510(K) Summary

MAR 2 5 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:	Scott Paulson
	Manager, Regulatory Affairs
E-mail:	Scott.Paulson@sonosite.com
Telephone:	(425) 951-6926
Facsimile:	(425) 491-8356
Date prepared:	December 21, 2012

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 Maxx™ Series 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:

FUJIFILM SonoSite, Inc. believes that the System described in this Submission is substantially equivalent to a combination of the SonoSite Maxx™ Series Ultrasound System (K082098, K101757), the SonoSite Edge® Ultrasound System (K113156), the Terason t3000 Ultrasound System (K112953).

4) Device Description:

The SonoSite Maxx Series Ultrasound System is a full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data in a number of exam types and clinical applications. The SonoSite Maxx Series is a design that readily lends itself to be configured to specific ultrasound imaging applications through physical packaging adaptations and system feature selections. Maxx Series can operate on either battery or AC power.

5) Intended Use:

The SonoSite Maxx Series 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 include: Ophthalmic, Fetal - OB/GYN, Abdominal, Intraoperative (abdominal organs and vascular), Intra-operative (Neuro.), Pediatric, Small Organ (breast, thyroid, testicle, prostate), Neonatal Cephalic, Adult Cephalic, Trans-Rectal, Trans-Vaginal, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (cardiac), Peripheral Vessel

6) Technological Characteristics:

SonoSite Maxx Series Ultrasound System is a Track 3 device that employs the same fundamental scientific technology as Maxx Series and Edge Ultrasound System predicates. The SonoSite Maxx Series Ultrasound System is substantially equivalent to the Terason T3000 Ultrasound System in that the Terason 10V5S transducer (K112953) is substantially the same (with the major exception of the system connector) as the SonoSite P11x transducer in this submission. The 10V5S and P11x transducers are both manufactured by SOMA Access Systems LLC.

Feature	SonoSite Maxx Series Ultrasound System (This Submission)	SonoSite Maxx Series Ultrasound System (K082098, K101757)	SonoSite Edge™ Ultrasound System (K113156)	Terason T3000 Ultrasound System (K112953)
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	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indications for Use	Opthalmic	Opthalmic	Opthalmic	
	Fetal - OB/GYN	Fetal - OB/GYN	Fetal - OB/GYN	Fetal - OB/GYN
	Abdominal	Abdominal	Abdominal	Abdominal
	Intraoperative (abdominal organs and vascular)	Intraoperative (abdominal organs and vascular)	Intraoperative (abdominal organs and vascular)	Intraoperative (abdominal organs and vascular)
	Intra-operative (Neuro.)	Intra-operative (Neuro.)	Intra-operative (Neuro.)	Intra-operative (Neuro.)
		Laparoscopic	Laparoscopic	Laparoscopic
	Pediatric	Pediatric	Pediatric	Pediatric
	Small Organ (breast, thyroid, testicle, prostate)	Small Organ (breast, thyroid, testicle, prostate)	Small Organ (breast, thyroid, testicle, prostate)	Small Organ (breast, thyroid, testicle, prostate)
	Neonatal Cephalic	Neonatal Cephalic	Neonatal Cephalic	Neonatal Cephalic
	Adult Cephalic	Adult Cephalic	Adult Cephalic	Adult Cephalic
	Trans-Rectal	Trans-Rectal	Trans-Rectal	Trans-Rectal
	Trans-Vaginal	Trans-Vaginal	Trans-Vaginal	Trans-Vaginal
	Musculo-skeletal (Conventional)	Musculo-skeletal (Conventional)	Musculo-skeletal (Conventional)	Musculo-skeletal (Conventional)
	Musculo-skeletal (Superficial)	Musculo-skeletal (Superficial)	Musculo-skeletal (Superficial)	Musculo-skeletal (Superficial)
	Cardiac Adult	Cardiac Adult	Cardiac Adult	Cardiac Adult
	Cardiac Pediatric	Cardiac Pediatric	Cardiac Pediatric	Cardiac Pediatric
	Trans-esophageal (cardiac)	Trans-esophageal (cardiac)	Trans-esophageal (cardiac)	
	Peripheral Vessel	Peripheral Vessel	Peripheral Vessel	Peripheral Vessel
	Biopsy guidance	Biopsy guidance	Biopsy guidance	Biopsy guidance
	Needle guidance	Needle guidance	Needle guidance	Needle guidance
Transducer Types	Linear Array Curved Linear Array Intracavitary	Linear Array Curved Linear Array Intracavitary	Linear Array Curved Linear Array Intracavitary	Linear Array Curved Linear Array

Feature	SonoSite Maxx Series Ultrasound System (This Submission)	SonoSite Maxx Series Ultrasound System (K082098, K101757)	SonoSite Edge™ Ultrasound System (K113156)	Terason T3000 Ultrasound System (K112953)
	Phased Array Static Probes Trans-esophageal	Phased Array Static Probes Trans-esophageal Wobbler Probes	Phased Array Static Probes Trans-esophageal	Phased Array Endocavitary Microconvex
Transducer Frequency	1.0 – 15.0 MHz	1.0 – 15.0 MHz	1.0 – 15.0 MHz	Unknown
Modes of Operation	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	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	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	2D/B-Mode M-Mode Power Doppler Directional Power Doppler Color Doppler Pulsed Wave Spectral Doppler Continuous Wave Spectral Doppler Duplex Doppler (Simultaneous, Real-Time 2-D and Spectral Doppler Display) Triplex Display (Simultaneous, Real-Time 2-D, Color Doppler and Spectral Doppler Display) ECG trace
PW Doppler	Available	Available	Available	Available
CW Doppler	Available	Available	Available	Available
Velocity Color Doppler	Available	Available	Available	Unknown
Elastography (Strain), and Strain Rate Imaging	Available	Available	Available	Unknown
ECG Feature	Available	Available	Available	Available
DICOM	DICOM 3.0	DICOM 3.0	DICOM 3.0	DICOM 3.0

Feature	SonoSite Maxx Series Ultrasound System (This Submission)	SonoSite Maxx Series Ultrasound System (K082098, K101757)	SonoSite Edge™ Ultrasound System (K113156)	Terason T3000 Ultrasound System (K112953)
IMT Measurement	SonoCalc IMT provides the capability for automated measurement of intima-media thickness (IMT) of the carotid artery.	SonoCalc IMT provides the capability for automated measurement of intima-media thickness (IMT) of the carotid artery.	SonoCalc IMT provides the capability for automated measurement of intima-media thickness (IMT) of the carotid artery.	Unknown
#Transmit Channels	128 digital channels	128 digital channels	128 digital channels	Unknown
#Receive Channels	128 digital channels (using SA)	128 digital channels (using SA)	128 digital channels (using SA)	Unknown
Patient Contact Materials	**Transducers:** Acrylonitrile-butadien-styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive, Polysulfone 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 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 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone Rubber Urethane **Needle Guides:** Acetal copolymer Acrylonitrile-butadien-styrene (ABS)	**Transducers (10VSS only):** Polycarbonate Silicon Rubber Poly-Vinyl-Chloride (PVC)
System Characteristics	**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) 100 – 240V options, 50/60 Hz Various obstetrical, cardiac, volume, M-	**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) 100 – 240V options, 50/60 Hz Various obstetrical, cardiac, volume, M-	**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) 100 – 240V options, 50/60 Hz, 15VDC output	**T3000** 15.4"(diagonal)TFTLED backlit hi-res widescreen display Anti-glare screen Adjustable brightness Dimensions:14.35 x 9.82 x 2.25" Weight:10.5lbs/4.8kg RechargeableLithium-Ionbatteryor ACpower Universal medical-gradepower supply Inputvoltage:100to240 V AC

Feature	SonoSite Maxx Series Ultrasound System (This Submission)	SonoSite Maxx Series Ultrasound System (K082098, K101757)	SonoSite Edge™ Ultrasound System (K113156)	Terason T3000 Ultrasound System (K112953)
	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	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	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	Frequency:50to60 Hz Preset-specific caliper measurements and annotations User-configurable measurements and annotations Electronicbeam steering OmniBeam™ TeraVision™ II Split-screendualdisplay Simultaneous2D/Color Trapezoidal imaging
510(k) Track	Track 3	Track 3	Track 3	Track 3

7) Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The SonoSite Maxx Series 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. The Maxx Series system also complies with voluntary standards which are detailed in Table 1.1-1 and 1.1-2 of this premarket submission. Assurance of quality was established by employing the following elements of product development: Design Phase Reviews, Risk Assessment, Requirements Development, System and Software Verification, Hardware Verification, Safety Compliance Verification, Clinical Validation, Human Factors Validation. All patient contact materials are biocompatible. Reports for these elements of product development are referenced in Attachment 6.

Summary of Clinical Tests:

The SonoSite Maxx Series Ultrasound System and transducers did not require clinical studies to support the determination of substantial equivalence.

The SonoSite Maxx Series Ultrasound System is designed to comply with the following standards.

FDA Consensus Standards

Reference No.	Title
AAMI/ANSI/ISO 10993-1	ISO 10993-1:2003(E), Biological evaluation of medical devices – Part 1: Evaluation and testing
AAMI/ANSI/ISO 10993-5	ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
AAMI/ANSI/ISO 10993-12	ISO 10993-12:2007, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
AAMI/ANSI/ISO 10993-10	ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
AAMI/ANSI/ISO 10993-11	ISO 10993-11:2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.
IEC 60601-1	IEC 60601-1:1988, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
IEC 60601-1-1	IEC 60601-1-1:2000, Medical electrical equipment – Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
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 60601-1-4	IEC 60601-1-4:2000 Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1

IEC 60601-2-37	IEC 60601-2-37:2001, Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
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
AAMI/ANSI EC53	AAMI / ANSI EC53:1995/(R) 2008, ECG cables and leadwires
AIUM MUS	AIUM MUS, Medical Ultrasound Safety
ISO /FDIS 15223-1	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements

Miscellaneous Standards

Reference No.	Title
Title 21 CFR Part 820	Quality System Regulation – Medical Devices: Current Good Manufacturing Practice (CGMP); Final Rule
ISO 9001	ISO 9001:2008, Quality management systems -- Requirements International Organization for Standardization
ISO 13485	ISO 13485:2003, Medical devices -- Quality management systems – Requirements for regulatory purposes
ISO 14971	ISO 14971:2007, Medical devices – Application of risk management to medical devices
RTCA D160E	Radio Technical Commission for Aeronautics: Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy
CAN/CSA C22.2	CAN/CSA C22.2, No. 60601-1, Canadian Standards Association, Medical Electrical Equipment–Part 1. General Requirements for Safety
EN 60529	Degrees of protection provided by enclosures (IP Code) (1992)
UL 94	Underwriters Laboratories, Inc., Tests for Flammability of Plastic Materials for Parts in Devices and Appliances, 5th Edition
CISPR 11	International Electrotechnical Commission, International Special Committee on Radio Interference. Industrial, Scientific, and Medical (ISM) Equipment - Radio-Frequency Disturbance Characteristics-Limits and Methods of Measurement. Classification for the ultrasound system, docking system, accessories, and peripherals when configured together: Group 1, Class A.
NEMA PS 3.15	Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B. 118
HIPAA	The Health Insurance and Portability and Accountability Act, Pub.L. No. 104-191 45 CFR 160, General Administrative Requirements 45 CFR 164, Security and Privacy

8) Conclusion:

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The product development process conforms to 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable electro medical device safety standards with compliance verified through independent evaluation and ongoing factory audits. Medical diagnostic ultrasound has an established history of safety and effectiveness. It is the opinion of FUJIFILM SonoSite, Inc. that the SonoSite Maxx™ Series Ultrasound System is substantially equivalent with regard to safety and effectiveness to other devices already cleared for market.

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 25, 2013

FujiFilm SonoSite, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 24th Street NW
BUFFALO MN 55313

Re: K130173
Trade/Device Name: SonoSite Maxx™ Series Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, LLZ
Dated: March 12, 2013
Received: March 13, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite Maxx™ Series Ultrasound System as described in your premarket notification:

Transducer Model Number

P11x/10-5	HFL38x/13-6	P10x/8-4
L38xi/10-5	HFL50x/15-6	P21x/5-1
C8x/8-5	ICTx/8-5	SLAx/13-6
C11x/8-5	L25x/13-6	TEEx/8-3
D2x/2	L38x/10-5	
C60x/5-2	L52x/10-5	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Mr. Joshua Nipper at (301) 796-6524.

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

Enclosures

Indications for Use Form

510(k) Number (if known): TBD

Device Name: SonoSite Maxx™ Series Ultrasound System

Indications for Use:

The SonoSite Maxx™ Series 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 include: Ophthalmic, Fetal - OB/GYN, Abdominal, Intraoperative (abdominal organs and vascular), Intra-operative (Neuro.), Pediatric, Small Organ (breast, thyroid, testicle, prostate), Neonatal Cephalic, Adult Cephalic, Trans-Rectal, Trans-Vaginal, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (cardiac), Peripheral Vessel.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K130173

Table 1.3- 1 Diagnostic Ultrasound Indications for Use Form – SonoSite Maxx™ Series Ultrasound System

System:	SonoSite Maxx™ Series 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	
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, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB/**MBe** compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, 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 anatomical M-Mode, and color M-Mode. System includes wireless voice activated remote control capabilities. System includes the ability to perform measurements on recalled images.

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3- 2 Diagnostic Ultrasound Indications for Use Form – P11x/10-5 Transducer

System:	SonoSite Maxx™ Series 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	N	N			N	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	N	N			N	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, SonoRes/SonoHD imaging, 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.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-3 Diagnostic Ultrasound Indications for Use Form - L38xi/10-5 Transducer

System:	SonoSite Maxx™ Series 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, SonoRes/SonoHD 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 1.3-4 Diagnostic Ultrasound Indications for Use Form – C8x/8-5 Transducer

System:	SonoSite Maxx™ Series 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, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, 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 anatomical M-Mode, and color M-Mode.

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

Prescription Use (Per 21 CFR 801.109)

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

System:	SonoSite Maxx™ Series 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							2.
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, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate 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 includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-6 Diagnostic Ultrasound Indications for Use Form - D2x/2 Transducer

System:	SonoSite Maxx™ Series 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) K082098.

Prescription Use (Per 21 CFR 801.109)

Table 1.3-7 Diagnostic Ultrasound Indications for Use Form - C60x/5-2 Transducer

System:	SonoSite Maxx™ Series 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, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, 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 anatomical M-Mode, and color M-Mode.

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-8 Diagnostic Ultrasound Indications for Use Form - HFL38x/13-6 Transducer

System:	SonoSite Maxx™ Series 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, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, 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 anatomical M-Mode, and color M-Mode.

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-9 Diagnostic Ultrasound Indications for Use Form – HFL50x/15-6 Transducer

System:	SonoSite Maxx™ Series 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, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, 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 anatomical M-Mode, and color M-Mode.

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-10 Diagnostic Ultrasound Indications for Use Form – ICTx/8-5 Transducer

System:	SonoSite Maxx™ Series 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, **3-D/4-D** imaging, tissue harmonic imaging, **SonoRes/SonoHD** imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), **elastography imaging, strain rate imaging,** 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 anatomical M-Mode, and color M-Mode.**

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-11 Diagnostic Ultrasound Indications for Use Form – L25x/13-6 Transducer

System:	SonoSite Maxx™ Series 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, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB/MBe compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate 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 includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-12 Diagnostic Ultrasound Indications for Use Form - L38x/10-5 Transducer

System:	SonoSite Maxx™ Series 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, **3-D/4-D** imaging, tissue harmonic imaging, **SonoRes/SonoHD** imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), **elastography imaging, strain rate imaging,** 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 anatomical M-Mode, and color M-Mode.**

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-13 Diagnostic Ultrasound Indications for Use Form – L52x/10-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	L52x/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	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)	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, **3-D/4-D** imaging, tissue harmonic imaging, **SonoRes/SonoHD** imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), **elastography imaging, strain rate imaging,** 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 anatomical M-Mode, and color M-Mode.**

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-14 Diagnostic Ultrasound Indications for Use Form – P10x/8-4 Transducer

System:	SonoSite Maxx™ Series 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	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	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, **3-D/4-D** imaging, tissue harmonic imaging, **SonoRes/SonoHD** imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), **color TDI, elastography imaging, strain rate 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 includes velocity color Doppler. Color Doppler can be combined with any imaging mode. **M-Mode includes anatomical M-Mode, and color M-Mode.**

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-15 Diagnostic Ultrasound Indications for Use Form – P21x/5-1 Transducer

System:	SonoSite Maxx™ Series 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, **3-D/4-D** imaging, tissue harmonic imaging, **SonoRes/SonoHD** imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), **color TDI, elastography imaging, strain rate imaging,** 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 anatomical M-Mode, and color M-Mode.**

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-16 Diagnostic Ultrasound Indications for Use Form – SLAx/13-6 Transducer

System:	SonoSite Maxx™ Series 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	P	P	P		P	B+M; B+PWD; B+CD	Note 1
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, **3-D/4-D** imaging, tissue harmonic imaging, **SonoRes/SonoHD** imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), **elastography imaging, strain rate 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 includes velocity color Doppler. Color Doppler can be combined with any imaging mode. **M-Mode includes anatomical M-Mode, and color M-Mode.**

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

Prescription Use (Per 21 CFR 801.109)

Table 1.3-17 Diagnostic Ultrasound Indications for Use Form – TEEx/8-3 Transducer

System:	SonoSite Maxx™ Series 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, **3-D/4-D** imaging, tissue harmonic imaging, **SonoRes/SonoHD** imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), **color TDI, elastography imaging, strain rate imaging,** 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 anatomical M-Mode, and color M-Mode.**

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

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) ____K130173_____