K040652

MAY 17 2004

Section 3: *510(k) Summary*

This summary of safety and effectiveness has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR807.92(a).

Submitter Information

Mobilsonic Inc.
560 Parrott Street
San Jose, CA 95112
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Fax: (408) 271-0195
Contact Person: Bao Le
Date: February 18, 2004

Device Information

Trade Name: VUE 100 Ultrasound Imaging System
Common Name: Ultrasound Imaging System
Classification Name: Ultrasonic Pulsed Echo Imaging System (FR# 892.1560)
Classification Number: 90-IYO

Predicate Device

Company	*Device Name*	*510(k) Number*
Pie Medical	50S Tringa	K020112

Additional substantial equivalence information is provided in the following Comparison Chart for Substantial Equivalence.

Device Description

The VUE 100 is a portable ultrasound system. It is used to acquire and display real time 2D ultrasound images. Currently the system supports two mechanical sector probes, 4S2 (3MHz) and 6S4 (5MHz).

Intended Use(s)

The VUE 100 ultrasound system is used by or under the direction of a certified physician to perform general non-invasive diagnostic ultrasound imaging studies, to include: abdominal, peripheral vascular, fetal, and small organ applications.

Comparison Chart for Substantial Equivalence

General Characteristics	Mobilsonic VUE 100 *(This Submission)*	Pie Medical 50S Tringa *(K020112)*
Intended use		
Fetal	Yes	Yes
Abdominal	Yes	Yes
Pediatric	Yes	Yes
Small Organ	Yes	Yes
Peripheral Vascular	Yes	Yes
Cardiac	No	Yes
Neonatal Cephalic	No	No
Adult Cephalic	No	No
Transesophageal	No	No
Transrectal	No	No
Transvaginal	No	No
Transurethral	No	No
Intravascular	No	No
Musculoskeletal	No	No
Transducer type		
Mechanical Sector	Yes	Yes
Linear	No	No
Convex	No	No
2D Freq MHZ	3.0/5.0	3.5/5.0/7.5
CFM/Doppler Freq MHZ	N/A	N/A
Biopsy Guidance	No	No
Display type	LCD	LCD
Imaging modes	2D	2D/M-Mode
Monitor size (inches)	5.6	5.4
Digital archival capabilities	Yes	Yes
VCR	Yes	Yes
M&A capabilities	Fetal & Abdominal	Cardiac, Fetal & Abdominal
Safety		
Electrical safety	UL 2601	EN60601-1
Ultrasound safety	Track 1	Track 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

Mr. Bao Le
Regulatory Engineer
Mobilsonic, Inc.
560 Parrott Street
SAN JOSE CA 95112

Re: K040652
Trade Name: VUE 100 Ultrasound 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 IYO and ITX
Dated: April 22, 2004
Received: April 26, 2004

Dear Mr. Le:

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 VUE 100 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

4S2 Mechanical Sector Probe (3MHz)
6S4 Mechanical Sector Probe (5MHz)

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:

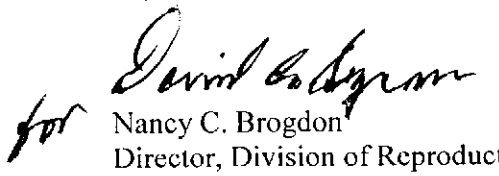
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 (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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 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)

Diagnostic Ultrasound Indications for Use Form

Device Name: VUE 100 Ultrasound Imaging System
Intended Use: Diagnostic ultrasound imaging 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		N								
Abdominal		N								
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA
Additional Comments: Small organs include Thyroid, Breast, and Testicles.

(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 K041058

Diagnostic Ultrasound Indications for Use Form

Device Name: 4S2 Mechanical Sector Probe (3MHz)
Intended Use: Diagnostic ultrasound imaging 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		N								
Abdominal		N								
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA
Additional Comments: Small organs include Thyroid, Breast, and Testicles.

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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 K042665

Diagnostic Ultrasound Indications for Use Form

Device Name: 6S4 Mechanical Sector Probe (5MHz)
Intended Use: Diagnostic ultrasound imaging 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		N								
Abdominal		N								
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA
Additional Comments: Small organs include Thyroid, Breast, and Testicles.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lehrman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K07-1065