DEC 20 1999

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 - Regulatory Affairs and Quality Systems
SonoSite, Inc.
19807 North Creek Parkway, Suite 200
Bothell, WA 98011-8214
(425) 951 – 1297
E-mail: michael.hoffman@sonosite.com

Date prepared: November 3, 1999

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

SonoHeart™ Hand-Carried Echocardiography System (subject to change)

Classification Names

	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 SonoHeart™ Hand-Carried Echocardiography System is substantially equivalent to the currently

marketed Toshiba PowerVision 6000 (K991710), and the General Electric LOGIQ 500 MD (K991611), and the previously cleared SonoSite™ 180 Hand-Carried Ultrasound System (K990806 and K981505).

4) Device Description:

The SonoHeart™ Hand-Carried Echocardiography System is a general purpose, highly portable, software-controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and display it on a monitor in 2D, Color Power Doppler, and **2D PowerMap™ Directional Color Power Doppler** or in a combination of modes. The SonoHeart™ Hand-Carried Echocardiography System also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used for clinical diagnostic purposes.

The SonoHeart™ Hand-Carried Echocardiography System is designed to accept curved or linear transducers of the types and frequency listed in the table below. All actions affecting the performance of the transducer are activated from the main system control panel.

Frequency Range:	2.0 - 7.0 MHz
Transducer Types:	Linear array Curved linear array

The SonoHeart™ Hand-Carried Echocardiography System is designed to comply with the standards listed below.

EN 60601-1:1997	IEC 61000-4-4:1995
CAN/CSA C22.2, No. 601.1:1998	IEC 61000-4-5:1999
UL 2601-1:1999	CISPR11:97
EN 60601-1-2:1998	ISO 10993
CEI/IEC 61157:1992	21 CFR 820
IEC 61000-4-2:1999	ISO 9002
IEC 61000-4-3:1997	EN 46002
Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1998	Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993
Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD2-1998	European Active Medical Device Directive (93/42/EEC)
	Japanese National Standard, JIS-T-100x series

5) Intended Use:

The SonoHeart™ Hand-Carried Echocardiography System intended uses as defined FDA guidance documents are:

Fetal - OB/GYN	Small Organs (breast, thyroid, testicle)	Musculo-skeletal (conventional)
Abdominal	Neonatal Cephalic	Cardiac (adult and pediatric)
Intraoperative (abdominal organs and vascular)	Trans-Rectal	Peripheral Vessel
Pediatric	Trans-vaginal	

Typical examinations performed using SonoHeart™ Hand-Carried Echocardiography System are:

Abdomen: This system transmits ultrasound energy into the upper and lower quadrants of the abdomen of an adult or pediatric patient to obtain 2D or Color Power Doppler images, or PowerMap™ Directional Color Power Doppler which can be used to assess the presence and extent of disease and injury.

Study of small parts and superficial structures including breasts, shoulders, thyroid, and the abdominal wall: This system transmits ultrasound energy into the superficial soft tissue structures of body to obtain 2D, Color Power Doppler, or PowerMap™ Directional Color Power Doppler images of normal structure and pathology of the breast, thyroid abdominal wall, shoulders, wrist, ankle and knee.

Pediatric scans of organs, superficial structures, and bony structures: This system transmits ultrasound energy into the abdomen, pelvis and superficial structures of pediatric patients to obtain 2D, Color Power Doppler, or PowerMap™ Directional Color Power Doppler images of the abdominal organs, great vessels, pelvic structures and pediatric hips.

General cardiac studies in adults and pediatrics: This system transmits ultrasound energy into the thorax of adult and pediatric patients to obtain 2D, Color Power Doppler, or PowerMap™ Directional Color Power Doppler images of the heart, great vessels, and jusxtaposed anatomic and pathologic structures. This can be used to assess overall cardiac performance and size, determine the presence and size of fluid around the heart and lungs, and as an aid in certain procedures (namely pericardialcentesis, and pleuralcentesis).

GYN/Infertility: This system transmits ultrasound energy into the lower abdomen or vagina of a female patient to obtain 2D or Color Power Doppler, or PowerMap™ Directional Color Power Doppler images of the reproductive system, which can be used to assess the presence and

extent of disease in the female pelvic organs, monitor ovarian follicle size, and as an aid in CVS procedures.

Obstetrics: This system transmits ultrasound energy into the abdomen or vagina of a pregnant woman to obtain 2D images of a fetus, which can be used to estimate gestational age, number and weight, and assess the presence and extent of disease and confirm viability. Color Power Doppler or PowerMap™ Directional Color Power Doppler 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.

Prostate: This system transmits ultrasound energy through the prostate of an adult patient to obtain 2D or Color Power Doppler, or PowerMap™ Directional Color Power Doppler images of structures, which can be used to assess the presence and extent of disease or injury.

6) Technological Characteristics:

This device operates identical 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, Color Power Doppler, and PowerMap™ Directional Color Power Doppler) are the same as 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, 1998) 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:

All Applications:

I_{SPTAd}	720 mW/cm^2 (Maximum)
TIS/TIB/TIC	0.1 - 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)

I_{SPPAd}	0 - 700 W/cm^2 (Range)

The limits are same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 1999

SonoSite, Inc.
c/o Carole Stamp
TUV Product Services, Inc.
175 Old Highway 8 NW
New Brighton, MN 55112

Re: K994096
Trade Name: SonoHeart™ Hand-Carried Echocardiography System
Regulatory Class: II
Product Code: 90 IYN and 90 IYO
21 CFR 892.1550 and 1560
Dated: December 2, 1999
Received: December 3, 1999

Dear Ms. Stamp:

We have reviewed your Section 510(k) 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 SonoHeart™ Hand-Carried Echocardiography System, as described in your premarket notification:

Transducer Model Number
ICT/7-4 7-4 MHz Intercavitary Transducer
L7-4 MHz Linear Array
C60/5-2 5-2 MHz Curved Array
C15/402 MHz MCX Convex Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Rod Perez at (301) 594-1212.

Sincerely yours,

for CAPT. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM K994096

System: SonoHeart™ Hand-Carried Echocardiography System

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 Imaging & Other	Fetal	P	P				B+M	Note 1
	Abdominal	P	P				B+M	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P				B+M	Note 1
	Neonatal Cephalic	P	P				B+M	Note 1
	Adult Cephalic							
	Trans-rectal	P	P				B+M	Note 2
	Trans-vaginal	P	P				B+M	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P				B+M	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P				B+M	Note 1
	Cardiac Pediatric	P	P				B+M	Note 2
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P				B+M	Note 1
	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, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.

Note 2: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Prescription Use (Per 21 CFR 801.109)

David A. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994096

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoHeart™ Hand-Carried Echocardiography System
Transducer: ICT/7-4 7-4 MHz Intracavitary Transducer

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 Imaging & Other	Fetal	P	P				B+M	Note 1
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P				B+M	Note 2
	Trans-vaginal	P	P				B+M	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral 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, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.

Note 2: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Prescription Use (Per 21 CFR 801.109)

David G. Segem
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994096

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoHeart™ Hand-Carried Echocardiography System
Transducer: L7-4 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 Imaging & Other	Fetal	P	P				B+M	Note 1
	Abdominal	P	P				B+M	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P				B+M	Note 1
	Neonatal Cephalic	P	P				B+M	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P				B+M	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P				B+M	Note 2
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P				B+M	Note 1
	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, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.

Note 2: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Prescription Use (Per 21 CFR 801.109)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994096

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoHeart™ Hand-Carried Echocardiography System
Transducer: C60/5-2 5-2 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 Imaging & Other	Fetal	P	P				B+M	Note 1
	Abdominal	P	P				B+M	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note 1
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P				B+M	Note 1
	Cardiac Pediatric	P	P				B+M	Note 2
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral 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, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.

Note 2: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Prescription Use (Per 21 CFR 801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994096

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoHeart™ Hand-Carried Echocardiography System
Transducer: C15/4-2 MHz MCX Convex 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 Imaging & Other	Fetal	N	N				B+M	Note 1
	Abdominal	N	N				B+M	Note 1
	Intra-operative (Abdominal organs and vascular)	N	N				B+M	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N				B+M	Note 1
	Small Organ (breast, thyroid, testicles.)	N	N				B+M	Note 1
	Neonatal Cephalic	N	N				B+M	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N				B+M	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N				B+M	Note 2
	Cardiac Pediatric	N	N				B+M	Note 2
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N				B+M	Note 1
	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, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.

Note 2: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994096