February 7, 2019

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

Re: K183235
Trade/Device Name: SonoSite SII Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN IYO ITX
Dated: January 30, 2019
Received: February 4, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183235

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.

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

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

SonoSite SII Ultrasound System:

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

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

System:	FUJIFILM SonoSite SII 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	N		P	B+M; B+PWD;B+CD	1-5
Fetal	P	P	N		P	B+M; B+PWD; B+CD	1-5
Abdominal	P	P	N		P	B+M; B+PWD; B+CD	1-5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD;B+CD	1-5
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		P	B+M; B+PWD; B+CD	1-5
Neonatal Cephalic	P	P	N		P	B+M; B+PWD; B+CD	1-3,5
Adult Cephalic	P	P	N		P	B+M; B+PWD; B+CD	1-3,5
Trans-rectal	P	P	N		P	B+M; B+PWD; B+CD	1,5
Trans-vaginal	P	P	N		P	B+M; B+PWD; B+CD	1,5
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	N		P	B+M; B+PWD; B+CD	1,2,4,5
Musculo-skel. (Superfic.)	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	N	N	P	B+M; B+PWD; B+CWD;B+CD	1-5
Cardiac Pediatric	P	P	N	N	P	B+M; B+PWD;B+CWD;B+CD	1-5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	N		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) K162045 and K160734

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	C8x/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							
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	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	C11x/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	P	P	N		P	B+M; B+PWD; B+CD	1,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,5
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic	P	P	N		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	N		P	B+M; B+PWD; B+CD	1,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	C35x/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	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Abdominal	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		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	N		P	B+M; B+PWD;B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P	N		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	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	rC60xi/5-2 MHz Transducer, rC60xi/5-2 MHz Armored 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	N		P	B+M; B+PWD; B+CD	1,2,4,5
Abdominal	P	P	N		P	B+M; B+PWD; B+CD	1,2,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		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	N		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	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	HFL38xi/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	N		P	B+M; B+PWD; B+CD	1,4,5
Fetal							
Abdominal	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		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	N		P	B+M; B+PWD; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	N		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) K160734 & K162045.

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	HFL50x/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	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		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	N		P	B+M; B+PWD; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P	N		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	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	HSL25x/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	N		P	B+M; B+PWD; B+CD	1,4,5
Fetal							
Abdominal	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		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	N		P	B+M; B+PWD; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	ICTx/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	P	P	N		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	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	L25x/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	N		P	B+M; B+PWD; B+CD	1,4,5
Fetal							
Abdominal	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		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	N		P	B+M; B+PWD; B+CD	1,4,5
Musculo-skel. (Superfic.)	P	P	N		P	B+M; B+PWD;B+CD	1,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	L38xi/10-5 MHz Transducer, L38xi/10-5 MHz Armored 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	N		P	B+M; B+PWD; B+CD	1,4,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,4,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		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	N		P	B+M; B+PWD; B+CD	1,4,5
Cardiac Pediatric	P	P	N		P	B+M; B+PWD;B+CD	1,4,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	P10x/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	P	P	N		P	B+M; B+PWD; B+CD	1,5
Abdominal	P	P	N		P	B+M; B+PWD; B+CD	1,5
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD; B+CD	1,5
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		P	B+M; B+PWD; B+CD	1,5
Neonatal Cephalic	P	P	N		P	B+M; B+PWD; B+CD	1,5
Adult Cephalic	P	P	N		P	B+M; B+PWD; B+CD	1,5
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	N		P	B+M; B+PWD; B+CD	1,5
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	N	N	P	B+M;B+PWD; B+CWD; B+CD	1,3,5
Cardiac Pediatric	P	P	N	N	P	B+M; B+PWD; B+CWD; B+CD	1,3,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	P11x/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							
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 1.3-14: Diagnostic Ultrasound Indications for Use Form – rP19x/5-1 MHz Transducer, rP19x/5-1 MHz Armored Transducer

System:	FUJIFILM SonoSite SII Ultrasound System						
Transducer:	rP19x/5-1 MHz Transducer, rP19x/5-1 MHz Armored 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	N		P	B+M; B+PWD; B+CD	1-3
Abdominal	P	P	N		P	B+M; B+PWD; B+CD	1-3
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	N		P	B+M; B+PWD;B+CD	1-3
Small Organ (breast, thyroid, testicles, prostate)	P	P	N		P	B+M; B+PWD; B+CD	1-3
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1-3
Adult Cephalic	N	N	N		N	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	N	N	P	B+M; B+PWD; B+CWD;B+CD	1-3
Cardiac Pediatric	P	P	N	N	P	B+M; B+PWD; B+CWD; B+CD	1-3
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	N		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) K160734 (SII).

Prescription Use (Per 21 CFR 801.109)

510(k) Summary K183235

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: Aditi Chaubal
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Date prepared: September 26, 2018

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 SII Ultrasound System
Classification Names

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

3) Identification of the predicate or legally marketed device:

SonoSite Edge II Ultrasound System	K162045
SonoSite SII Ultrasound System	K162045

4) Device Description:

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 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 SII ULTRASOUND SYSTEM

SonoSite SII and Edge II 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 (K162045)	SonoSite Edge II Ultrasound System (K162045)
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indications for Use	Opthalmic 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 Needle guidance	Opthalmic 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 Needle guidance	Opthalmic 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 Needle guidance
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 Trans-esophageal
Transducer Frequency	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz
Global Maximum Outputs/Worst Case Setting	$I_{spta.3}$: 598.9 (HFL50x) TI Type: TIB (rP19x) TI Value: 4.98 (rP19x) MI: 1.7 (rP19x) $I_{pa.3}$@MI Max: 776 (L38xi)	Ispta.3: 420.2 (L38xi) TI Type: TIC (rC60xi) TI Value: 3.05 (rC60xi) MI: 1.7 (rP19x) Ipa.3@MI Max: 776 (L38xi)	$I_{spta.3}$: 598.9 (HFL50x) TI Type: TIB (rP19x) TI Value: 4.98 (rP19x) MI: 1.7 (rP19x) $I_{pa.3}$@MI Max: 776 (L38xi)
Acoustic Output Display & FDA Limits	Display Feature for Higher Outputs MI Output Display TI Output Display	Display Feature for Higher Outputs MI Output Display TI Output Display	Display Feature for Higher Outputs MI Output Display TI Output Display
Modes of Operation	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	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	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

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite SII Ultrasound System (K162045)	SonoSite Edge II Ultrasound System (K162045)
	Compounding Steered CW Doppler Velocity Color Doppler Tissue Doppler Imaging (TDI)	Velocity Color Doppler	Steered CW Doppler Velocity Color Doppler Tissue Doppler Imaging (TDI)
PW Doppler	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	Not available	Available on all imaging transducers except P11x Adjustable sample volume size: 1.0 – 25 mm Simultaneous or duplex mode of operation Simultaneous B-mode and PW Doppler High PRF capability
CW Doppler	Available on P10x and rP19x Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler	Not available	Available on P10x, rP19x, TEExi Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler
Velocity Color Doppler	Available on all transducers	Available on all transducers	Available on all transducers
ECG Feature	3-lead ECG input, *or* ECG Slave Cable	Not available	3-lead ECG input, *or* ECG Slave Cable
DICOM	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment	DICOM 3.0 Store, Print, Modality Worklist, Perform Procedure Step (PPS), Storage Commitment
IMT Measurement	Not available	Not available	Not 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) Cycoloy Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polycarbonate Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)
Product Safety Certification	AAMI/ANSI ES60601-1:2005 (R2012) IEC 60601-2-37 Ed. 2.1:2015 CAN/CSA C22.2 No. 60601-1:08 NEMA UD2-2004	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 Ed. 2.1 :2015 CAN/CSA C22.2 No. 60601-1:08 NEMA UD2-2004 IEC 62359:2017

Feature	SonoSite SII Ultrasound System (This submission)	SonoSite SII Ultrasound System (K162045)	SonoSite Edge II Ultrasound System (K162045)
	IEC 62359:2017		
EMC Compliance	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
DICOM	NEMA PS3.15 2011	NEMA PS3.15 2003	NEMA PS3.15 2011
Airborne Equipment Standards	RTCA/DO160 (section 21)	RTCA/DO160 (section 21)	RTCA/DO160 (section 21)
System Characteristics	**SII:** 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 Wireless 802.11 support for image transfer	**SII:** 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 Wireless 802.11 support for image transfer	**Edge II:** Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD 2 USB ports Dimensions: 12.8"(W) x 12.1" (L) x 2.5"(H) Weight: 9.0 lbs System operates via battery or AC power Battery life: 1.5 - 4 hour operation per charge 100 – 240V options, 50/60 Hz, 15VDC output Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Wireless 802.11 (b/g/n) support for image transfer
510(k) Track	Track 3	Track 3	Track 3

7) Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The **SonoSite SII 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(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 SII Ultrasound System** is 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 60601-1-2	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 Edition 2.1 2015, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	AAMI / ANSI / IEC 62304:2006+A1:2015, Medical device software - Software life cycle processes
IEC 62359	IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERISON, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
ISO 14971	ISO 14971:2007, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004 (R2009)	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

Summary of Clinical Tests:
The **SonoSite SII Ultrasound System**, 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 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 SII Ultrasound System** is substantially equivalent with regard to safety and effectiveness to the predicate devices.