K102390
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510(K) Summary of Safety and Effectiveness

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

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

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

Corresponding Official:	Jessica R. Stenberg Sr. Regulatory Affairs Specialist
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Telephone:	(425) 951-1432
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Date prepared:	July 30, 2010

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® NanoMaxx™ 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
Medical image communications device	892.2020	LMD

3. Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that the system described in this submission is substantially equivalent to the SonoSite NanoMaxx Series Ultrasound System (K092058) and the Maxx Series Ultrasound System (K071134 and K082098).

4. Device Description:

The SonoSite NanoMaxx 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 2D, Doppler, M-Mode, Color Power Doppler or in a combination of these modes. The hand-carried system weighs less than 6 pounds and has a touch screen interface with minimal controls to facilitate disinfection and cleaning.

The system provides measurement capabilities for anatomical structures and fetal biometry that

provide information used for clinical diagnostic purposes. The system also includes the ability to measure the intima-media thickness (IMT) of the carotid artery using digital ultrasound images, which is used in conjunction with traditional risk assessment models to assess individual cardiovascular disease risk.

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The system includes Digital Imaging and Communications (DICOM) capabilities as well as general computer communication capabilities, including wireless networking, to provide the acceptance, transfer, display, storage, and digital processing of ultrasound images. Security support is also provided to facilitate HIPAA compliance.

The system supports the eFilm Lite™ application, which allows studies stored on a memory device in DICOMDIR format to be viewed. This viewing software can be launched on a PC when the license option is enabled.

The system includes a variety of accessories including a stand, dock featuring a video in/out port, a printer port, printer, VESA mounting arm and needle guide kits. The system includes three USB host supports for peripherals and an Ethernet port for data transfer of patient data. The system also features SiteLink™ allowing an additional method for the export of patient data. Storage devices include memory sticks.

The V-Universal™ stand provides a mobile work platform for the NanoMaxx, as well as a storage area for transducers and other supplies. It also provides connections for system accessories and peripherals.

The PowerPark docking stand consists of two components, the dock (plugs into a power outlet and sits on the floor) and the stand module (attaches to underside of stand). An AC adapter on the stand module allows for manual connection to AC power.

The PowerPack battery uses lithium-ion technology and mounts on the V Universal™ stand. LED lights on the PowerPack indicate the amount of available battery power, as well as charge status.

SonoSite Workflow Solutions (SWS) is a software program for organizing exams from the NanoMaxx. SWS operates on a host server and users require a login to access the program. Patient exam information can be transferred from the ultrasound to SWS by exporting data from the ultrasound to a USB storage device, then importing it from the USB storage device.

The use of a USB keyboard, barcode reader and medical grade printer is supported by the system, which allows manual entry of patient demographics, scanning entry of patient demographics and the capability to print images and/or reports.

The system/transducer is capable of exceeding a TI or an MI of 1.0 in certain operating modes or mode combinations. The system monitor displays the current output level in terms of the bioeffects indices ("Mechanical Index [MI]" and "Thermal Index [TI]") in accordance with the AIUM/NEMA Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

Frequency Range:	**1.0 – 13.0 MHz**	
Transducer Types:	Linear array Curved array	Phased array

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

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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	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 NanoMaxx Series Ultrasound System as defined by FDA guidance documents are:

Peripheral vessel
Fetal - OB/GYN
Abdominal
Musculo-skel. (Conventional)
Musculo-skel. (Superficial)
Cardiac
Pediatric
Small Organ (breast, thyroid, testicles, prostate)
Trans-rectal
Trans-vaginal

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Typical examinations performed using the SonoSite NanoMaxx Series Ultrasound System are:

Abdominal Imaging Applications

This system transmits ultrasound energy into the abdomen of patients using 2D, color Doppler (Color), color power Doppler (CPD) to obtain ultrasound images. The liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally.

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, Tissue Harmonic Imaging, or PW and CW Doppler images of the heart, great vessels, and anatomic or pathologic structures. 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 assess the presence and extent of some injuries and diseases.

Gynecology and Infertility Imaging Applications

This system transmits ultrasound energy in the pelvis and lower abdomen using 2D, color Doppler, and color power Doppler (CPD) to obtain ultrasound images. The uterus, ovaries, adnexa, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally.

Obstetrical Imaging Applications

This system transmits ultrasound energy into the pelvis of pregnant women using 2D, M Mode, color Doppler (Color) and color power Doppler (CPD) to obtain ultrasound images. The fetal anatomy, viability, estimated fetal weight, gestational age, amniotic fluid, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally or transvaginally. CPD and color Doppler (Color) imaging is intended for high-risk pregnant women. High-risk pregnancy indications include, but are not limited to, multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

- To prevent injury or misdiagnosis do not use this system for Percutaneous Umbilical Blood Sampling (PUBS) or in vitro Fertilization (IVF) The system has not been validated to be proven effective for these two uses.

  CPD, or Color images can be used as an adjunctive method, not as a screening tool, for the detection of structural anomalies of the fetal heart and as an adjunctive method, not as a screening tool for the diagnosis of Intrauterine Growth Retardation (IUGR).

Pediatric and Neonatal Imaging Applications

This system transmits ultrasound energy into the pediatric patients using 2D, color Doppler, and color power Doppler (CPD) to obtain ultrasound images. The pediatric abdominal, pelvic, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Superficial Imaging Applications
This system transmits ultrasound energy into various parts of the body using 2D, color Doppler and color power Doppler (CPD) to obtain ultrasound images. The breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, and surrounding anatomical structures can be assessed for the presence or absence of pathology. This system can be used to provide ultrasound guidance for drainage procedures, vascular line placement, peripheral nerve blocks, and spinal nerve blocks and taps.

Vascular Imaging Applications
This system transmits ultrasound energy into the various parts of the body using 2D, color Doppler and color power Doppler (CPD) to obtain ultrasound images. The carotid arteries, deep veins, and arteries in the arms and legs, superficial veins in the arms and legs, great vessels in the abdomen, and various small vessels feeding organs can be assessed for the presence or absence of pathology.

6. Technological Characteristics:
This device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, velocity color) are the same as a combination of the predicate devices identified in item 3. Transducer patient contact materials are biocompatible.

This device conforms to the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA UD 3-2004) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

I_{SPTA} (d)	720 mW/cm^2	Maximum
Tis/TIb/TIc	0.0 – 4.0	Range
Mechanical Index (MI)	1.9	Maximum
I_{SPPA} (d)	0 - 700 W/cm^2	Range

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

NOV 19 2010

Re: K102390
Trade/Device Name: SonoSite NanoMaxx™ Series Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, and LMD
Dated: November 1, 2010
Received: November 2, 2010

Dear Me. 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 NanoMaxx™ Series Ultrasound System, as described in your premarket notification:

Transducer Model Number

C11/n8-5
C60n/5-2
ICTn/8-5
L25n/13-6
L38n/10-5

L52n/10-5
P21n/5-1Phased Array

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 Brendan O'Leary at (301) 796-6898.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

K102390
P 1 of 9

Indications for Use Form

NOV 1 9 2010

510(k) Number (if known): TBD K102390

Device Name: NanoMaxx: SonoSite NanoMaxx™ Series Ultrasound System

Indications for Use:

The SonoSite NanoMaxx 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 and exam types include: Fetal/OB; Abdominal; Pediatric; Small Organ (breast, thyroid, testicles, prostate); Trans-rectal; Trans-vaginal Peripheral Vessel; Intra-operative (abdominal organs, vascular); Musculoskeletal Conventional & Superficial, Cardiac Adult and Pediatric.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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) K102390

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	N			P	B+M, B+CD, B+CPD	Note 1
	Abdominal	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	B+M, B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N			N	B+M, B+CD, B+CPD	Note 1
	Trans-vaginal	N	N			N	B+M, B+CD, B+CPD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Musculo-skeletal (**Superficial**)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P	N			P	B+M, B+CD, B+CPD	Note 1
	Cardiac Pediatric	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N			P	B+M, 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) K092058

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) Number K102390

Table 1.3-2 Diagnostic Ultrasound Indications for Use Form - C11n/8-5 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		C11n/8-5 8.0-5.0 MHz Curved 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	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	B+M, B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P	N			P		
	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							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P	N			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, SonoHD Imaging, SonoMB Compound 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 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 K102390

Table 1.3-3 Diagnostic Ultrasound Indications for Use Form - C60n/5-2 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		C60n/5-2 5.0-2.0 MHz Curved 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	P	N			P	B+M, B+CD, B+CPD	Note 1
	Abdominal	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	B+M, B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P	N			P	B+M, 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							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N			P	B+M, 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 Imaging, 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. 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 K102390

Table 1.3-4 Diagnostic Ultrasound Indications for Use Form – ICTn/8-5 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		ICTn/8-5MHz Curved 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	N	N			N	B+M, B+CD, B+CPD	Note 1
	Abdominal							
	Intra-operative (Abdominal Organs, Vascular)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Breast, Thyroid, Testicles, Prostate)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N			N	B+M, B+CD, B+CPD	Note 1
	Trans-vaginal	N	N			N	B+M, B+CD, B+CPD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
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. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures, and expanded intended use for imaging guidance for peripheral nerve block procedures.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) Number K102390

NOV 19 2010

Table 1.3-5 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	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	B+M, B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Musculo-skeletal (**Superficial**)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P	N			P	B+M, B+CD, B+CPD	Note 1
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N			P	B+M, 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, 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 K102390

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Table 1.3-6 Diagnostic Ultrasound Indications for Use Form - L38n/10-5 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		L38n/10-5 10.05.0 MHz Linear 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							
	Abdominal	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	B+M, B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Musculo-skeletal (**Superficial**)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P	N			P	B+M, B+CD, B+CPD	Note
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P	N			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, SonoHD Imaging, SonoMB Compound 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)

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Table 1.3-7 Diagnostic Ultrasound Indications for Use Form – L52n/10-5 Transducer – Veterinary only

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		L52n 10-5 MHz Linear Array						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of animal bodies 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	N	N			N	B+M, B+CD, B+CPD	Note 1
	Abdominal	N	N			N	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)							
	Intra-operative (Neuro)	N	N			N	B+M, B+CD, B+CPD	Note 1
	Laparoscopic							
	Pediatric	N	N			N	B+M, B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	N	N			N	B+M, B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)	N	N			N	B+M, B+CD, B+CPD	Note 1
	Musculo-skeletal (**Superficial**)	N	N			N	B+M, B+CD, B+CPD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N	N			N	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, SonoHD Imaging, SonoMB Compound 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 expanded intended use for imaging guidance for peripheral nerve block procedures.

Prescription Use (Per 21 CFR 801.109)

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Table 1.3-8 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	N			P	B+M, B+CD, B+CPD	Note 1
	Abdominal	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	N			P	B+M, B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	P	N			P	B+M, 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	N			P	B+M, B+CD, B+CPD	Note 1
	Cardiac Pediatric	P	N			P	B+M, B+CD, B+CPD	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	N			P	B+M, 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 Imaging, SonoMB Compound Imaging, Tissue Doppler. 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.

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

Prescription Use (Per 21 CFR 801.109)

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