



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

August 22, 2014

FUJIFILM SONOSITE, INC.
C/O MARK JOB
RESPONSIBLE THIRD PARTY OFFICIAL
1394 25TH STREET NW
BUFFALO, MN 55313

Re: K142017
Trade/Device Name: 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: July 24, 2014
Received: July 25, 2014

Dear Mr. 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.

This determination of substantial equivalence applies to the following transducers intended for use with the X-PORTE Ultrasound System, as described in your premarket notification:

Transducer Model Number		
C11xp/8-5 MHz	C35xp/8-3 MHz	C60xp/5-2 MHz
HFL38xp/13-6 MHz	HFL50xp/15-6 MHz	HSL25xp/13-6 MHz
ICTxp/9-5 MHz	L25xp/13-6 MHz	L38xp/10-5 MHz
P10xp/8-4 MHz	P21xp/5-1 MHz	

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

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

TBD K142017

Device Name

FUJIFILM SonoSite X-Porte Ultrasound System

Indications for Use (Describe)

The FUJIFILM SonoSite X-Porte Ultrasound System is a general purpose ultrasound system intended for use by a qualified physician 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

Intra-operative (Abdominal organs and vascular)

Pediatric

Small Organ (breast, thyroid, testicles, prostate)

Neonatal Cephalic

Adult Cephalic

Trans-vaginal

Musculo-skel. (Convent.)

Musculo-skel. (Superfic.)

Cardiac Adult

Cardiac Pediatric

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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

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

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,5
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	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	N	N	N		N	B+M; B+PWD; B+CD	1,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	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

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
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+CD	1,2,5
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
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

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	1,2,5
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1,2,5
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+CD	1,2,5
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+CD	1,2,5
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

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 – HFL38xp/13-6 Transducer

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Musculo-skel. (Superfic.)	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	E	E	E		E	B+M; B+PWD; B+CD	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

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	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+CD	1,4,5
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	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+CD	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

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-7: Diagnostic Ultrasound Indications for Use Form – HSL25xp/13-6 Transducer

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Fetal							
Abdominal	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Musculo-skel. (Superfic.)	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	E	E	E		E	B+M; B+PWD; B+CD	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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-8: Diagnostic Ultrasound Indications for Use Form – ICTxp/9-5Transducer

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	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+CD	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

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-9: Diagnostic Ultrasound Indications for Use Form – L25xp/13-6 Transducer

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	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+CD	1,4,5
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	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

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 – L38xp/10-5 Transducer

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	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+CD	1,4,5
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	E	E	E		E	B+M; B+PWD; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	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

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-11: Diagnostic Ultrasound Indications for Use Form – P10xp/8-4 Transducer

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N		N	B+M; B+PWD; B+CD	1,5
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	1,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,5
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	1,5
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1,5
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	1,5
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	1,3,5
Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	1,3,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-12: Diagnostic Ultrasound Indications for Use Form – P21xp/5-1 Transducer

System:	FUJIFILM 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	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	1-3,5
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	1-3,5
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	1-3,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD	1-3,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	1-3,5
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1-3,5
Adult Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1-3,5
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	1-3,5
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	1-3,5
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	1-3,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	1-3,5
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

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

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

Corresponding Official: Patricia Liao
Regulatory Affairs Specialist
E-mail: Patricia.Liao@sonosite.com
Telephone: (425) 951-6870
Facsimile: (425) 951-6713
Date prepared: July 2, 2014

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 (*subject to change*)

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 K133134
SonoSite Edge Ultrasound System K133454

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 FUJIFILM SonoSite X-Porte Ultrasound System is a general purpose ultrasound system intended for use by a qualified physician 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
Intra-operative (Abdominal organs and vascular)
Pediatric
Small Organ (breast, thyroid, testicles, prostate)
Neonatal Cephalic
Adult Cephalic
Trans-vaginal
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Cardiac Adult
Cardiac Pediatric
Peripheral Vessel

6) Technological Characteristics:

SonoSite X-Porte and Edge 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 (K133134)	SonoSite Edge Ultrasound System (K133454)
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	<p>Ophthalmic Fetal - OB/GYN Abdominal Intraoperative (abdominal organs and vascular)</p> <p>Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic</p> <p>Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric</p> <p>Peripheral Vessel Needle guidance</p>	<p>Ophthalmic Fetal - OB/GYN Abdominal Intraoperative (abdominal organs and vascular)</p> <p>Pediatric Small Organ (breast, thyroid, testicle, prostate)</p> <p>Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric</p> <p>Peripheral Vessel Needle guidance</p>	<p>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 Needle guidance</p>
Transducer Types	Linear Array Curved Linear Array Intracavitary Phased Array	Linear Array Curved Linear Array Intracavitary Phased Array	Linear Array Curved Linear Array Intracavitary Phased Array Static Probes Trans-esophageal
Transducer Frequency	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz

Feature	SonoSite X-Porte Ultrasound System (This submission)	SonoSite X-Porte Ultrasound System (K133134)	SonoSite Edge Ultrasound System (K133454)
Acoustic Output Display & FDA Limits	$I_{STPA,3} \leq 720 \text{ (mW/cm}^2\text{)}$ $TI \leq 4.0$ $MI \leq 1.9$ Display Feature for Higher Outputs MI Output Display TI Output Display	$I_{STPA,3} \leq 720 \text{ (mW/cm}^2\text{)}$ $TI \leq 4.0$ $MI \leq 1.9$ Display Feature for Higher Outputs MI Output Display TI Output Display	$I_{STPA,3} \leq 720 \text{ (mW/cm}^2\text{)}$ $TI \leq 4.0$ $MI \leq 1.9$ 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 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 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	Available	Available
CW Doppler	Available	Available	Available
Velocity Color Doppler	Available	Available	Available
Elastography (Strain), and Strain Rate Imaging	Not available	Not available	Available
ECG Feature	3-lead ECG input	3-lead ECG input	3-lead ECG input
DICOM	DICOM 3.0	DICOM 3.0	DICOM 3.0
IMT Measurement	Not available	Not available	Available
#Transmit 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)
Patient Contact Materials	Transducers: Acrylonitrile-butadien-styrene (ABS) Cycloxy Dow Medical Adhesive, Type A Epoxy paste adhesive 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) Dow Medical Adhesive, Type A Epoxy paste adhesive Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone Rubber Urethane Needle Guides: Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	Transducers: Acrylonitrile-butadien-styrene (ABS) Cycloxy Dow Medical Adhesive, Type A Epoxy paste adhesive Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane Needle Guides: Acetal copolymer Acrylonitrile-butadien-styrene (ABS)
System Characteristics	X-Porte (stand configuration): Beamformer 128/128 using SA (configurable) 12.1" Capacitive touch screen interface	X-Porte (stand configuration): Beamformer 128/128 using SA (configurable) 12.1" Capacitive touch screen interface	Edge: Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display

Feature	SonoSite X-Porte Ultrasound System (This submission)	SonoSite X-Porte Ultrasound System (K133134)	SonoSite Edge Ultrasound System (K133454)
	<p>19" LED LCD HD monitor 256 gray shades on LED LCD</p> <p>6 USB 2.0 ports</p> <p>Stand Base Dimensions: 26.4" L x 21.2" W Stand Height (max): 64" (monitor up) Stand Height (min): 42.2" (monitor down)</p> <p>Weight: 149.35 lbs (fully configured w/ 3 transducers)</p> <p>System operates via battery or AC power</p> <p>Battery life: 1 hour operational - 3 days idle</p> <p>Input: 100 – 240 VAC, 50/60 Hz Output 1: 24VDC output, 275 W max Output 2: 100-240VAC, 50-60 Hz (AC Printer)</p> <p>Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages</p> <p>ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Measurement on Recalled Images.</p> <p>Wireless 802.11 (a/b/g/n) support for image transfer</p> <p>X-Porte (desktop configuration):</p> <p>Same software features/capabilities as the stand configuration. Does not have the stand, touch panel interface, DVR, and mobile power unit.</p> <p>Weight: 32.80 lbs (w/ 1 transducer)</p> <p>AC power only. 100 – 240V options, 50/60 Hz</p>	<p>19" LED LCD HD monitor 256 gray shades on LED LCD</p> <p>6 USB 2.0 ports</p> <p>Stand Base Dimensions: 26.4" L x 21.2" W Stand Height (max): 64" (monitor up) Stand Height (min): 42.2" (monitor down)</p> <p>Weight: 149.35 lbs (fully configured w/ 3 transducers)</p> <p>System operates via battery or AC power</p> <p>Battery life: 1 hour operational - 3 days idle</p> <p>Input: 100 – 240 VAC, 50/60 Hz Output 1: 24VDC output, 275 W max Output 2: 100-240VAC, 50-60 Hz (AC Printer)</p> <p>Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages</p> <p>ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Measurement on Recalled Images.</p> <p>Wireless 802.11 (a/b/g/n) support for image transfer</p> <p>X-Porte (desktop configuration):</p> <p>Same software features/capabilities as the stand configuration. Does not have the stand, touch panel interface, DVR, and mobile power unit.</p> <p>Weight: 32.80 lbs (w/ 1 transducer)</p> <p>AC power only. 100 – 240V options, 50/60 Hz</p>	<p>(LCD) 256 gray shades on LCD</p> <p>2 USB ports</p> <p>Dimensions: 12.9"(W) x 12.4 (L) x 2.5"(H)</p> <p>Weight: 8.5 lbs Battery operated (1.5 - 4 hour operation per charge)</p> <p>System operates via battery or AC power</p> <p>100 – 240V options, 50/60 Hz, 15VDC output</p> <p>Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages</p> <p>ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media</p> <p>Wireless 802.11 (a\b\g) support for image transfer</p>
510(k) Track	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.