DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 16, 2016

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

Re: K160406
Trade/Device Name: FUJIFILM FC1 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 12, 2016
Received: February 16, 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,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
~~TBD~~ K160406

Device Name
FUJIFILM FC1 Ultrasound System

Indications for Use *(Describe)*
The FUJIFILM FC1Ultrasound 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:

Fetal – OB/GYN
Abdominal
Intra-operative (Abdominal organs and vascular)
Pediatric
Small Organ (breast, thyroid, testicles, prostate)
Neonatal Cephalic
Trans-vaginal
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Cardiac Adult
Cardiac Pediatric
Peripheral Vessel

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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
Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

Table 1.3-1: Diagnostic Ultrasound Indications for Use Form – FUJIFILM FC1 Ultrasound System

System:	FUJIFILM FC1 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							
Fetal	N	N	N		N	B+M; B+PWD; B+CD	1-3,5
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Adult Cephalic							
Trans-rectal							
Trans-vaginal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	1-3,5
Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CD	1,2,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	C11xp/8-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Cardiac Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	C35xp/8-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

Table 1.3-4 – Diagnostic Ultrasound Indications for Use Form – C60xf/5-2 Transducer

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	C60xf/5-2 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

Table 1.3-5 – Diagnostic Ultrasound Indications for Use Form – HFL38xp/13-6 Transducer

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	HFL38xp/13-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	HFL50xp/15-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

Table 1.3-7 – Diagnostic Ultrasound Indications for Use Form – ICTxp/9-5 Transducer

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	ICTxp/9-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
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	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
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.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

Table 1.3-8 – Diagnostic Ultrasound Indications for Use Form – L25xp/13-6 Transducer

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	L25xp/13-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

Table 1.3-9 – Diagnostic Ultrasound Indications for Use Form – L38xp/10-5 Transducer

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	L38xp/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	1,2,4,5
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	1,2,5
Other (spec.)							

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

Additional Comments:

1: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Color Doppler includes Power/Velocity/Variance.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

Prescription Use (Per 21 CFR 801.109)

Table 1.3-10 – Diagnostic Ultrasound Indications for Use Form – P21xp/5-1 Transducer

System:	FUJIFILM FC1 Ultrasound System						
Transducer:	P21xp/5-1 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N		N	B+M; B+PWD; B+CD	1,2
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	1,2
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	1,2
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	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	1-3
Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	1-3
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; 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.
2: Tissue Harmonic Imaging (THI)
3: Tissue Doppler Imaging (TDI)
4: Steep Needle Profiling
5: Spatial Compounding

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:

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Date prepared:	November 22, 2015

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

FUJIFILM FC1 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 Ultrasound System	K133454 (primary predicate device)
SonoSite X-Porte Ultrasound System	K152209

4) Device Description:

The FC1 Ultrasound System is a highly featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes.

5) Intended Use:

The FC1 Ultrasound System is a general purpose ultrasound system and non-continuous patient monitoring platform intended in clinical care 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:

Fetal – OB/GYN
Abdominal
Intra-operative (Abdominal organs and vascular)
Pediatric
Small Organ (breast, thyroid, testicles, prostate)
Neonatal Cephalic
Trans-vaginal
Musculo-skel. (Convent.)
Musculo-skel. (Superfic.)
Cardiac Adult
Cardiac Pediatric
Peripheral Vessel

6) <u>Technological Characteristics:</u>

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

Feature	SonoSite X-Porte Ultrasound System (K152209)	SonoSite Edge Ultrasound System (K133454)	FC1 Ultrasound System (this submission)
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 Intraoperative (abdominal organs and vascular) Pediatric Small Organ (breast, thyroid, testicle, prostate) Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel Needle guidance	Opthalmic Fetal - OB/GYN Abdominal Intraoperative (abdominal organs and vascular) Intra-operative (Neuro.) Laparoscopic 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	Fetal – OB/GYN Abdominal Intraoperative (Abdominal organs and vascular) Pediatric Small Organ (breast, thyroid, testicles, prostate) Neonatal Cephalic Trans-vaginal Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Cardiac Adult Cardiac Pediatric Peripheral Vessel Needle guidance
Transducer Types	Linear Array Curved Linear Array Intracavitary Phased Array Trans-esophageal	Linear Array Curved Linear Array Intracavitary Phased Array Static Probes Trans-esophageal	Linear Array Curved Linear Array Intracavitary Phased Array
Transducer Frequency	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz
Modes of Operation	B-Mode Tissue Harmonic Imaging	B-Mode Tissue Harmonic Imaging	B-Mode Tissue Harmonic Imaging

Feature	SonoSite X-Porte Ultrasound System (K152209)	SonoSite Edge Ultrasound System (K133454)	FC1 Ultrasound System (this submission)
	Pulse Inversion Harmonic Imaging M-mode Velocity Color Doppler Color Power Doppler Pulsed Wave Doppler Pulsed Wave Tissue Doppler Continuous Wave Doppler, ECG	Pulse Inversion Harmonic Imaging M-mode Velocity Color Doppler Color Power Doppler Pulsed Wave Doppler Pulsed Wave Tissue Doppler Continuous Wave Doppler, ECG	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
PW Doppler	Available	Available	Available
CW Doppler	Available	Available	Available
Patient Contact Materials	Complies with ISO 10993	Complies with ISO 10993	Complies with ISO 10993
System Characteristics	12.1" Capacitive touch screen interface 19" LED LCD HD monitor 256 gray shades on LED LCD System operates via battery or AC power Input: 100 – 240 VAC, 50/60 Hz Output 1: 24VDC output, 275 W max Output 2: 100-240VAC, 50-60 Hz (AC Printer) Ability to perform measurements and calculations in the following: obstetrical, cardiac, volume, M-mode, PW and CW Doppler ECG acquisition and display capabilities (non-diagnostic) CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Measurement on Recalled Images. Wireless 802.11 (a/b/g/n) support for image transfer	Hand carried display and controls Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD System operates via battery or AC power 100 – 240V options, 50/60 Hz, 15VDC output Ability to perform measurements and calculations in the following: obstetrical, cardiac, volume, M-mode, PW and CW Doppler ECG acquisition and display capabilities (non-diagnostic) CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Wireless 802.11 (a\b\g) support for image transfer	Hand carried display and controls Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD System operates via battery or AC power 100 – 240V options, 50/60 Hz, 15VDC output Ability to perform measurements and calculations in the following: obstetrical, cardiac, volume, M-mode, PW and CW Doppler ECG acquisition and display capabilities (non-diagnostic) CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Wireless 802.11 (a\b\g) support for image transfer
510(k) Track	Track 3	Track 3	Track 3

7) Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The FUJIFILM FC1 Ultrasound System has been evaluated for electrical, thermal, mechanical, and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated, and the device has been found to conform to applicable mandatory medical device safety standards. Assurance of quality was established by employing the following elements of product development but were not limited to: Design Phase Reviews, Risk Assessment, Requirements Development, and Verification and Validation.

The FUJIFILM FC1 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 60601-2-37:2007 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
NEMA UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

Summary of Clinical Tests:
The FC1 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 FC1 system and predicates meet FDA requirements for Track 3 devices, share indications for use, have biosafety equivalence, and conform to applicable electro-medical device safety standards. FUJIFILM SonoSite, Inc. believes that the FC1 Ultrasound System is substantially equivalent with regard to safety and effectiveness to the predicate devices.