K133454

Pg 1 of 6

510(K) Summary

DEC 16 2013

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) **Submitter's name, address, telephone number, contact person:**

FUJIFILM SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official:	Patricia Liau Regulatory Affairs Specialist
E-mail:	Patricia.Liau@sonosite.com
Telephone:	(425) 951-6870
Facsimile:	(425) 951-6713
Date prepared:	October 17, 2013

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® 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
Picture Archiving and Communications System	892.2050	LLZ

3) **Identification of the predicate or legally marketed device:**

SonoSite Edge Ultrasound System	K113156
SonoSite Maxx Series Ultrasound System	K130173

4) **Device Description:**

The SonoSite Edge Ultrasound System is a portable laptop style, full featured, general purpose, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. Edge 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 can operate on either battery or AC power.

5) Intended Use:

The SonoSite Edge Ultrasound System is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Ophthalmic
Fetal - OB/GYN
Abdominal
Intra-operative (abdominal organs and vascular)
Intra-operative (Neuro.)
Pediatric
Small Organ (breast, thyroid, testicle, prostate)
Neonatal Cephalic
Adult Cephalic
Trans-rectal
Trans-vaginal
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Cardiac Adult
Cardiac Pediatric
Trans-esophageal (cardiac)
Peripheral Vessel

6) Technological Characteristics:

SonoSite Edge and Maxx Series Ultrasound Systems are both Track 3 devices that employ the same fundamental scientific technology. A comparison table is provided below.

Feature	SonoSite Edge Ultrasound System (This Submission)	SonoSite Edge Ultrasound System (K113156)	SonoSite M-Turbo (Maxx Series) Ultrasound System (K130173)
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 Intra-operative (abdominal organs and vascular) Intra-operative (Neuro.) Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Rectal Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel Needle guidance	Opthalmic Fetal - OB/GYN Abdominal Intra-operative (abdominal organs and vascular) Intra-operative (Neuro.) Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Rectal Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel Needle guidance	Opthalmic Fetal - OB/GYN Abdominal Intra-operative (abdominal organs and vascular) Intra-operative (Neuro.) Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Rectal Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel Needle guidance
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

Feature	SonoSite Edge Ultrasound System (This Submission)	SonoSite Edge Ultrasound System (K113156)	SonoSite M-Turbo (Maxx Series) Ultrasound System (K130173)
	Static Probes Trans-esophageal	Static Probes Trans-esophageal	Static Probes 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	*$I_{spta.3}$: .709 (TEEx)* *TI Type:* TIB(P21x) *TI Value:* 3.7 (P21x) *MI: 1.5* (P21x & L38xi) *$I_{pa.3}$@MI Max: 776 (L38xi)*	*$I_{spta.3}$: .709 (TEEx)* *TI Type:* TIB(P21x) *TI Value:* 3.7 (P21x) *MI: 1.5* (P21x & L38xi) *$I_{pa.3}$@MI Max: 776 (L38xi)*	*$I_{spta.3}$: .709 (TEEx)* *TI Type:* TIB(P21x) *TI Value:* 3.9 (P21x) *MI: 1.51* (P21x) *$I_{pa.3}$@MI Max: 439.9 (L38x)*
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 Compounding Steered CW Doppler Velocity Color Doppler Color 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 Color TDI	B-mode Grayscale Imaging 3D/4D Grayscale Imaging Tissue Harmonic Imaging M-mode Anatomical M-Mode Color M-Mode Color Power Doppler Zoom Combination Modes Pulsed Wave (PW) Doppler Continuous Wave (CW) Doppler SonoRes/SonoHD Noise Reduction SonoMB Image Compounding Steered CW Doppler Velocity Color Doppler Color TDI
PW Doppler	Available on all imaging transducers except D2x/2 MHz. Adjustable sample volume size: 1.0 – 25 mm Simultaneous or duplex mode of operation Simultaneous B-mode and PW Doppler High PRF capability	Available on all imaging transducers except D2x/2 MHz. Adjustable sample volume size: 1.0 – 25 mm Simultaneous or duplex mode of operation Simultaneous B-mode and PW Doppler High PRF capability	Available on all imaging transducers except D2x/2 MHz Adjustable sample volume size: 1.0 – 25 mm Simultaneous or duplex mode of operation Simultaneous B-mode and PW Doppler High PRF capability
CW Doppler	Available on C11x, D2x/2, P10x, P21x, TEEx Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler	Available on C11x, D2x/2, P10x, P21x, TEEx Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler	Available on C11x, D2x/2, P10x, P17x, P21x, TEEx Simultaneous or duplex mode of operation Simultaneous B-mode and CW Doppler
Velocity Color Doppler	Available on all transducers except D2x/2	Available on all transducers except D2x/2	Available on all transducers except D2x/2
Elastography (Strain), and Strain Rate Imaging	Available on all transducers except D2x/2	Available on all transducers except D2x/2	Available on all transducers except D2x/2
ECG Feature	One 3-lead ECG input, *or* One external ECG input, *or* One other physio input	One 3-lead ECG input, *or* One external ECG input, *or* One other physio input	One 3-lead ECG input, *or* One external ECG input, *or* One other physio input
DICOM	DICOM 3.0 CStore, Print, and Modality Worklist service class user features.	DICOM 3.0 CStore, Print, and Modality Worklist service class user features.	DICOM 3.0 CStore, Print, and Modality Worklist service class user features.

Feature	SonoSite Edge Ultrasound System (This Submission)	SonoSite Edge Ultrasound System (K113156)	SonoSite M-Turbo (Maxx Series) Ultrasound System (K130173)
IMT Measurement	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.	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.	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.
#Transmit Channels	128 digital channels	128 digital channels	128 digital channels
#Receive Channels	128 digital channels (using SA)	128 digital channels (using SA)	128 digital channels (using SA)
Patient Contact Materials	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive, Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive, Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive, Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)
Product Safety Certification	CAN/CSA C22.2 No. 601.1 EN 60601-1 EN 60601-1-1 UL 60601-1 JIS T 0601-1, JIS T 1507 CEI/IEC 61157 ANSI/AAMI EC53	CAN/CSA C22.2 No. 601.1 EN 60601-1 EN 60601-1-1 UL 60601-1 JIS T 0601-1, JIS T 1507 CEI/IEC 61157 ANSI/AAMI EC53	CAN/CSA C22.2 No. 601.1 EN 60601-1 EN 60601-1-1 UL 60601-1 JIS T 0601-1, JIS T 1507 CEI/IEC 61157 ANSI/AAMI EC53
EMC Compliance	EN 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5	EN 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5	EN 60601-1-2:2007 CISPR 11 IEC 61000-4 pt 2-5
DICOM	NEMA PS3.15 2003	NEMA PS3.15 2003	NEMA PS3.15 2003
Airborne Equipment Standards	RTCA/DO160D (section 21)	RTCA/DO160D (section 21)	RTCA/DO160D (section 21)
System Characteristics	**Edge:** Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD Dimensions: 12.9"(W) x 12.4 (L) x 2.5"(H) Weight: 8.5 lbs Battery operated (1.5 - 4 hour operation per charge)	**Edge:** Beamformer 128/128 using SA (configurable) Hand held display and control Single 12.1" Liquid Crystal Display (LCD) 256 gray shades on LCD Dimensions: 12.9"(W) x 12.4 (L) x 2.5"(H) Weight: 8.5 lbs Battery operated (1.5 - 4 hour operation per charge)	**M Series:** Beamformer 128/128 using SA (configurable) Hand held display and control Single 10.4" Liquid Crystal Display (LCD) 256 gray shades on LCD Dimensions: 10.9"(W) x 11.8 (L) x 3.0"(H) Weight: 8.3 lbs Battery operated (1.5 - 4 hour operation per charge)

Feature	SonoSite Edge Ultrasound System (This Submission)	SonoSite Edge Ultrasound System (K113156)	SonoSite M-Turbo (Maxx Series) Ultrasound System (K130173)
	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 (a\b\g) support for image transfer	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 (a\b\g) support for image transfer	100 – 240V options, 50/60 Hz Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Measurement on Recalled Images. Wireless 802.11 (a\b\g) support for image transfer and Bluetooth® 20. for voice activated remote control. **S Series:** Beamformer 128/128 using SA (configurable) Hand held display and control Single 10.4" Liquid Crystal Display (LCD) 256 gray shades on LCD Dimensions: 11.5"(W) x 14.8 (L) x 2.8"(H) Weight: 8.5 lbs Battery operated (1.5 - 4 hour operation per charge) 100 – 240V options, 50/60 Hz Various obstetrical, cardiac, volume, and M-mode measurement and calculation packages ECG acquisition and display capabilities Image storage on removable media Measurement on recalled images Wireless 802.11 (a\b\g) support for image transfer and Bluetooth® 2.0 for voice activated remote control
510(k) Track	Track 3	Track 3	Track 3

7) Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:
The SonoSite Edge 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 all applicable mandatory medical device safety standards. Assurance of quality was established by employing the following elements of product development: Design Phase Reviews, Risk Assessment, Requirements Development, System and Software Verification, Hardware Verification, Safety Compliance Verifcation, Clinical Validation, Human Factors Validation. All patient contact materials are biocompatible. Reports for these elements of product development are referenced in Attachment 6.

The Edge Ultrasound System is designed to comply with the following voluntary standards.

Reference No.	Title
AAMI/ANSI/ISO 10993-1	ISO 10993-1:2009, 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	IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
IEC 60601-2-37	IEC 60601-2-37:2007, Particular Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO 14971	ISO 14971: 2007, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD 3-2004	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine
NEMA PS 3.15	NEMA Ps 3.15:2011, Digital Imaging and Communications in Medicine (DICOM), Part 15: Security and System Management Profiles

Summary of Clinical Tests:
The SonoSite Edge Ultrasound System and transducers 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 Edge and predicate device both conform to applicable electromedical device safety standards with compliance verified through independent evaluation. The Edge and predicate device both meet FDA requirements for Track 3 devices, share indications for use, have biosafety equivalence, and are manufactured using the same ISO 13485 quality system. FUJIFILM SonoSite, Inc. believes that the Edge Ultrasound System is substantially equivalent with regard to safety and effectiveness to the predicate device.

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

December 16, 2013

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

Re: K133454
Trade/Device Name: Sonosite Edge® Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 11, 2013
Received: November 12, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Transducer Model Number

C8x/8-5 MHz	C11x/8-5 MHz	D2x/2 MHz
C60x/5-2 MHz	HFL38x/13-6 MHz	HFL50x/15-6 MHz
ICTx/8-5 MHz	L25x/13-6 MHz	L38xi/10-5 MHz
L38x/10-5 MHz	P10x/8-4 MHz	P11x/10-5 MHz
P21x/5-1 MHz	SLAx/13-6 MHz	TEEx/8-3 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

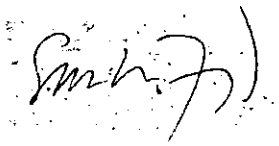
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
~~TBD~~ K133454

Device Name
SonoSite Edge Ultrasound System

Indications for Use *(Describe)*
The SonoSite Edge Ultrasound System is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

Ophthalmic
Fetal - OB/GYN
Abdominal
Intra-operative (abdominal organs and vascular)
Intra-operative (Neuro.)
Pediatric
Small Organ (breast, thyroid, testicle, prostate)
Neonatal Cephalic
Adult Cephalic
Trans-rectal
Trans-vaginal
Musculo-skeletal (Conventional)
Musculo-skeletal (Superficial)
Cardiac Adult
Cardiac Pediatric
Trans-esophageal (cardiac)
Peripheral Vessel

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

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

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

FOR FDA USE ONLY

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

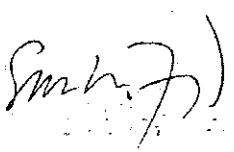


Table 1.3-1 Diagnostic Ultrasound Indications for Use Form – FUJIFILM SonoSite Edge Ultrasound System

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

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), color TDI, and imaging for guidance of biopsy. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. 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. Includes imaging of spinal cord to provide guidance for central nerve block procedures. Includes picture archiving, communications and storage functionality. M-Mode includes color M-Mode

All items marked "P" were previously cleared in 510(k) K113156.

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite Edge 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	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134 and K082098.

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite Edge 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	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were **previously cleared in 510(k) K071134.**

Prescription Use (Per 21 CFR 801.109)

Table 1.3-4 Diagnostic Ultrasound Indications for Use Form – D2x/2 Transducer

System:	FUJIFILM SonoSite Edge Ultrasound System						
Transducer:	D2x/2 MHz Dual Element Circular Array						
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							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult				P			
Cardiac Pediatric				P			
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

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

Additional Comments:

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-5 Diagnostic Ultrasound Indications for Use Form – C60x/5-2 Transducer

System:	FUJIFILM SonoSite Edge Ultrasound System						
Transducer:	C60x/5-2 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
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	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-6 Diagnostic Ultrasound Indications for Use Form – HFL38x/13-6 Transducer

System:	FUJIFILM SonoSite Edge Ultrasound System						
Transducer:	HFL38x/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	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite Edge 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	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles. prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite Edge 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	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-9 Diagnostic Ultrasound Indications for Use Form – L25x/13-6 Transducer

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

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134 and K082098.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-10 Diagnostic Ultrasound Indications for Use Form - L38xi/10-5 Transducer

System:	FUJIFILM SonoSite Edge Ultrasound System						
Transducer:	L38xi/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K113156.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-11 Diagnostic Ultrasound Indications for Use Form - L38x/10-5 Transducer

System:	FUJIFILM SonoSite Edge Ultrasound System						
Transducer:	L38x/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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

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

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), color TDI, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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

System:	FUJIFILM SonoSite Edge 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	Note 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	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, M-Mode, SonoHD2 imaging, SonoMB/MBe compound imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler can be combined with any imaging mode. Can be used with disposable kit cleared with K113680.

All items marked "P" were previously cleared in 510(k) K130173.

Prescription Use (Per 21 CFR 801.109).

Table 1.3-14 Diagnostic Ultrasound Indications for Use Form – P21x/5-1 Transducer

System:	FUJIFILM SonoSite Edge Ultrasound System						
Transducer:	P21x/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	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Fetal	P	P	P		P	B+M; B+PWD B+CD	Note 1
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Neonatal Cephalic	P	P	P		P	B+M; B+PWD B+CD	Note 1
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), color TDI, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-15 Diagnostic Ultrasound Indications for Use Form – SLAx/13-6 Transducer

System:	FUJIFILM SonoSite Edge Ultrasound System						
Transducer:	SLAx/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							
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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	Note 1
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134 and K082098.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-16 Diagnostic Ultrasound Indications for Use Form – TEEx/8-3 Transducer

System:	FUJIFILM SonoSite Edge Ultrasound System						
Transducer:	TEEx/8-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	**Mode of Operation**						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
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	Note 1
Other (spec.)							
Peripheral vessel							
Other (spec.)							

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

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, tissue harmonic imaging, SonoHD2 imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), color TDI, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)