5. 510(K) SUMMARY

OCT 1 4 2008

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
Date Prepared: August 10, 2008

510(k) number: K082543

Applicant Information:
SonoCiné, Inc.

5475 Reno Corporate Drive
Reno, NV 89511

Contact Person
Robert J. Chin, Ph.D.
Regulatory Consultant
(650) 593-5225

Device Information:

Trade Name:	SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100
Classification:	Class II
Classification Name:	*System, imaging, pulsed echo, ultrasonic*

Physical Description: SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100 consisting of SonoCiné Image Acquisition Station Model 100 and SonoCiné Image Reading Station Model 100.

The SonoCiné Image Acquisition Station Model 100 is a probe guiding adjunct to ultrasound systems which have been previously cleared by FDA. The SonoCiné Image Acquisition Station Model 100 uses a servo motor guided arm to control the speed and direction of the ultrasound transducer during breast scanning examinations. In addition, the SonoCiné Image Acquisition Station Model 100 contains a computer which interfaces to the video output of ultrasound system to record and store, electronically, the ultrasound images at regular time intervals.

The SonoCiné Image Reading Station Model 100 is a software product intended to operate on a personal computer with minimum performance configurations. The SonoCiné Image Reading Station Model 100 is a software product intended to allow after-the-fact review of the images obtained and stored by the SonoCiné Image Acquisition Station Model 100.

Intended Use: The SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100 is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of the patient's breast when used with an automatic scanning linear array transducer. This device is not intended to be used as a replacement for screening mammography.

Equivalent Device: The subject device is substantially equivalent in intended use and/or method of operation to the following devices which were previously cleared by FDA

The Orison Embrace System (Orison, Corp; Johnson City, TN) (K070477) and

The ABUS Diagnostic Ultrasound System (U-Systems, Inc; San Jose, CA) (K052355)

SonoCiné, Inc. claims that the SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100 is substantially equivalent to the devices previously cleared by FDA in K070477 and K052355. SonoCiné, Inc. claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical and operational specifications compared to the predicate devices.

Test Results: DESIGN VERIFICATION TEST: The design specifications of the SonoCiné Adjunctive Breast Ultrasound System (ABU) Station Model 100 were tested and verified to confirm that the product performance fulfilled those specification requirements.

DESIGN VALIDATION TESTS:

NON-CLINICAL TESTING: System Validation Testing was performed on a breast phantom with 10 (ten) masses randomly positioned. All 10 of the masses were successfully identified.)

The results indicate that the SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100 is substantially equivalent to the listed predicate devices.

Summary:
Based on the intended use, product, performance and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 4 2008

SonoCine, Inc.
% Mr. Morten S. Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
455 E. Trimble Rd.
SAN JOSE CA 35131

Re: K082543
Trade/Device Name: SonoCiné Adjunctive Breast Ultrasound System (AUB) Model 100
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed imaging system
Regulatory Class: II
Product Code: IYO
Dated: September 26, 2008
Received: September 29, 2008

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

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 letter will allow you to begin marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082543

Device Name: SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100

Indications for Use: The SonoCiné Adjunctive Breast Ultrasound System (ABU) Model 100 is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of the patient's breast when used with an automatic scanning linear array transducer. This device is not intended to be used as a replacement for screening mammography.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE).

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082543

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: Small Organ - Breast, B-Mode

The SonoCine Adjunctive Breast Ultrasound System is intended for B-Mode ultrasonic imaging of a patient's breast.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082543