K981605

MAY 8 1998

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:

Terrence J. Sweeney
Regulatory Affairs Consultant
SonoSight, Inc.
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, WA 98041-3003
(425) 487-7602

Date prepared: March 16, 1998

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

Cozumel Ultrasound System

Classification Names

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

3) Identification of the predicate or legally marketed device:

SonoSight, Inc. believes that Cozumel ultrasound system is substantially equivalent to the currently marketed ATL HDI® 5000 and Medison SA600 diagnostic ultrasound systems and the previously marketed ATL Ultramark® 4 system.

4) Device Description:

Cozumel 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 Color Power Angio (CPA) or in a combination of modes. Cozumel also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used for clinical diagnostic purposes. Cozumel has an output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

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

The Cozumel system is designed to accept scanheads of the following types and frequency:

frequency range:	2.0 - 7.0 MHz
scanhead 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 field of view, focal depth, image quality, gain etc.

Cozumel 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:

Cozumel intended uses as defined FDA guidance documents are:

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

Typical examinations performed using Cozumel 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.

6) Technological Characteristics:

This device operate 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 Color Power Angio) are the same as predicate devices identified in item 3. Scanhead 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

MAY 8 1998

SonoSight, Inc.
c/o Robert Mosenkis
Citech
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K981505
Cozumel Ultrasound System
Dated: April 23, 1998
Received: April 24, 1998
Regulatory class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Mosenkis:

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 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. You may, therefore, market the device, subject to the general controls provisions of the Act (Act). The general controls provisions of the Act include requirements for 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 Cozmel Ultrasound System, as described in your premarket notification:

Transducer Model Number

C7-4 MHz IVT
L7-3 MHz Linear Array
C4-2 MHz Curved 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 Robert Phillips, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Feigal

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Ultrasound Device Indications Statement

510(k) Number: TBD
Device Name: Cozumel Ultrasound System

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation (* includes simultaneous B-mode)

Clinical Applications	A	B	M*	PWD	CWD	Color Doppler	Amplitude Doppler*	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		N	N				N			Note 1
Fetal		N	N				N			Note 1
Abdominal		N	N				N			Note 1
Intraoperative: (Abdominal organs and vascular)		N	N							
Intraoperative Neurological							N			Note 1
Pediatric		N	N				N			Note 1
Small Organ (breast, thyroid, testicle).		N	N				N			
Neonatal Cephalic		N	N							
Adult Cephalic							N			
Cardiac		N	N							
Transesophageal										
Transrectal		N	N				N			Note 1
Transvaginal										
Transurethral										
Intravascular		N	N				N			
Peripheral vessel										
Laparoscopic		N	N				N			
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

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

Note 1: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legorn

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981505

Ultrasound Device Indications Statement

510(k) Number: TBD
Device Name: Cozumel Ultrasound System
Transducer: C7-4 MHz IVT

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation (* includes simultaneous B-mode)

Clinical Applications	A	B	M*	PWD	CWD	Color Doppler	Amplitude Doppler*	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal - OB/GYN		N	N				N			Note 1
Abdominal										
Intraoperative: **(Specify)**										
Intraoperative Neurological										
Pediatric										
Small Organ **(Specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		N	N				N			Note 1
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

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

Note 1: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Hymm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981505

Ultrasound Device Indications Statement

510(k) Number: TBD
Device Name: Cozumel Ultrasound System
Transducer: L7-4 MHz Linear Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation (* includes simultaneous B-mode)

Clinical Applications	A	B	M*	PWD	CWD	Color Doppler	Amplitude Doppler*	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal - OB/GYN										
Abdominal		N	N				N			Note 1
Intraoperative: (Abdominal organs and vascular)		N	N				N			Note 1
Intraoperative Neurological										
Pediatric		N	N				N			
Small Organ (breast, thyroid,testicle)		N	N				N			Note 1
Neonatal Cephalic		N	N				N			
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N	N				N			
Laparoscopic										
Musculo-skeletal Conventional		N	N				N			
Musculo-skeletal Superficial										
Other (Specify)										

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

Note 1: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981505

Ultrasound Device Indications Statement

510(k) Number: TBD
Device Name: Cozumel Ultrasound System
Transducer: C4-2 MHz Curved Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation (* includes simultaneous B-mode)

Clinical Applications	A	B	M*	PWD	CWD	Color Doppler	Amplitude Doppler*	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal - OB/GYN		N	N				N			Note 1
Abdominal		N	N				N			Note 1
Intraoperative: (Abdominal organs, vascular)		N	N				N			
Intraoperative Neurological										
Pediatric		N	N				N			Note 1
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N				N			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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