DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FUJIFILM SonoSite, Inc.
% Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

June 12, 2017

Re: K171437
Trade/Device Name: SonoSite X-Porte Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: May 12, 2017
Received: May 16, 2017

Dear Mr. Mark Job:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171437

Device Name
SonoSite X-Porte Ultrasound System

Indications for Use *(Describe)*
The SonoSite X-Porte 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:

Ophthalmic
Fetal – OB/GYN
Abdominal
Pediatric
Small Organ (breast, thyroid, testicles, prostate)
Neonatal Cephalic
Adult Cephalic
Trans-vaginal
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Cardiac Adult
Cardiac Pediatric
Trans-esophageal (card.)
Peripheral Vessel

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Table 1.3-1: Diagnostic Ultrasound Indications for Use Form – SonoSite X-Porte Ultrasound System

System:	SonoSite X-Porte 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	P	P	P		P	B+M; **B+PWD;** B+**C**; **(B+C)+PWD**	**1-5**
Fetal	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,2,5**
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+**C; (B+C)+PWD; (B+C)+CWD**	**1,2,5**
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CWD; B+**C**; **(B+C)+PWD; (B+C)+CWD**	1-5
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,4,5**
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+**C; (B+C)+PWD**	**1,5**
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1,5**
Trans-rectal							
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+**C; (B+C)+PWD**	1,5
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,2,4,5**
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1,4,5**
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+**C; (B+C)+PWD; (B+C)+CWD**	**1-3**
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+**C; (B+C)+PWD; (B+C)+CWD**	**1-3**
Trans-esophageal (card.)	**P**	**P**	**P**	**P**	**P**	B+M; B+PWD; B+CWD; B+**C**; **(B+C)+PWD; (B+C)+CWD**	**1,3**
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+**C**; **B+PW; (B+C)+PWD**	**1,2,4-6**
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K152209, K142017, K133134.
Prescription Use (Per 21 CFR 801.109)

Table 1.3-2: Diagnostic Ultrasound Indications for Use Form – C11xp/8-5 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	C11xp/8-5 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							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,5
Small Organ (breast, thyroid, testicles. prostate)							
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	1,5
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	1,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K142017.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-3: Diagnostic Ultrasound Indications for Use Form – C35xp/8-3 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	C35xp/8-3 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							
Abdominal	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,2,5**
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,2,4,5
Small Organ (breast, thyroid, testicles. prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,2,4,5
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,2,4,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K142017.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-4: Diagnostic Ultrasound Indications for Use Form – C60xp/5-2 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	C60xp/5-2 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	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,2,5
Abdominal	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,2,5**
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,2,4,5
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,2,4,5
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,2,4,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K133134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-5: Diagnostic Ultrasound Indications for Use Form – D2xp/2 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	D2xp/2 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							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult				E			
Cardiac Pediatric				E			
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "E" were released via Letter to File/Non-filing Justification documentation since K152209.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-6: Diagnostic Ultrasound Indications for Use Form – HFL38xp/13-6 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	HFL38xp/13-6 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	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Small Organ (breast, thyroid, testicles. prostate)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,4,5
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	**P**	**P**	**P**		**P**	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,5
Cardiac Pediatric	**P**	**P**	**P**		**P**	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+**C;** **B+PW; (B+C)+PWD**	1,4,5,**6**
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K152209 and K142017.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-7: Diagnostic Ultrasound Indications for Use Form – HFL50xp/15-6 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	HFL50xp/15-6 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	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Small Organ (breast, thyroid, testicles. prostate)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K133134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-8: Diagnostic Ultrasound Indications for Use Form – HSL25xp/13-6 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	HSL25xp/13-6 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	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,4,5
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,4,5
Small Organ (breast, thyroid, testicles. prostate)	P	P	P		P	B+M; B+PWD; B+**C**	1,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,4,5
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+**C**	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	**1,5**
Cardiac Pediatric	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	**1,5**
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+**C;** **(B+C)+PWD**	1,4,5,**6**
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K142017.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-9: Diagnostic Ultrasound Indications for Use Form – ICTxp/9-5 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	ICTxp/9-5 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							
Fetal	P	P	P		P	B+M; B+PWD; B+**C; (B+C)+PWD**	1,5
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	P	P	P		P	B+M; B+PWD; B+**C; (B+C)+PWD**	1,5
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:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K133134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-10: Diagnostic Ultrasound Indications for Use Form – L25xp/13-6 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	L25xp/13-6 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	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,5**
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,5**
Cardiac Pediatric	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1,5**
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	1,4,5,**6**
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K142017 and K133134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-11: Diagnostic Ultrasound Indications for Use Form – L38xp/10-5 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	L38xp/10-5 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							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Small Organ (breast, thyroid, testicles. prostate)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,5**
Cardiac Pediatric	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1,5**
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	1,4,5,**6**
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K142017 and K133134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-12: Diagnostic Ultrasound Indications for Use Form – P10xp/8-4 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	P10xp/8-4 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	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1**
Abdominal	P	P	P		P	B+M; B+PWD; B+CWD; B+C; **(B+C)+PWD**	**1**
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1**
Small Organ (breast, thyroid, testicles. prostate)	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1**
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1**
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1**
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+C; **(B+C)+PWD; (B+C)+CWD**	**1,3**
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+C; **(B+C)+PWD; (B+C)+CWD**	**1,3**
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1**
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Simultaneous PW

All items marked "P" were previously cleared in 510(k) K142017.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-13 – Diagnostic Ultrasound Indications for Use Form – rP19xp/5-1 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	rP19xp/8-5 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	E	E	E		E	B+M; B+PWD; B+C; (B+C)+PWD	1-2
Fetal	E	E	E		E	B+M; B+PWD; B+C; (B+C)+PWD	1-3
Abdominal	E	E	E		E	B+M; B+PWD; B+CWD; B+C; (B+C)+PWD; (B+C)+CWD	1-2
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	E	E	E		E	B+M; B+PWD; B+C; (B+C)+PWD	1-3
Small Organ (breast, thyroid, testicles, prostate)	E	E	E		E	B+M; B+PWD; B+C; (B+C)+PWD	1-3
Neonatal Cephalic	E	E	E		E	B+M; B+PWD; B+C; (B+C)+PWD	1
Adult Cephalic	E	E	E		E	B+M; B+PWD; B+C; (B+C)+PWD	1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	E	E	E		E	B+M; B+PWD; B+C; (B+C)+PWD	1-2
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	E	E	E	E	E	B+M; B+PWD; B+CWD; B+C; (B+C)+PWD; (B+C)+CWD	1-3
Cardiac Pediatric	E	E	E	E	E	B+M; B+PWD; B+CWD; B+C; (B+C)+PWD; (B+C)+CWD	1-3
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	E	E	E		E	B+M; B+PWD; B+C; (B+C)+PWD	1-2
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Update and Simultaneous PW

All items marked "E" were released via Letter to File/Non-filing Justification documentation since K152209.
Prescription Use (Per 21 CFR 801.109)

Table 1.3-14: Diagnostic Ultrasound Indications for Use Form – P21xp/5-1 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	P21xp/5-1 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	**P**	**P**	**P**		**P**	B+M; B+PWD; B+C; (B+C)+PWD	1
Fetal	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1-3**
Abdominal	P	P	P		P	B+M; B+PWD; B+CWD; B+C; **(B+C)+PWD; (B+C)+CWD**	**1-3**
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; **B+CWD; B+C**	**1-3**
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1-3**
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1-3**
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1-3**
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+C; **(B+C)+PWD**	**1-3**
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+**C**; **(B+C)+PWD; (B+C)+CWD**	**1-3**
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+**C**; **(B+C)+PWD; (B+C)+CWD**	**1-3**
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+**C**; **(B+C)+PWD**	**1-3**
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Update and Simultaneous PW

All items marked "P" were previously cleared in 510(k) K142017 and K133134.
Prescription Use (Per 21 CFR 801.109)

Table 1.3-15: Diagnostic Ultrasound Indications for Use Form – TEExp/8-3 MHz Transducer

System:	SonoSite X-Porte Ultrasound System						
Transducer:	TEExp/8-3 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							
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							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)	**P**	**P**	**P**	**P**	**P**	B+M; B+PWD; B+CWD; B+C; **(B+C)+PWD; (B+C)+CWD**	**1,3**
Other (spec.)							
Peripheral vessel							
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance. M-Mode includes Simultaneous M-Mode.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling (Sono MBe)
5: Multi-beam Imaging (SonoMB) in B-Mode
6: B+PWD and (B+C)+PWD includes Update and Simultaneous PW

All items marked "P" were previously cleared in 510(k) K152209.

Prescription Use (Per 21 CFR 801.109)

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

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Date prepared:	April 19, 2017

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 X-Porte™ Ultrasound System

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the predicate or legally marketed device:

SonoSite X-Porte Ultrasound System	K152209
SonoSite Edge Ultrasound System	K133454
SonoSite Edge II Ultrasound System	K162045

4) Device Description:

The SonoSite X-Porte Ultrasound System is a highly mobile, full featured, general purpose, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. X-Porte is a custom fabricated digital electronic design that readily lends itself to be configured for specific ultrasound imaging applications through different system feature selections. The system interface can be customized for the user and controlled using a backlit touchscreen much like what is used in consumer tablet products. X-Porte can be operated in two different configurations, stand-based with AC power or battery, and desktop-based with AC power only. In desktop configuration the ultrasound engine can be removed from the stand and used by itself with a single transducer and external monitor.

5) Intended Use:

The SonoSite X-Porte 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:

Ophthalmic
Fetal – OB/GYN
Abdominal
Small Organ (breast, thyroid, testicles, prostate)
Neonatal Cephalic
Adult Cephalic
Trans-vaginal
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Cardiac Adult
Cardiac Pediatric
Trans-esophageal (card.)
Peripheral Vessel

6) Technological Characteristics:

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

Feature	SonoSite X-Porte Ultrasound System (This submission)	SonoSite X-Porte Ultrasound System (K152209)	SonoSite Edge Ultrasound System (K133454)	SonoSite Edge II Ultrasound System (K162045)
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	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indications for Use	Ophthalmic Fetal - OB/GYN Abdominal Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel	Ophthalmic Fetal - OB/GYN Abdominal Intraoperative (abdominal organs and vascular) Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel	Ophthalmic Fetal - OB/GYN Abdominal Intraoperative (abdominal organs and vascular) Intra-operative (Neuro.) Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Rectal Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel	Ophthalmic Fetal – OB/GYN Abdominal Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Rectal Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel

Feature	SonoSite X-Porte Ultrasound System (This submission)	SonoSite X-Porte Ultrasound System (K152209)	SonoSite Edge Ultrasound System (K133454)	SonoSite Edge II Ultrasound System (K162045)
	Needle guidance	Needle guidance	Needle guidance	Needle guidance
Transducer Types	Linear Array Curved Linear Array Intracavitary Phased Array Static Probes Trans-esophageal	Linear Array Curved Linear Array Intracavitary Phased Array Trans-esophageal	Linear Array Curved Linear Array Intracavitary Phased Array Static Probes Trans-esophageal	Linear Array Curved Linear Array Intracavitary Phased Array Trans-esophageal
Transducer Frequency	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz
Global Maximum Outputs/Worst Case Setting	*$I_{spta.3}$: 629.3 (P21xp)* *TI Type:* TIB *(P21xp)* *TI Value:* 4.0 *(P21xp)* *MI: 1.7 (P21xp)* *$I_{pa.3}$@MI Max: 678 (L38xp)*	*$I_{spta.3}$: 629.3 (P21xp)* *TI Type:* TIB *(P21xp)* *TI Value:* 4.0 *(P21xp)* *MI: 1.7 (P21xp)* *$I_{pa.3}$@MI Max: 678 (L38xp)*	*$I_{spta.3}$: 709 (TEEx)* *TI Type:* TIB *(P21x)* *TI Value:* 3.7 *(P21x)* *MI: 1.51 (P21x)* *$I_{pa.3}$@MI Max: 776 (L38xi)*	$I_{spta.3}$: 598.9 (HFL50x) TI Type: TIB (rP19x) TI Value: 4.98 (rP19x) MI: 1.7 (rP19x) $I_{pa.3}$@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	Display Feature for Higher Outputs MI Output Display TI Output Display

Feature	SonoSite X-Porte Ultrasound System (This submission)	SonoSite X-Porte Ultrasound System (K152209)	SonoSite Edge Ultrasound System (K133454)	SonoSite Edge II Ultrasound System (K162045)
Modes of Operation	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)	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 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 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 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)
PW Doppler	Available on all imaging transducers except D2xp. Adjustable sample volume size: 1.0 – 25 mm Simultaneous or duplex mode of operation Simultaneous B-mode and PW Doppler High PRF capability	Available on all imaging transducers. Adjustable sample volume size: 1.0 – 25 mm Simultaneous or duplex mode of operation Simultaneous B-mode and PW Doppler High PRF capability	Available on all imaging transducers except D2x/2 MHz. Adjustable sample volume size: 1.0 – 25 mm Simultaneous or duplex mode of operation Simultaneous B-mode and PW Doppler High PRF capability	Available on all imaging transducers except P11x. Adjustable sample volume size: 1.0 – 25 mm Simultaneous or duplex mode of operation Simultaneous B-mode and PW Doppler High PRF capability
CW Doppler	Available on D2xp, P10xp, rP19xp, P21xp, TEExp Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler	Available on P10xp, P21xp, TEExp Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler	Available on C11x, D2x, P10x, P21x, TEEx Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler	Available on P10x, rP19x, TEExi Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler
Velocity Color Doppler	Available on all transducers except D2xp.	Available on all transducers	Available on all transducers except D2x	Available on all transducers
Elastography (Strain), and Strain Rate Imaging	Not available	Not available	Available on all transducers except D2x	Not available

Feature	SonoSite X-Porte Ultrasound System (This submission)	SonoSite X-Porte Ultrasound System (K152209)	SonoSite Edge Ultrasound System (K133454)	SonoSite Edge II Ultrasound System (K162045)
ECG Feature	One 3-lead ECG input, *or* One external ECG input, *or* ECG Slave Cable One other physio input	One 3-lead ECG input, *or* One external ECG input, *or* One other physio input	One 3-lead ECG input, *or* One external ECG input, *or* One other physio input	3-lead ECG input, *or* ECG Slave Cable
DICOM	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	DICOM 3.0 Store, Print, and Modality Worklist service class user features	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment
IMT Measurement	Not available	Not available	SonoCalc IMT provides the capability for automated measurement of intima-media thickness (IMT) of the carotid artery. IMT functionality is available both on the ultrasound system and in a stand alone software program that runs on a personal computer.	Not available
#Transmit Channels	128 digital channels	128 digital channels	128 digital channels	128 digital channels
#Receive Channels	64 digital channels (128 digital channels using Synthetic Aperture)	64 digital channels (128 digital channels using Synthetic Aperture)	64 digital channels (128 digital channels using Synthetic Aperture)	64 digital channels (128 digital channels using Synthetic Aperture)
Patient Contact Materials	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive Epoxy resin Polyetherimide Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polysulfone UDEL P1700 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 Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polysulfone UDEL P1700 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) Polycarbonate Polysulfone UDEL P1700 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 Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)

Feature	SonoSite X-Porte Ultrasound System (This submission)	SonoSite X-Porte Ultrasound System (K152209)	SonoSite Edge Ultrasound System (K133454)	SonoSite Edge II Ultrasound System (K162045)
Product Safety Certification	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	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	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 AIUM RTD2-2004 (NEMA UD3-2004 (R2009))	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
EMC Compliance	IEC 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5	IEC 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5	IEC 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A
DICOM	NEMA PS3.15 2003	NEMA PS3.15 2003	NEMA PS3.15 2003	NEMA PS3.15 2003
Airborne Equipment Standards	RTCA/DO160D (section 21)	RTCA/DO160D (section 21)	RTCA/DO160D (section 21)	RTCA/DO160 (section 21)
System Characteristics	**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 operational - 3 days idle Input: 100 – 240 VAC, 50/60 Hz Output 1: 24VDC output, 275 W max	**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 operational - 3 days idle Input: 100 – 240 VAC, 50/60 Hz Output 1: 24VDC output, 275 W max Output 2: 100-240VAC, 50-60 Hz (AC Printer)	**Edge:** 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: 12.9"(W) x 12.4 (L) x 2.5"(H) Weight: 8.5 lbs Battery operated (1.5 - 4 hour operation per charge) System operates via battery or AC power 100 – 240V options, 50/60 Hz, 15VDC output	**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 System operates via battery or AC power Battery life: 1.5 - 4 hour operation per charge 100 – 240V options, 50/60 Hz, 15VDC output

Feature	SonoSite X-Porte Ultrasound System (This submission)	SonoSite X-Porte Ultrasound System (K152209)	SonoSite Edge Ultrasound System (K133454)	SonoSite Edge II Ultrasound System (K162045)
	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 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 **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	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 Measurement on Recalled Images. Wireless 802.11 (a/b/g/n) support for image transfer **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	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 Wireless 802.11 (a\b\g) support for image transfer	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 Wireless 802.11 (b/g/n) support for image transfer
510(k) Track	Track 3	Track 3	Track 3	Track 3

7) Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:
The X-Porte 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. Reports for these elements of product development are referenced in Attachment 6.

The X-Porte Ultrasound System is designed to comply with the following voluntary standards.

Reference No.	Title
AAMI / ANSI / ISO 10993-1	ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
IEC 60601-1	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	AAMI / ANSI / IEC 60601-1-2:2007(R)2012, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
IEC 60601-2-37	IEC 60601-2-37:2007, Particular Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62359	IEC 62359:2010, Ultrasonics – Field Characterization – Test Methods For The Determination Of Thermal And Mechanical Indices Related To Medical Diagnostic Ultrasonic Fields [Including: Technical Corrigendum 1 (2011)] (Edition 2)
ISO 14971	ISO 14971: 2007, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA PS 3.15	NEMA Ps 3.15:2011, Digital Imaging and Communications in Medicine (DICOM), Part 15: Security and System Management Profiles

Summary of Clinical Tests:
The SonoSite X-Porte Ultrasound System and transducers, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

8) Conclusion:

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