adult Cardiac Pediatric Fetal – OB/GYN Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Ophthalmic Pediatric Small Organ (breast, thyroid, testicles, prostate) Trans-vaginal Peripheral vessel Neonatal Cephalic 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, testicles, prostate) Trans-vaginal Peripheral vessel Neonatal Cephalic Trans-esophageal (cardiac) Needle Guidance
Transducer Types	Linear Array Curved Array Phased Array Intracavitary	Linear Array Curved Linear Array Phased Array Intracavitary Trans-esophageal	Linear Array Curved Linear Array Phased Array Intracavitary Static Probes Trans-esophageal
Transducer Frequency	1.0-19.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz
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)*	$I_{spta.3}$: 598.9 (HFL50x) TI Type: TIB (rP19x) TI Value: 4.98 (rP19x) MI: 1.7 (rP19x)	*$I_{spta.3}$: 629.3 (P21xp)* *TI Type:* TIB *(P21xp)* *TI Value:* 4.0 *(P21xp)* *MI: 1.7 (P21xp)* *$I_{pa.3}$@MI Max: 678 (L38xp)*

Feature	Sonosite PX Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K162045)	SonoSite X-Porte Ultrasound System (K171437)
		$I_{pa.3}$@MI Max: 776 (L38xi)	
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
Modes of Operation	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 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)	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Simultaneous M-Mode Color Power Doppler Zoom Combination Modes Simultaneous PW Imaging 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)
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 Procedure Step (PPS), Storage Commitment
#Transmit Channels	128 digital channels	128 digital channels	128 digital channels
#Receive Channels	128 digital channels	64 digital channels	64 digital channels (128 digital channels using Synthetic Aperture)

Feature	Sonosite PX Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K162045)	SonoSite X-Porte Ultrasound System (K171437)
		(128 digital channels using Synthetic Aperture)	
Patient Contact Materials	Silicone Rubber Polysulfone PolyVinylChloride (PVC) Silicone RTV Adhesive Silicone	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive Epoxy resin Polyetherimide Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polysulfone Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)
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 NEMA UD 2-2004 (R2009) IEC 62359:2010+AMD1:2017	AAMI/ANSI ES60601-1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 60601-1:08 NEMA UD2-2004 IEC 62359:2010	AAMI/ANSI ES60601-1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 601.1 JIS T 0601-1, JIS T 1507 CEI/IEC 61157 ANSI/AAMI EC53 NEMA UD2-2004 IEC 62359:2010

Feature	Sonosite PX Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K162045)	SonoSite X-Porte Ultrasound System (K171437)
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	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A	IEC 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5
DICOM	DICOM PS3.15 2019	NEMA PS3.15 2003	NEMA PS3.15 2003
Airborne Equipment Standards	Not applied	RTCA/DO160 (section 21)	RTCA/DO160D (section 21)
System Characteristics	**Sonosite PX:** Beamformer 128/128 using SA (configurable) 12.1" Capacitive touch screen interface 15.6" 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)	**Edge II:** Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD 2 USB ports Dimensions: 12.8"(W) x 12.1" (L) x 2.5"(H) Weight: 9.0 lbs	**X-Porte (stand configuration):** Beamformer 128/128 using SA (configurable) 12.1" Capacitive touch screen interface 19" LED LCD HD monitor 256 gray shades on LED LCD 6 USB 2.0 ports 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

	System operates via battery or AC power Battery life: 1 hour imaging - 10 days idle	System operates via battery or AC power Battery life: 1.5 - 4 hour operation per Charge	System operates via battery or AC power Battery life: 1 hour operational - 3 days idle
	Input: 100 – 240 VAC, 50/60 Hz Output 1: 26.7VDC output, 220 W max **System on stand:** Input: 100 – 240 VAC, 50/60 Hz Output 1: 26.7VDC output, 220 W max Output 2: 100-240VAC, 50-60 Hz (AC Printer)	100 – 240V options, 50/60 Hz, 15VDC Output	Input: 100 – 240 VAC, 50/60 Hz Output 1: 24VDC output, 275 W max Output 2: 100-240VAC, 50-60 Hz (AC Printer, DC Printer)
	Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages	Various obstetrical, cardiac, volume, M- mode, PW and CW Doppler measurement and calculation packages	Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages
		ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media	ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Measurement on Recalled Images.
	Wireless 802.11 (a/b/g/n) support for image transfer	Wireless 802.11(b/g/n) support for image transfer	Wireless 802.11 (a/b/g/n) support for image transfer
	Additional system features: Assisted Cardiac Output (ACO) – Available on Sonosite PX system	**Additional system features:** Assisted Cardiac Output (ACO) – Available on Edge II system	**X-Porte (desktop configuration):** Same software features/capabilities as the stand configuration. Does not have the stand, touch panel interface, DVR, and mobile power unit. Weight: 32.80 lbs (w/ 1 transducer) AC power only. 100 – 240V options, 50/60 Hz
510(k) Track	Track 3	Track 3	Track 3

7) Determination of Substantial Equivalence:

Summary of Technological Comparison to Predicate Devices:

Sonosite PX Ultrasound System is enhanced implementation of previous FDA Cleared predicate devices Sonosite Edge II Ultrasound System (K162045) and Sonosite X-Porte Ultrasound System (K171437). 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 Sonosite Edge II Ultrasound System (K162045) and Sonosite X-Porte Ultrasound System (K171437). The Sonosite PX Ultrasound device and predicates share indications for use, share modes of operation and have biosafety equivalence. The primary differences are a new form factor to the control panel, which now includes both touch and tactile control panel. Display size on the Sonosite PX is slightly different than those on the predicate devices, but performance evaluation has deemed the screen size not to impact intended use and image quality of the system. Additionally, the Sonosite PX Ultrasound System has a higher transducer frequency range compared to the predicate devices. Where differences are noted with respect to transducer frequency, between the range for the subject device and the predicates, testing to applicable performance standards demonstrates that it does not introduce any new safety or effectiveness concerns. The Sonosite PX Ultrasound system remains substantially unchanged from the predicate with respect to its intended use and performance claims.

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 mandatory 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	2-220	AAMI ANSI ISO 10993-1:2009/(R) 2013, 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
NEMA UD 2-2004	12-105	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

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

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The Sonosite PX Ultrasound device and predicates conform to applicable electromedical device safety standards with compliance verified through independent evaluation. The Sonosite PX 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, 21CFR820 quality system. FUJIFILM SonoSite, Inc. believes that the Sonosite PX Ultrasound System is substantially equivalent with regard to safety and effectiveness to the predicate devices.