SonoSite.

DEC 21 2004

K043452

SonoSite, Inc.
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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:

Daina L. Graham
Vice-President – Regulatory Affairs and Quality Assurance
SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

(425) 951 – 1275

E-mail: daina.graham@sonosite.com

Date prepared: December 3, 2004

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® 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),and the SonoSite® Ultrasound System (K014116).

This 510(k) adds the clinical application 'intra-operative (neurological)' as a indication to the SonoSite Ultrasound Systems (K030949, K014116). No other change, including technological change were made to these systems. Predicate devices that have 'intra-operative (neurological)' as a clinical application or indication are Siemens SONOLINE Omnia X/XS Diagnostic Ultrasound System (K020353) and Advanced Technology Laboratories HDI 5000 Ultrasound System (K011224)

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 'intra-operative (neurological)' 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
SonoSite® Ultrasound System	C11/7-4	Curved Array	7.0 – 4.0 MHz

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

EN 980 A1:2003	IEC 60601-2-37
AAMI/ANSI/ISO 10993-1:1997	CAN/CSA C22.2, No. 601.1:1998
AAMI/ANSI/ISO 10993-4:1992	UL 2601-1:1999
AAMI/ANSI/ISO 10993-5:1999	UL 94, 5th ed.
AAMI/ANSI/ISO 10993-10:1995	EN ISO 13485:1996
AAMI/ANSI/ISO 10993-11:1993	CISPR 11:2003
AAMI/ANSI/ISO 10993-12:1996	JIS-T-0601-1
IEC 60601-1:1988	RTCA/DO160D:1997
IEC 60601-1/A1:1991	ANSI/AAMI EC53:1995
IEC 60601-1/A2:1995	ASTM D5276-98
IEC 60601-1-1:2000	ASTM D999-96
IEC 60601-1-2:2001	NEMA PS3.15 2000
IEC 60601-1-4:1996	NEMA UD2-1998
IEC 60601-2-25:1996	NEMA UD3:1998
AIUM Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (1994)	Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993

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 the addition of 'intra-operative (neurological)' as a new intended use.

The SonoSite Ultrasound Systems are intended for use for ultrasound evaluation of fetal - OB/GYN, abdominal, intra-operative (abdominal organs, **neurological**, 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 biopsy guidance, imaging to assist in the placement of needles and catheters in vascular or other anatomical structures, and imaging guidance for

peripheral nerve block procedures.

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, as referenced in Section 4. Reports were previously included in the referenced predicate submissions. No additional clinical testing is required, as the added indication for use is not a novel indication as shown by the predicate devices in Section 3. The anatomical site is amenable to current transducer and post-processing ultrasound technology available with the SonoSite systems and predicate devices. Additionally, the modes of operation that are indicated with this clinical application for the SonoSite systems is consistent with those identified with the predicate devices. SonoSite has incorporated the specific labeling required by the FDA for the neurological intra-operative indication in its user guides to mitigate risk to that defined level.

8) **Conclusion:**

SonoSite believes that the testing and analysis described in Section 7 demonstrates that the TITAN™ High-Resolution Ultrasound System (K030949),and the SonoSite® Ultrasound System (K014116), incorporating the 'intra-operative (neurological) indication, are substantially equivalent with respect to safety and effectiveness to the predicate devices identified in Section 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

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

Re: K043452
Trade Name: TITAN™ High-Resolution Ultrasound System 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: December 10, 2004
Received: December 15, 2004

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 TITAN™ High-Resolution Ultrasound System and SonoSite® Ultrasound System, as described in your premarket notification:

Transducer Model Number

C11/8-5 8.0 – 5.0MHz Curved Array (TITAN™)
C11/7-4 7.0 – 4.0MHz Curved Array (SonoSite®)

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain

other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

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

Sincerely yours,

for 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.)	**N**	**N**	**N**		**N**	**B+M; B+PWD; B+CD**	**Note 1**
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 previously cleared in K030949. Imaging guidance for peripheral nerve block procedures was previously cleared in K033367.

Prescription Use (Per 21 CFR 801.109)

David A. Ferrara

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043452

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)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)	**N**	**N**	**N**		**N**	**B+M; B+PWD; B+CD**	**Note 1**
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, and picture archiving, communications and storage functionality were previously cleared in K030949. Imaging guidance for peripheral nerve block procedures was previously cleared in K033367.

Prescription Use (Per 21 CFR 801.109)

David A. Lagman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043452

Table 4.3- 3 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.)	**N**	**N**	**N**		**N**	**B+M; B+PWD; B+CD**	**Note 1**
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. Imaging guidance for peripheral nerve block procedures and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared in K033367.

Prescription Use (Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043452

Table 4.3- 4 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.)	**N**	**N**	**N**		**N**	**B+M; B+PWD; B+CD**	**Note 1**
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. Imaging guidance for peripheral nerve block procedures and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures was previously cleared in K033367.

Prescription Use (Per 21 CFR 801.109)

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043452