



Food and Drug Administration  
10903 New Hampshire Avenue  
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FUJIFILM SonoSite, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street, NW  
BUFFALO MN 55313

August 18, 2016

Re: K162045  
Trade/Device Name: SonoSite SII Ultrasound System and SonoSite Edge II  
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 21, 2016  
Received: July 25, 2016

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.

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,



Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

For

Enclosure

## Indications for Use

510(k) Number (if known)

K162045

Device Name

SonoSite Edge II Ultrasound System

Indications for Use (Describe)

The SonoSite Edge II 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, 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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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## SonoSite Edge II Ultrasound System:

The following are the Indications for Use for the SonoSite Edge II Ultrasound System

Table 1.3-1: Diagnostic Ultrasound Indications for Use Form – FUJIFILM SonoSite Edge II Ultrasound System

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	N/A						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	1-5
Fetal	P	P	P		P	B+M; B+PWD; B+CD	1-5
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1-5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1-5
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	1-5
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	1-3,5
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	1-3,5
Trans-rectal	N	N	N		N	B+M; B+PWD; B+CD	1,5
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	1,2,4,5
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	1-5
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	1-5
Trans-esophageal (card.)	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	1,3
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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-2: Diagnostic Ultrasound Indications for Use Form – C8x/8-5 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	C8x/8-5 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	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	P	P	P		P	B+M; B+PWD; B+CD	1,5
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.)							
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 color 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) K133454 (Edge).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-3: Diagnostic Ultrasound Indications for Use Form – C11x/8-5 Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	C11x/8-5 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1,5
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic	P	P	P		P	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	P	P	P		P	B+M; B+PWD; B+CD	1,5
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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-4: Diagnostic Ultrasound Indications for Use Form – C35x/8-3 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	C35x/8-3 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
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+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 color 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) K160406 (FC1).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-5: Diagnostic Ultrasound Indications for Use Form – rC60xi/5-2 Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	rC60xi/5-2 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	1,2,4,5
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1,2,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	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+CD	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+CD	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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-6: Diagnostic Ultrasound Indications for Use Form – HFL38xi/13-6 Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	HFL38xi/13-6 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	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)							
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	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	P	P	P		P	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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-7: Diagnostic Ultrasound Indications for Use Form – HFL50x/15-6 Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	HFL50x/15-6 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	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)							
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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-8: Diagnostic Ultrasound Indications for Use Form – HSL25x/13-6 Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	HSL25x/13-6 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	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)							
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	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	P	P	P		P	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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

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

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	ICTx/8-5 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-10: Diagnostic Ultrasound Indications for Use Form – L25x/13-6 Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	L25x/13-6 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	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)							
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	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	P	P	P		P	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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-11: Diagnostic Ultrasound Indications for Use Form - L38xi/10-5 Transducer, L38xi/10-5 Armored Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	L38xi/10-5 MHz Transducer, L38xi/10-5 MHz Armored Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	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)							
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.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P		P	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	P	P	P		P	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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-12: Diagnostic Ultrasound Indications for Use Form – P10x/8-4 Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	P10x/8-4 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	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	P	P	P		P	B+M; B+PWD; B+CD	1,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	1,5
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	1,5
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	1,5
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	1,5
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	1,5
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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-13: Diagnostic Ultrasound Indications for Use Form – P11x/10-5 Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	P11x/10-5 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1
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.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; B+CD	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 color 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) K153626 (Edge II).

Prescription Use (Per 21 CFR 801.109)

Table 1.3-14: Diagnostic Ultrasound Indications for Use Form – rP19x/5-1 Transducer, rP19x/5-1 Armored Transducer

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	rP19x/5-1 MHz Transducer, rP19x/5-1 MHz Armored Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	1-3
Fetal	P	P	P		P	B+M; B+PWD; B+CD	1-3
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	1-3
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	1-3
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	1-3
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	1-3
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	1-3
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	1-3
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	1-3
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

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

<b>System:</b>	FUJIFILM SonoSite Edge II Ultrasound System						
<b>Transducer:</b>	TEExi/8-3 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	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+CD	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 color 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) K153626 (Edge II).**

Prescription Use (Per 21 CFR 801.109)

## Indications for Use

510(k) Number (if known)

K162045

Device Name

SonoSite SII Ultrasound System

Indications for Use (Describe)

The SonoSite SII 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, testicle, prostate)

Neonatal Cephalic

Adult Cephalic

Trans-rectal

Trans-vaginal

Musculo-skeletal (Conventional)

Musculo-skeletal (Superficial)

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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## SonoSite SII Ultrasound System:

The following are the Indications for Use for the SonoSite SII Ultrasound System

Table 1.3-16: Diagnostic Ultrasound Indications for Use Form – FUJIFILM SonoSite SII Ultrasound System

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	N/A						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P			P	B+M; B+CD	1,4,5
Fetal	P	P			P	B+M; B+CD	1,2,4,5
Abdominal	P	P			P	B+M; B+CD	1,2,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,2,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; B+CD	1,2,4,5
Neonatal Cephalic	P	P			P	B+M; B+CD	1,5
Adult Cephalic	P	P			P	B+M; B+CD	1,5
Trans-rectal	N	N			N	B+M; B+CD	1,5
Trans-vaginal	P	P			P	B+M; B+CD	1,5
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P			P	B+M; B+CD	1,2,4,5
Musculo-skel. (Superfic.)	P	P			P	B+M; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P			P	B+M; B+CD	1,2,4,5
Cardiac Pediatric	P	P			P	B+M; B+CD	1,2,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; B+CD	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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-17: Diagnostic Ultrasound Indications for Use Form – C8x/8-5 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	C8x/8-5 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	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	P	P			P	B+M; B+CD	1,5
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.)							
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 color 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) K133454 (Edge).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-18: Diagnostic Ultrasound Indications for Use Form – C11x/8-5 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	C11x/8-5 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P			P	B+M; B+CD	1,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,5
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic	P	P			P	B+M; 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	P	P			P	B+M; B+CD	1,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; 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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-19: Diagnostic Ultrasound Indications for Use Form – C35x/8-3 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	C35x/8-3 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P			P	B+M; B+CD	1,4,5
Abdominal	P	P			P	B+M; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,4,5
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	B+M; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P			P	B+M; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; 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 color 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) K160406 (FC1).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-20: Diagnostic Ultrasound Indications for Use Form – rC60xi/5-2 MHz Transducer, rC60xi/5-2 MHz Armored Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	rC60xi/5-2 MHz Transducer, rC60xi/5-2 MHz Armored Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P			P	B+M; B+CD	1,2,4,5
Abdominal	P	P			P	B+M; B+CD	1,2,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	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	B+M; B+CD	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	B+M; B+CD	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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-21: Diagnostic Ultrasound Indications for Use Form – HFL38xi/13-6 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	HFL38xi/13-6 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P			P	B+M; B+CD	1,4,5
Fetal							
Abdominal	P	P			P	B+M; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; 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	B+M; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P			P	B+M; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P			P	B+M; B+CD	1,4,5
Cardiac Pediatric	P	P			P	B+M; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; 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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-22: Diagnostic Ultrasound Indications for Use Form – HFL50x/15-6 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	HFL50x/15-6 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P			P	B+M; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; 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	B+M; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P			P	B+M; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; 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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-23: Diagnostic Ultrasound Indications for Use Form – HSL25x/13-6 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	HSL25x/13-6 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P			P	B+M; B+CD	1,4,5
Fetal							
Abdominal	P	P			P	B+M; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; 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	B+M; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P			P	B+M; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P			P	B+M; B+CD	1,4,5
Cardiac Pediatric	P	P			P	B+M; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; 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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-24: Diagnostic Ultrasound Indications for Use Form – ICTx/8-5 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	ICTx/8-5 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P			P	B+M; 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	B+M; 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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-25: Diagnostic Ultrasound Indications for Use Form – L25x/13-6 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	L25x/13-6 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P			P	B+M; B+CD	1,4,5
Fetal							
Abdominal	P	P			P	B+M; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; 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	B+M; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P			P	B+M; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P			P	B+M; B+CD	1,4,5
Cardiac Pediatric	P	P			P	B+M; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; 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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-26: Diagnostic Ultrasound Indications for Use Form - L38xi/10-5 MHz Transducer, L38xi/10-5 MHz Armored Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	L38xi/10-5 MHz Transducer, L38xi/10-5 MHz Armored Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P			P	B+M; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; B+CD	1,4,5
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	P	P			P	B+M; B+CD	1,4,5
Cardiac Pediatric	P	P			P	B+M; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; 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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-27: Diagnostic Ultrasound Indications for Use Form – P10x/8-4 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	P10x/8-4 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P			P	B+M; B+CD	1,5
Abdominal	P	P			P	B+M; B+CD	1,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,5
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; B+CD	1,5
Neonatal Cephalic	P	P			P	B+M; B+CD	1,5
Adult Cephalic	P	P			P	B+M; B+CD	1,5
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P			P	B+M; B+CD	1,5
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P			P	B+M; B+CD	1,5
Cardiac Pediatric	P	P			P	B+M; B+CD	1,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; 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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-28: Diagnostic Ultrasound Indications for Use Form – P11x/10-5 MHz Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	P11x/10-5 MHz Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1
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.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; B+CD	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 color 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) K160734 (SII).**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-29: Diagnostic Ultrasound Indications for Use Form – rP19x/5-1 MHz Transducer, rP19x/5-1 MHz Armored Transducer

<b>System:</b>	FUJIFILM SonoSite SII Ultrasound System						
<b>Transducer:</b>	rP19x/5-1 MHz Transducer, rP19x/5-1 MHz Armored Transducer						
<b>Intended Use:</b>	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
<b>Clinical Application</b>	<b>Mode of Operation</b>						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P			P	B+M; B+CD	1,2
Abdominal	P	P			P	B+M; B+CD	1,2
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CD	1,2
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; B+CD	1,2
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	P	P			P	B+M; B+CD	1,2
Cardiac Pediatric	P	P			P	B+M; B+CD	1,2
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; B+CD	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 color 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) K160734 (SII).**

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 30<sup>th</sup> Drive SE  
Bothell, WA 98021-3904

**Corresponding Official:** Jordan Grimmer  
Regulatory Affairs Specialist  
**E-mail:** jordan.grimmer@fujifilm.com  
**Telephone:** (425) 951-6984  
**Facsimile:** (425) 951-1201  
**Date prepared:** July 12, 2016

### 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 Edge II Ultrasound System (*subject to change*)  
SonoSite SII 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 Edge II Ultrasound System	K153626
SonoSite SII Ultrasound System	K160734
SonoSite Edge Ultrasound System	K133454
FUJIFILM FC1 Ultrasound System	K160406

### 4) Device Description:

#### **SONOSITE EDGE II ULTRASOUND SYSTEM:**

The SonoSite Edge II Ultrasound System is a portable laptop style, full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. Edge II is a custom fabricated digital electronic design that readily lends itself to be configured for specific ultrasound imaging applications through different system feature selections. Edge II can operate on either battery or AC power.

## **SONOSITE SII ULTRASOUND SYSTEM**

The SonoSite SII Ultrasound System is a mountable style, full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. SII is a custom fabricated digital electronic design that readily lends itself to be configured for specific ultrasound imaging applications through different system feature selections. SII can operate on either battery or AC power.

### **5) Intended Use:**

## **SONOSITE EDGE II ULTRASOUND SYSTEM**

The SonoSite Edge II 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, 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

## **SONOSITE SII ULTRASOUND SYSTEM**

The SonoSite SII 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, testicle, prostate)  
Neonatal Cephalic  
Adult Cephalic  
Trans-rectal  
Trans-vaginal  
Musculo-skeletal (Conventional)  
Musculo-skeletal (Superficial)  
Cardiac Adult  
Cardiac Pediatric  
Peripheral Vessel

**6) Technological Characteristics:**

**SONOSITE EDGE II ULTRASOUND SYSTEM:**

SonoSite Edge II, Edge, and FC1 Ultrasound Systems are all Track 3 devices that employ the same fundamental scientific technology. A comparison table is provided below.

<b>Feature</b>	<b>SonoSite Edge II Ultrasound System (This submission)</b>	<b>SonoSite Edge II Ultrasound System (K153626)</b>	<b>SonoSite Edge Ultrasound System (K133454)</b>	<b>FUJIFILM FC1 Ultrasound System (K160406)</b>
<b>Intended Use</b>	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
<b>Indications for Use</b>	<p>Ophthalmic Fetal – OB/GYN Abdominal</p> <p>Pediatric Small Organ (breast, thyroid, testicle, prostate)</p> <p>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>	<p>Ophthalmic Fetal – OB/GYN Abdominal</p> <p>Pediatric Small Organ (breast, thyroid, testicle, prostate)</p> <p>Neonatal Cephalic Adult Cephalic</p> <p>Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) 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)</p> <p>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>	<p>Fetal – OB/GYN Abdominal Intra-operative (Abdominal organs and vascular)</p> <p>Pediatric Small Organ (breast, thyroid, testicles, prostate)</p> <p>Neonatal Cephalic</p> <p>Trans-vaginal Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Cardiac Adult Cardiac Pediatric</p> <p>Peripheral Vessel Needle guidance</p>
<b>Transducer Types</b>	<p>Linear Array Curved Linear Array Intracavitary Phased Array</p> <p>Trans-esophageal</p>	<p>Linear Array Curved Linear Array Intracavitary Phased Array</p> <p>Trans-esophageal</p>	<p>Linear Array Curved Linear Array Intracavitary Phased Array Static Probes Trans-esophageal</p>	<p>Linear Array Curved Linear Array Intracavitary Phased Array</p>
<b>Transducer Frequency</b>	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz
<b>Global Maximum Outputs/Worst Case Setting</b>	<p>I<sub>spta.3</sub>: 598.9 (HFL50x) TI Type: TIB (rP19x) TI Value: 4.98 (rP19x) MI: 1.7 (rP19x) I<sub>pa.3</sub>@MI Max: 776 (L38xi)</p>	<p>I<sub>spta.3</sub>: 598.9 (HFL50x) TI Type: TIB (rP19x) TI Value: 4.98 (rP19x) MI: 1.7 (rP19x) I<sub>pa.3</sub>@MI Max: 776 (L38xi)</p>	<p>I<sub>spta.3</sub>: 708.8 (TEEx) TI Type: TIB (L38xi) TI Value: 4.06 (L38xi) MI: 1.51 (P21x) I<sub>pa.3</sub>@MI Max: 776 (L38xi)</p>	<p>I<sub>spta.3</sub>: 434mW/cm2 TI Type: TIC TI Value: 1.8 MI: 1.1 I<sub>pa.3</sub>@MI Max: 265.4 W/cm2</p>
<b>Acoustic</b>	Display Feature for	Display Feature for	Display Feature for	Display Feature for

<b>Feature</b>	<b>SonoSite Edge II Ultrasound System (This submission)</b>	<b>SonoSite Edge II Ultrasound System (K153626)</b>	<b>SonoSite Edge Ultrasound System (K133454)</b>	<b>FUJIFILM FC1 Ultrasound System (K160406)</b>
<b>Output Display &amp; FDA Limits</b>	Higher Outputs MI Output Display TI Output Display	Higher Outputs MI Output Display TI Output Display	Higher Outputs MI Output Display TI Output Display	Higher Outputs MI Output Display TI Output Display
<b>Modes of Operation</b>	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)	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 Pulse Inversion Harmonic Imaging Compound Harmonic Imaging Spatial Compound Imaging M-mode Velocity Color Doppler Color Power Doppler Directional Color Power Doppler Pulsed Wave Doppler Pulsed Wave Tissue Doppler Continuous Wave Doppler, ECG
<b>PW Doppler</b>	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	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	Available on all imaging transducers except D2x and P11x  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. Simultaneous Duplex Triplex Simultaneous B-mode and PW Doppler High PRF capability
<b>CW Doppler</b>	Available on P10x, rP19x, TEExi 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	Available on C11x, D2x, P10x, P21x, TEEx Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler	Available on P21x Simultaneous Duplex Triplex Simultaneous B-mode and CW Doppler
<b>Velocity Color Doppler</b>	Available on all transducers	Available on all transducers	Available on all transducers except D2x	Available on all transducers
<b>ECG Feature</b>	3-lead ECG input, <i>or</i> ECG Slave Cable	3-lead ECG input, <i>or</i> ECG Slave Cable	3-lead ECG input	One 3-lead ECG input, <i>or</i> One external ECG input, <i>or</i> One other physio input
<b>DICOM</b>	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step	DICOM 3.0 Store, Print, and Modality Worklist	DICOM 3.0 Store, Print, and Modality Worklist service class user

Feature	SonoSite Edge II Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K153626)	SonoSite Edge Ultrasound System (K133454)	FUJIFILM FC1 Ultrasound System (K160406)
	(PPS), Storage Commitment	(PPS), Storage Commitment		features
<b>IMT Measurement</b>	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.	Manual IMT measurement functionality available.
<b>#Transmit Channels</b>	128 digital channels	128 digital channels	128 digital channels	64 digital channels
<b>#Receive Channels</b>	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
<b>Patient Contact Materials</b>	<b>Transducers:</b> 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 <b>Needle Guides:</b> Acetal copolymer Acrylonitrile-butadien- styrene (ABS)	<b>Transducers:</b>  Cycoloy  Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane <b>Needle Guides:</b> Acetal copolymer Acrylonitrile-butadien- styrene (ABS)	<b>Transducers:</b> Acrylonitrile-butadien- styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane <b>Needle Guides:</b> Acetal copolymer Acrylonitrile-butadien- styrene (ABS)	<b>Transducers:</b> Acrylonitrile-butadien- styrene (ABS)  Dow Medical Adhesive, Type A Epoxy paste adhesive,   Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC)  Silicone Rubber Urethane <b>Needle Guides:</b> Acetal copolymer Acrylonitrile-butadien- styrene (ABS)
<b>Product Safety Certification</b>	AAMI/ANSI ES60601- 1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 60601-1:08 NEMA UD2-2004 IEC 62359:2010	AAMI/ANSI ES60601- 1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 60601-1:08 NEMA UD2-2004 IEC 62359:2010	AAMI/ANSI ES60601- 1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 60601-1:08 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. 601.1 JIS T 0601-1, JIS T 1507 CEI/IEC 61157 ANSI/AAMI EC53

Feature	SonoSite Edge II Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K153626)	SonoSite Edge Ultrasound System (K133454)	FUJIFILM FC1 Ultrasound System (K160406)
				NEMA UD2-2004 AIUM RTD2-2004 (NEMA UD3-2004 (R2009))
<b>EMC Compliance</b>	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A	IEC 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5
<b>DICOM</b>	NEMA PS3.15 2003	NEMA PS3.15 2003	NEMA PS3.15 2003	NEMA PS3.15 2003
<b>Airborne Equipment Standards</b>	RTCA/DO160 (section 21)	RTCA/DO160 (section 21)	RTCA/DO160 (section 21)	None
<b>System Characteristics</b>	<p><b>Edge II:</b> Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD</p> <p>2 USB ports</p> <p>Dimensions: 12.8"(W) x 12.1" (L) x 2.5"(H)</p> <p>Weight: 9.0 lbs</p> <p>System operates via battery or AC power Battery life: 1.5 - 4 hour operation per charge</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 (b/g/n)</p>	<p><b>Edge II:</b> Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD</p> <p>2 USB ports</p> <p>Dimensions: 12.8"(W) x 12.1" (L) x 2.5"(H)</p> <p>Weight: 9.0 lbs</p> <p>System operates via battery or AC power Battery life: 1.5 - 4 hour operation per charge</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 (b/g/n)</p>	<p><b>Edge:</b> Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (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</p> <p>System operates via battery or AC power Battery life: 1.5 - 4 hour operation per charge</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 (b/g/n)</p>	<p><b>FC1:</b> Beamformer 64/64</p> <p>Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD</p> <p>4 USB ports</p> <p>Dimensions: 12.24"(W) x 13.03" (L) x 3.03"(H)</p> <p>Weight: 11.9 lbs</p> <p>System operates via battery or AC power Battery operated (1.5 - 4 hour operation per charge)</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>

Feature	SonoSite Edge II Ultrasound System (This submission)	SonoSite Edge II Ultrasound System (K153626)	SonoSite Edge Ultrasound System (K133454)	FUJIFILM FC1 Ultrasound System (K160406)
	support for image transfer	support for image transfer	support for image transfer	Wireless 802.11 (a\b\g) support for image transfer
<b>510(k) Track</b>	Track 3	Track 3	Track 3	Track 3

### SONOSITE SII ULTRASOUND SYSTEM

SonoSite SII, Edge, and FC1 Ultrasound Systems are all Track 3 devices that employ the same fundamental scientific technology. A comparison table is provided below.

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite SII Ultrasound System (K160734)	SonoSite Edge Ultrasound System (K133454)	FUJIFILM FC1 Ultrasound System (K160406)
<b>Intended Use</b>	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
<b>Indications for Use</b>	<p>Ophthalmic Fetal – OB/GYN Abdominal</p> <p>Pediatric Small Organ (breast, thyroid, testicle, prostate)</p> <p>Neonatal Cephalic Adult Cephalic Trans-Rectal 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</p> <p>Pediatric Small Organ (breast, thyroid, testicle, prostate)</p> <p>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) Intra-operative (Neuro.) Pediatric Small Organ (breast, thyroid, testicle, prostate)</p> <p>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>	<p>Fetal – OB/GYN Abdominal Intra-operative (Abdominal organs and vascular)</p> <p>Pediatric Small Organ (breast, thyroid, testicles, prostate) Neonatal Cephalic</p> <p>Trans-vaginal Musculo-skel. (Convent.) Musculo-skel. (Superfic.)</p> <p>Cardiac Adult Cardiac Pediatric</p> <p>Peripheral Vessel Needle guidance</p>
<b>Transducer Types</b>	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	Linear Array Curved Linear Array Intracavitary Phased Array

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite SII Ultrasound System (K160734)	SonoSite Edge Ultrasound System (K133454)	FUJIFILM FC1 Ultrasound System (K160406)
			Trans-esophageal	
<b>Transducer Frequency</b>	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz
<b>Global Maximum Outputs/Worst Case Setting</b>	Ispta.3: 420.2 (L38xi) TI Type: TIC (rC60xi) TI Value: 3.05 (rC60xi) MI: 1.7 (rP19x) Ipa.3@MI Max: 776 (L38xi)	Ispta.3: 420.2 (L38xi) TI Type: TIC (rC60xi) TI Value: 3.05 (rC60xi) MI: 1.7 (rP19x) Ipa.3@MI Max: 776 (L38xi)	Ispta.3: 708.8 (TEEx) TI Type: TIB (L38xi) TI Value: 4.06 (L38xi) MI: 1.51 (P21x) Ipa.3@MI Max: 776 (L38xi)	Ispta.3: 434mW/cm2 TI Type: TIC TI Value: 1.8 MI: 1.1 Ipa.3@MI Max: 265.4 W/cm2
<b>Acoustic Output Display &amp; FDA Limits</b>	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
<b>Modes of Operation</b>	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Color M-Mode Color Power Doppler Zoom Combination Modes  SonoHD2 Noise Reduction SonoMB/MBe Image Compounding  Velocity Color Doppler	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Color M-Mode Color Power Doppler Zoom Combination Modes  SonoHD2 Noise Reduction SonoMB/MBe Image Compounding  Velocity Color Doppler	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 Pulse Inversion Harmonic Imaging Compound Harmonic Imaging Spatial Compound Imaging M-mode Velocity Color Doppler Color Power Doppler Directional Color Power Doppler Pulsed Wave Doppler Pulsed Wave Tissue Doppler Continuous Wave Doppler, ECG
<b>PW Doppler</b>	Not available	Not available	Available on all imaging transducers except D2x and P11x  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.  Simultaneous Duplex Triplex Simultaneous B-mode and PW Doppler High PRF capability
<b>CW Doppler</b>	Not available	Not available	Available on C11x, D2x, P10x, P21x, TEEEx Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler	Available on P21x Simultaneous Duplex Triplex Simultaneous B-mode and CW Doppler
<b>Velocity Color</b>	Available on all	Available on all	Available on all	Available on all

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite SII Ultrasound System (K160734)	SonoSite Edge Ultrasound System (K133454)	FUJIFILM FC1 Ultrasound System (K160406)
<b>Doppler</b>	transducers	transducers	transducers except D2x	transducers
<b>ECG Feature</b>	Not available	Not available	3-lead ECG input	One 3-lead ECG input, <i>or</i> One external ECG input, <i>or</i> One other physio input
<b>DICOM</b>	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	DICOM 3.0 Store, Print, and Modality Worklist service class user features
<b>IMT Measurement</b>	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.	Manual IMT measurement functionality available.
<b>#Transmit Channels</b>	128 digital channels	128 digital channels	128 digital channels	64 digital channels
<b>#Receive Channels</b>	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
<b>Patient Contact Materials</b>	<b>Transducers:</b> Acrylonitrile-butadien-styrene (ABS) Cycoloy  Polycarbonate Polysulfone UDEL P1700  Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane <b>Needle Guides:</b> Acetal copolymer Acrylonitrile-butadien-	<b>Transducers:</b>  Cycoloy  Polycarbonate Polysulfone UDEL P1700  Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane <b>Needle Guides:</b> Acetal copolymer Acrylonitrile-butadien-	<b>Transducers:</b> Acrylonitrile-butadien-styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane <b>Needle Guides:</b> Acetal copolymer Acrylonitrile-butadien-	<b>Transducers:</b> Acrylonitrile-butadien-styrene (ABS)  Dow Medical Adhesive, Type A Epoxy paste adhesive,  Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC)  Silicone Rubber Urethane <b>Needle Guides:</b> Acetal copolymer Acrylonitrile-butadien-

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite SII Ultrasound System (K160734)	SonoSite Edge Ultrasound System (K133454)	FUJIFILM FC1 Ultrasound System (K160406)
	styrene (ABS)	styrene (ABS)	styrene (ABS)	styrene (ABS)
<b>Product Safety Certification</b>	AAMI/ANSI ES60601-1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 60601-1:08 NEMA UD2-2004 IEC 62359:2010	AAMI/ANSI ES60601-1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 60601-1:08 NEMA UD2-2004 IEC 62359:2010	AAMI/ANSI ES60601-1:2005 (R2012) IEC 60601-2-37: 2007 CAN/CSA C22.2 No. 60601-1:08 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. 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))
<b>EMC Compliance</b>	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A	AAMI / ANSI / IEC 60601-1-2:2007(R)2012 CISPR 11, Group 1, Class A	IEC 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5
<b>DICOM</b>	NEMA PS3.15 2003	NEMA PS3.15 2003	NEMA PS3.15 2003	NEMA PS3.15 2003
<b>Airborne Equipment Standards</b>	RTCA/DO160 (section 21)	RTCA/DO160 (section 21)	RTCA/DO160 (section 21)	None
<b>System Characteristics</b>	<b>SII:</b> Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD  3 USB ports  Dimensions: 11.5"(W) x 17.6" (L) x 4.8"(H)  Weight: 12.6 lbs  System operates via battery or AC power  100 – 240V options, 50/60 Hz, 15VDC output  Various obstetrical, cardiac, volume, and M-mode measurement and calculation packages	<b>SII:</b> Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD  3 USB ports  Dimensions: 11.5"(W) x 17.6" (L) x 4.8"(H)  Weight: 12.6 lbs  System operates via battery or AC power  100 – 240V options, 50/60 Hz, 15VDC output  Various obstetrical, cardiac, volume, and M-mode measurement and calculation packages	<b>Edge:</b> 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  System operates via battery or AC power Battery life: 1.5 - 4 hour operation per charge  100 – 240V options, 50/60 Hz, 15VDC output  Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages	<b>FC1:</b> Beamformer 64/64  Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD  4 USB ports  Dimensions: 12.24"(W) x 13.03" (L) x 3.03"(H)  Weight: 11.9 lbs  System operates via battery or AC power Battery operated (1.5 - 4 hour operation per charge)  100 – 240V options, 50/60 Hz, 15VDC output  Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite SII Ultrasound System (K160734)	SonoSite Edge Ultrasound System (K133454)	FUJIFILM FC1 Ultrasound System (K160406)
	Wireless 802.11 support for image transfer	Wireless 802.11 support for image transfer	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	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
<b>510(k) Track</b>	Track 3	Track 3	Track 3	Track 3

## 7) Determination of Substantial Equivalence:

### Summary of Non-Clinical Tests:

The **SonoSite Edge II Ultrasound System** and **SonoSite SII Ultrasound System** have been evaluated for electrical, thermal, mechanical, and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated, and the device(s) have been found to conform to applicable mandatory medical device safety standards. Assurance of quality was established by employing the following elements of product development but were not limited to: Design Phase Reviews, Risk Assessment, Requirements Development, and Verification and Validation.

The **SonoSite Edge II Ultrasound System** and **SonoSite SII Ultrasound System** are designed to comply with the following FDA recognized standards.

Reference No.	Title
ISO 10993-1	AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC 60601-1	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	AAMI / ANSI ES60601-1:2005/(R)2012 and 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 60601-1-6	IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-37	IEC 60601-2-37:2007 Edition 2.0 2007-08, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	AAMI / ANSI / IEC 62304:2006, Medical device software - Software life cycle processes
IEC 62359	IEC 62359 Edition 2.0 2010-10-10, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields [Including: Technical corrigendum 1 (2011)]
ISO 14971	ISO 14971:2007, Medical devices - Application of risk management to medical devices

Reference No.	Title
NEMA UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

**Summary of Clinical Tests:**

The **SonoSite Edge II Ultrasound System** and **SonoSite SII 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 **SonoSite Edge II Ultrasound System** and **SonoSite SII Ultrasound System** and predicates meet FDA requirements for Track 3 devices, share indications for use, have biosafety equivalence, and conform to applicable electromedical device safety standards. FUJIFILM SonoSite, Inc. believes that the **SonoSite Edge II Ultrasound System** and **SonoSite SII Ultrasound System** are substantially equivalent with regard to safety and effectiveness to the predicate devices.