SonoSite
Carrying Ultrasound into the Future

NOV - 5 2003

K033367

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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:

Michael A. Hoffman
Director – Quality Assurance and Regulatory Affairs
SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

(425) 951 – 1297

E-mail: michael.hoffman@sonosite.com

Date prepared: October 8, 2003

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 Names

TITAN™ High-Resolution Ultrasound System
SonoSite® iLook™ 25 Ultrasound System
SonoSite® Ultrasound System

Classification Names

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

3) Identification of the predicate or legally marketed device:

The SonoSite Ultrasound System that is the subject of this Submission is the collective term for the legally marketed TITAN™ High-Resolution Ultrasound System (K030949), the SonoSite® Ultrasound System (PowerSeries) (K021628), and the SonoSite® Ultrasound System (K014116).

This 510(k) premarket notification includes no changes, including no new system functions, to the ultrasound systems or accessories that were the subjects of those submissions. K014116 provided clearance for modes of operation that include "imaging for guidance of biopsy". Additionally, the indications for use under K030949 and K021628 specifically include "imaging to assist in the placement of needles and catheters in vascular or other anatomical structures".

This 510(k) premarket notification extends this indication to specifically identify use of the designated SonoSite ultrasound systems as substantially equivalent to the clinical application of the Site~Rite 3 Ultrasound System (K993624) marketed by Bard Access Systems for imaging guidance for peripheral nerve block procedures.

4) Device Description:

The devices referenced in this Submission are highly portable, software-controlled, diagnostic ultrasound systems with accessories. This Submission does not include any technological or feature changes from the previously cleared SonoSite devices or transducers.

By this Submission, the clinical application for imaging guidance for peripheral nerve block procedures is being added to previously cleared indications for use for each of these systems and to the following transducers:

System	Transducer	Transducer Type	Frequency Range
TITAN™ High-Resolution Ultrasound System	C11/8-5	Curved Array	8.0 – 5.0 MHz
	L25/10-5	Linear Array	10.0 – 5.0 MHz
	L38/10-5	Linear Array	10.0 – 5.0 MHz
SonoSite® Ultrasound System	C11/7-4	Curved Array	7.0 – 4.0 MHz
	L38/10-5	Linear Array	10.0 – 5.0 MHz
	L25/10-5	Linear Array	10.0 – 5.0 MHz
iLook™ 25 Ultrasound System	L25/10-5	Linear Array (integrated)	10.0 – 5.0 MHz

SonoSite ultrasound systems are designed, as applicable to their features, to comply with the standards listed below.

EN 540:1993	ISO 9001: 1994
EN 980 A1:1999	Title 21 CFR Part 820:1996
EN 1041:1998	CAN/CSA C22.2, No. 601.1:1998
EN 1441:1998	93/42/EEC:1993
EN 60529:1992	UL 2601-1:1999
EN ISO 10993-1:1997	UL 94, 5th ed.
EN 30993-4:1992	EN ISO 13485:1996
EN ISO 10993-5:1999	CISPR 11:2003
EN ISO 10993-10:1995	JIS-T-100x Series
EN 30993-11:1993	RTCA/DO160D:1997
EN ISO 10993-12:1996	ANSI/AAMI EC53:1995
EN 50103:1994	ASTM D5276-98
EN 60601-1:1998	ASTM D999-96
EN 60601-1/A1:1991	NEMA PS3.15 2000
EN 60601-1/A2:1995	NEMA UD2-1998
EN 60601-1-1:1993	NEMA UD3:1998
EN 60601-1-2:2001	Medical Ultrasound Safety, American Institute of Ultrasound in Medicine, 1994
EN 60601-1-4:1996	Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993
EN 60601-2-25:1996	Medical Devices Regulations of Health Canada, Therapeutic Products Directorate, 1998
EN 61157:1992	---

5) Intended Use:

As defined by FDA guidance documents, the intended uses of the SonoSite ultrasound systems referenced herein remain unchanged from previously cleared indications, except for a modification to their labeling to add imaging guidance for peripheral nerve blocks in musculoskeletal and intraoperative imaging applications.

The SonoSite ultrasound systems are intended for use for ultrasound evaluation of fetal - OB/GYN, abdominal, intra-operative (abdominal organs and vascular), laparoscopic, pediatric, small organ (breast, thyroid, testicles), neonatal cephalic, trans-rectal, trans-vaginal, musculoskeletal (conventional and superficial), cardiac (adult and pediatric), and peripheral vessel applications. The TITAN™ Ultrasound System has been additionally cleared for adult cephalic applications. The systems provide imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

6) Technological Characteristics:

There are no technological or feature changes in this Submission to any of the legally marketed ultrasound systems, transducers, or accessories identified in Section 3 of this Summary.

7) Testing:

Each of the referenced SonoSite systems has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, as well as thermal, electrical and mechanical safety, and has been found to conform to applicable medical device safety standards. Reports were previously included in the referenced predicate submissions. No additional clinical testing is required, as the specific indication for use adds no significant risk to the general indication for use of the referenced diagnostic ultrasound systems, in accordance with FDA's *Guidance for Industry: General/Specific Intended Use* document issued November 4, 1998.

8) Conclusion:

The clinical application and intended use described in this Submission is consistent with current clinical practice and FDA guidelines. Use of diagnostic ultrasound for the evaluation of soft tissue has been well established and its specific clinical application to the discrimination of small soft tissue parts, including nerves and other types of anatomical detail, adds no significant risk to the general indication for use. Therefore, it is SonoSite's opinion that the clinical applications as described in Section 5 of this Summary are substantially equivalent with respect to safety, effectiveness, and intended uses to similar devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

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

Re: K033367
Trade Name: SonoSite TITAN™ High-Resolution Ultrasound System, SonoSite® iLook Ultrasound System (Power Series), and SonoSite® Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: October 20, 2003
Received: October 21, 2003

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 Ultrasound Systems listed below, as described in your premarket notification:

1. SonoSite TITAN™ High-Resolution Ultrasound System:

- C11/8-5 8.0-5.0 MHz Curved Array
- L25/10-5 10.0-5.0 MHz Linear Array
- L38/10-5 10.0-5.0 MHz Linear Array

2. SonoSite® iLook Ultrasound System (Power Series):

    - L25/10-5 10.0-5.0 MHz Linear Array

3. SonoSite® Ultrasound System:

    - C11/7-4 7.0-4.0 MHz Curved Array
    - L38/10-5 10.0-5.0 MHz Linear Array
    - L25/10-5 10.0-5.0 MHz Linear 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Table 4.3- 1 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite TITAN™ high-resolution 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles)	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			B+M; B+PWD	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	Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures, and picture archiving, communications and storage functionality were all previously cleared in K030949. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033367

Table 4.3- 2 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite TITAN™ high-resolution ultrasound system
Transducer:	C11/8-5 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	**N**	**N**	**N**		**N**	**B+M; B+PWD; B+CD**	**Note 1**
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles)							
	Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared in 510(k) K030949. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033367

Table 4.3- 3 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite TITAN™ high-resolution ultrasound system
Transducer:	L25/10-5 10.0 – 5.0 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD; B+CD	Note 1
	Abdominal	P	P	P		P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P		P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles)	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							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P		P	B+M; B+PWD; B+CWD; B+CD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures, and picture archiving, communications and storage functionality were all previously cleared in K030949. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033367

Table 4.3- 4 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite TITAN™ high-resolution ultrasound system
Transducer:	L38/10-5 10.0- 5.0 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles)	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							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Color Doppler includes Velocity Color Doppler. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared in K030949. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033367

Table 4.3- 5 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite® iLook Ultrasound System (PowerSeries)
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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P	P		B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
Cardiac	Cardiac Pediatric	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared in K021628. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033367

Table 4.3- 6 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite® iLook Ultrasound System (PowerSeries)
Transducer:	L25/10-5 10.0 – 5.0 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P			B+M; B+PWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared in K021628. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033367

Table 4.3- 7 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite® 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Small Organ (breast, thyroid, testicles)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal	P	P	P			B+M; B+PWD	Note 1
	Trans-vaginal	P	P	P			B+M; B+PWD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
Cardiac	Cardiac Pediatric	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy cleared in K014116. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures. Also included in this 510(k) is imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033367

Table 4.3- 8 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite® Ultrasound System
Transducer:	C11/7-4 7.0 – 4.0 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Small Organ (breast, thyroid, testicles)							
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P	P		B+M; B+PWD; B+CWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy cleared in K014116. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures. Also included in this 510(k) is imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033367

Table 4.3- 9 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite® Ultrasound System
Transducer:	L38/10-5 10.0 – 5.0 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P			B+M; B+PWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, imaging for guidance of biopsy cleared in K010374. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures. Also included in this 510(k) is imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.**

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033367

Table 4.3- 10 Diagnostic Ultrasound Indications for Use Form

System:	SonoSite® Ultrasound System
Transducer:	L25/10-5 10.0 – 5.0 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 I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P			B+M; B+PWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P			B+M; B+PWD	Note 1
Vessel	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, imaging for guidance of biopsy cleared in K010374. **Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures. Also included in this 510(k) is imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.**

Prescription Use (Per 21 CFR 801.109)

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