510(K) Summary of Safety and Effectiveness

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:

K101757

Manufacturer's Name & Address:

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

AUG 1 2 2010

Corresponding Official:

Mary K. Moore
Vice President of Regulatory Affairs
21919 30th Drive SE
Bothell, WA 98021-3904

E-mail: mary.moore@sonosite.com

Telephone: (425) 951-1275

Facsimile: (425) 951-1201

Initial Distributor (if manufacturer is overseas):

Not Applicable

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Device Names:

NanoMaxx™ Series Ultrasound System (subject to change)

Maxx Series Ultrasound System (M Turbo®, S Series™) (subject to change)

SonoSite® Ultrasound System (subject to change)

Common Name:

Diagnostic ultrasound system with accessories

Classification:

Regulatory Class: II

Review Category: Tier 2

Classification Panel: Radiology

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

3) Identification of the predicate or legally marketed device:

SonoSite, Inc., believes that the *SonoSite Ultrasound Systems* described in this Submission, and previously cleared on 510(k)'s K071134, K082098 and K092058 are substantially equivalent to the SonoSite 180 Hand Carried Ultrasound System (K014116).

4) Device Description:

SonoSite ultrasound systems are highly portable, software-controlled ultrasound systems used to acquire and display high resolution, real-time ultrasound data in a variety of modes and clinical settings. The SonoSite 180™ Hand Carried Ultrasound System (K014116) provided clearance for a fully described cardiac indication including the imaging of surrounding structures, notably the Lung. The NanoMaxx Series Ultrasound System (K092058), and the Maxx Series (M turbo, S Series) Ultrasound System (K071134, K082098), which are collectively referred to as the *SonoSite Ultrasound System*, have all been previously cleared and are currently in interstate commerce.

This 510(k) premarket notification includes no changes, including no new system functions or technology changes, to the ultrasound systems, transducers, or accessories that were the subjects of the above-referenced submissions. This 510(k) premarket notification only extends the previously cleared indications to specifically identify the "Presence and location of fluid around the heart and lungs, aid in pericardialcentesis and pleuralcentesis and visualize bloodflow through cardiac valves". Additionally, the indications for use under K014116 specifically included the cardiac intended use; "The system can be used to assess the presence and extent of some injuries and diseases".

This clinical application and intended use is consistent with current clinical practice and FDA guidelines. Ultrasound is commonly used to visualize existing landmarks in the anatomy, and the use of diagnostic ultrasound for the evaluation of fluid flow in the cardiac system, including lung is well established. Specific clinical application to the discrimination of Lung anatomy, including other types of anatomical detail, adds no significant risk to the general indication for use.

By this Submission, then, the clinical application of imaging guidance for the presence or absence of pathology of the cardiac system including the lung is being added in order to support marketing claims only. This update required no new technology, no new software, and no new instructions for use.

Previously cleared indications for use for each of the referenced *SonoSite Ultrasound Systems* and to the following transducers:

System	Transducer	Transducer Type	Frequency Range
NanoMaxx High-Resolution Ultrasound System	P21n	Linear Array	5.0 – 1.0 MHz
	L25n	Linear Array	13.0 – 6.0 MHz
Maxx Series Ultrasound System	P21x	Linear Array	5.0 – 1.0 MHz
	L25x	Linear Array	13.0 – 6.0 MHz

Each of the SonoSite *Series Ultrasound Systems* were designed, developed and tested per the applicable standards detailed below. Safety and effectiveness are established by developing product per industry recognized standards. SonoSite development records demonstrate compliance and are maintained in the Device History Record, in compliance with 21 CFR 820.

SonoSite performs testing in order to verify compliance with the standards. Testing reports have been provided in previous submissions per guidance. As this submission is in support of expanding marketing claims only, there have been no changes to technology, software or hardware. As such no additional testing was performed in support of this submission.

Applicable 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 10993-12	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	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988
IEC 60601-2-37	Medical Electrical Equipment – Part 2-37; Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (2001)
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

Miscellaneous Standards

Reference No.	Title
ISO 9001:2008	Quality management systems – Requirements International Organization for Standardization (2008)
Title 21 CFR Part 820	Quality System Regulation – Medical Devices: Current Good Manufacturing Practice (CGMP); Final Rule
EN ISO 13485:2003	Medical devices – Quality management systems – Requirements for regulatory purposes (2003)
EN ISO 14971:2000	Medical devices – Application of risk management to medical devices (2000) (ISO 14971:2000)
RTCA D160E	Radio Technical Commission for Aeronautics: Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy

5) Intended Use:

The intended uses of the SonoSite *Series Ultrasound Systems* remain the same as the information supplied in the predicate 510(k)'s K071134, K082098 and K092058, except for the following addition.

Cardiac Imaging Applications

This system allows the clinician to perform focused cardiac studies. This system transmits ultrasound energy into the thorax of adult and pediatric patients to obtain 2D, PowerMap, DCPD, M-mode (where available), Tissue Harmonic Imaging, or PW and CW Doppler images of the heart, great vessels, and anatomic or pathologic structure. This system can be used to assess overall cardiac performance and size, **determine the presence and location of fluid around the heart and lungs, aid in pericardialcentesis and pleuralcentesis procedures, and visualize blood flow through cardiac valves. Also the system can be used to access the presence and extent of some injuries and diseases.** The ECG (where available) is used for accurate timing of diastolic and systolic function. The ECG trace is not used to diagnose cardiac rhythms and is not designed for long term cardiac rhythm monitoring.

6) Technological Characteristics:

The Technological Characteristics of the SonoSite *Series Ultrasound Systems* remain the same as those supplied and cleared in the predicate 510(k)'s K071134, K082098 and K092058.

7) Conclusion

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The product development process conforms with 21 CFR 820, and ISO 13485:2003 quality systems. The device conforms to applicable electromedical 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 SonoSite, Inc. that the SonoSite *Series Ultrasound System* is substantially equivalent with regard to safety and effectiveness to other devices already cleared for marketing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 12 2010

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

Re: K101757
Trade/Device Name: NonoMaxx: SonoSite NanoMaxx Series Ultrasound System, M Turbo: SonoSite Maxx Series Ultrasound System, S Series: SonoSite Maxx Series Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYO, ITX, and IYN
Dated: July 28, 2010
Received: July 29, 2010

Dear Ms. Stenberg:

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 NonoMaxx: SonoSite NanoMaxx Series Ultrasound System, M Turbo: SonoSite Maxx Series Ultrasound System, S Series: SonoSite Maxx Series Ultrasound System, as described in your premarket notification:

Transducer Model Number

L25n/13-6
P21n/5-1 Phased Array
P21x/5-1 MHz
L25x/13-6 MHz

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 Paul Hardy at (301) 796-6542.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): TBD AUG 12 2010

Device Names:

- NanoMaxx: SonoSite NanoMaxx Series Ultrasound System
- M Turbo: SonoSite Maxx Series Ultrasound System
- S Series: SonoSite Maxx Series Ultrasound System

Indications for Use:

The SonoSite Series Ultrasound Systems are 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; Abdominal; Intra-operative (abdominal organs and vascular); Laparoscopic; Pediatric; Small Organ (breast, thyroid, testicles, prostate); Neonatal Cephalic; Adult Cephalic; Trans-recta;, 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)_____

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101757

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

System:		SonoSite NanoMaxx™ 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						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P				P	B+CD, B+CPD	Note 1
	Abdominal	P				P	B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P				P	B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P				P	B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P				P	B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	P				P	B+CD, B+CPD	Note 1
	Musculo-skeletal (**Superficial**)	P				P	B+CD, B+CPD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P				P	B+CD, B+CPD	Note 1
	Cardiac Pediatric	P				P	B+CD, B+CPD	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral	Peripheral vessel	P				P	B+CD, B+CPD	Note 1
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, Tissue Harmonic Imaging, SonoHD, SonoMB Compound Imaging, Tissue Doppler Imaging. Color Doppler includes Color Velocity 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.

All items marked "P" were previously cleared in 510(k) K092058

Prescription Use (Per 21 CFR 801.109)

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

510(k) Number K101757

Table 1.3-2 Diagnostic Ultrasound Indications for Use Form – L25n/13-6 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		L25n/13-6 13.0-6.0 MHz Linear Array						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows						
Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P				P	B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P				P	B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P				P	B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P				P	B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	P				P	B+CD, B+CPD	Note 1
	Musculo-skeletal (**Superficial**)	P				P	B+CD, B+CPD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P				P	B+CD, B+CPD	Note 1
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral	Peripheral vessel	P				P	B+CD, B+CPD	Note 1
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, SonoHD Imaging, SonoMB Compound Imaging. Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and an expanded intended use for imaging guidance for peripheral nerve block procedures.

All items marked "P" were previously cleared in 510(k) K092058

Prescription Use (Per 21 CFR 801.109)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) Number K101757

Table 1.3-3 Diagnostic Ultrasound Indications for Use Form – P21n/5-1 Phased Array Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		P21n/5-1 5.0-1.0 MHz Phased Array Transducer						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows						
Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P				P	B+CD, B+CPD	Note 1
	Abdominal	P				P	B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P				P	B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P				P	B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P				P	B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P				P	B+CD, B+CPD	Note 1
	Cardiac Pediatric	P				P	B+CD, B+CPD	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral Vessel	Peripheral vessel	P				P	B+CD, B+CPD	Note 1
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, Tissue Harmonic Imaging, SonoHD, SonoMB Compound Imaging, Tissue Doppler Imaging. Color Doppler includes Color Velocity 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.

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

Prescription Use (Per 21 CFR 801.109)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) Number K101757

Table 1.3-4 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						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	
Fetal Imaging & Other	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, 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	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	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	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Musculo-skeletal (**Superficial**)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	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
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Intra-cardiac						B+M; B+PWD; B+CD	
	Other							
Peripheral Vessel	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, SonoHD Imaging, SonoMB Compound Imaging. Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and an expanded intended use for imaging guidance for peripheral nerve block procedures.

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

Prescription Use (Per 21 CFR 801.109)

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

510(k) Number K101757

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

System:		SonoSite Maxx™ Series Ultrasound System						
Transducer:		P21x/ 5.0 – 1.0 MHz Linear Array						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows						
Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Fetal Imaging & Other	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, 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-skeletal **(Conventional)**	P	P	P		P	B+CD, B+CPD	Note 1
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	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	
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral	Peripheral vessel	P	P	P		P	B+CD, B+CPD	Note 1
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, SonoHD Imaging, SonoMB Compound Imaging. Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and an expanded intended use for imaging guidance for peripheral nerve block procedures.

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

Prescription Use (Per 21 CFR 801.109)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) Number K101757

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

System:		SonoSite Maxx™ Series Ultrasound System						
Transducer:		L25x/ 13.0 – 6.0 MHz Linear Array						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows						
Clinical Application		Mode of Operation						
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic	P	P			P	B+M; B+CD	Note 1
Fetal Imaging & Other	Fetal							
	Abdominal	P	P			P	B+M; B+CD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P	P			P	B+M; B+CD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P			P	B+M; 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-skeletal (Conventional)	P	P			P	B+M; B+CD	Note 1
	Musculo-skeletal (Superficial)	P	P			P	B+M; B+CD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral	Peripheral vessel	P	P			P	B+M, B+CD, B+CPD	Note 1
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, Tissue Harmonic Imaging, SonoHD, SonoMB Compound Imaging, Tissue Doppler Imaging. Color Doppler includes Color Velocity 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.

All items marked "P" were previously cleared in 510(k) K043559 and K053069

Prescription Use (Per 21 CFR 801.109)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) Number K101757