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:

Howard Holman
Director, Program Management and Compliance
SonoSite, Inc.
19807 North Creek Parkway, Suite 200
Bothell, WA 98011-8214
(425) 487-7602

Date prepared: February 16, 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

C1 Ultrasound System (subject to change)

Classification Names

Ultrasonic Pulsed Doppler Imaging System	90-IYN	892.1550
Diagnostic Ultrasonic Transducer	90-ITX	892.1570
Ultrasonic Pulsed Echo Imaging System	90-IYO	892.1560

3) Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that C1 ultrasound system is substantially equivalent to the currently marketed ATL HDI® 5000 and Medison SA88 Plus diagnostic ultrasound systems and the previously cleared Cozumel ultrasound system.

4) Device Description:

C1 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, M-mode, and Amplitude Doppler or in a combination of modes. C1 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used for clinical diagnostic purposes. **C1 has an output display with two basic indices, a mechanical index (MI) and a thermal index (TI). One index is automatically displayed. MI is displayed in B-mode. TI is displayed in all other modes.**

The C1 system is designed to accept a curved or linear transducer. All actions affecting the performance of the transducer are activated from the main system control panel.

The C1 system is designed to accept transducers of the following types and frequency:

frequency range: 2.0 - 7.0 MHz

transducer types: Linear array
Curved linear array

Specific operating conditions (frame rate, line density, center frequency, number of active elements etc.) are automatically optimized by the system software in response to user inputs such as depth, exam type, transducer, and optimize.

C1 has been designed to meet the following electromechanical safety standards:

- EN 60601-1 (IEC 601-1,) European Norm, Medical Electrical Equipment
- UL 2601-1, Underwriters Laboratories Standards, Medical Electrical Equipment
- C22.2 No. 601.1, Canadian Standards Association, Medical Electrical Equipment
- CEI/IEC 1157:1992, International Electrotechnical Commission, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
- EN 60601-1-2 (IEC 601-1-2,) European Norm, Collateral Standard: Electromagnetic Compatibility

5) Intended Use:

C1 intended uses as defined FDA guidance documents are:

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

Typical examinations performed using C1 system are:

- General abdominal and pelvic studies including organ surveys, blood flow assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid, and the abdominal wall.
- Pediatric scans of organs, superficial, and bony structures.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Neonatal head studies.
- General cardiac studies in adults.
- Prostate, prostate biopsy guidance, rectal wall studies

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 a 2D and M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, M-mode, and Amplitude 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, 1992) 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/cm2	(Maximum)
TIS/TIB/TIC	0.1 - 4.0	(Range)
Mechanical Index (MI)	1.9	(Maximum)
I_{SPPAd}	0 - 700 W/cm2	(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

MAR 26 1999

Sonosite, Inc.
c/o TUV Product Service, Inc.
Carol Stamp
1775 Old Highway 8 NW
Suite 104
New Brighton, MN 55112

Re: K990806
C1 Ultrasound System
Regulatory Class: II/21 CFR 892.1550, 21 CFR 892.1570 and 21 CFR 892.1560
Product Code: 90 IYN, 90 ITX and 90 IYO
Dated: March 4, 1999
Received: March 11, 1999

Dear Mr. 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 C1 Ultrasound System, as described in your premarket notification:

Transducer Model Number

C7 – 4MHz IVT
L7 – 4MHz Linear Array
C4 – 2MHz Curves 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.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

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 Robert Phillips, Ph.D.at (301) 594-1212.

Sincerely yours,

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

Enclosures

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: C1 Ultrasound 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.)	Othe (Spec
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P				B+M	Note
	Abdominal	P	P				B+M	Note
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note
	Small Organ (breast, thyroid, testicles.)	P	P				B+M	Note
	Neonatal Cephalic	P	P				B+M	Note
	Adult Cephalic							
	Trans-rectal	N	N				B+M	Note
	Trans-vaginal	P	P				B+M	Note
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P				B+M	Note
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P				B+M	Note
	Cardiac Pediatric	N	N				B+M	Note
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P				B+M	Note
	Other (spec.)							

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

Additional Comments:
Note 1: Other includes Amplitude Doppler, combined B and Amplitude Doppler, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.
Note 2: Other includes Amplitude Doppler, combined B and Amplitude 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 K990806

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: C1 Ultrasound System
Transducer: C7-4 MHz IVT

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	N	N				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 Amplitude Doppler, combined B and Amplitude Doppler, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.
Note 2: Other includes Amplitude Doppler, combined B and Amplitude Doppler, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Prescription Use (Per 21 CFR 801.109)

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990806

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: C1 Ultrasound 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.)	Othe (Spec
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P				B+M	Note
	Abdominal	P	P				B+M	Note
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note
	Small Organ (breast, thyroid, testicles.)	P	P				B+M	Note
	Neonatal Cephalic	P	P				B+M	Note
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P				B+M	Note
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N				B+M	Note
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P				B+M	Note
	Other (spec.)							

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

Additional Comments:
Note 1: Other includes Amplitude Doppler, combined B and Amplitude Doppler, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.
Note 2: Other includes Amplitude Doppler, combined B and Amplitude Doppler, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Prescription Use (Per 21 CFR 801.109)

David A. Legerman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990806

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: C1 Ultrasound System
Transducer: C4-2 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.)	Othe (Spec
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P				B+M	Note
	Abdominal	P	P				B+M	Note
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note
	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
	Cardiac Pediatric	N	N				B+M	Note
	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 Amplitude Doppler, combined B and Amplitude Doppler, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K981505.
Note 2: Other includes Amplitude Doppler, combined B and Amplitude Doppler, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

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Prescription Use (Per 21 CFR 801.109)