DEC 28 1999

K991441

SAFETY AND EFFECTIVENESS SUMMARY
Medasonics Incorporated
Cadence Doppler Ultrasound System

Name and address of Device Manufacturer submitting 510(k) Notification:

Medasonics Incorporated
38875 Cherry Street
Newark, California 94560

Regulatory Correspondent of Device Manufacturer:

Don Killam
Medasonics Incorporated
38875 Cherry Street
Newark, California 94560
Phone:510-494-1097

Date Summary was prepared:

April 23,1999

Name of the device:

Cadence Doppler Ultrasound System

Classification:

Monitor, Fetal Doppler Ultrasound Class II per 21CFR 884.2660
Monitor, Blood Flow Class II per 21CFR 884.2660

Indications for Use:

Using the 2.3 MHz probe:

Early detection of fetal life, detection of multiple pregnancies, fetal screening from early gestation through delivery, general indication of fetal well being.

Using the 5.1 Mhz probe:

Detection of blood flow in the peripheral vascular system of the body

Description of the device:

The Cadence system utilizes the well understood principle of Doppler shift of an ultrasound signal to detect the flow of blood within the body. The system consists of a base unit that contains the speaker, the volume and on/off controls. The base unit is connected to a 2.3 MHz CW transducer, or to a 5.1 MHz CW transducer via a coil cord. The Cadence operates from a single 9 volt battery.

Substantial Equivalence:

The Medasonics Cadence Doppler Ultrasound System is substantially equivalent to the following legally marketed devices:

Medasonics Incorporated
38875 Cherry Street
Newark, California
Models FP3B and BF4B, Preamendment devices

Huntleigh Technologies
Manalapan, New Jersey
Dopplex II Pocket Doppler
K930200, Cleared 6/24/94

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 1999

Medasonics, Inc.
C/o William E. McKay
President
RCMDI
9712 S. Altamont Drive
Sandy, Utah 84092

Re: K991441
Cadence Doppler Ultrasound System
Dated: December 6, 1999
Received: December 7, 1999
Regulatory Class: II
21 CFR 884.2660/Procode: 85 KNG

Dear Mr. McKay:

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 Cadence Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

P338 (2 MHz Fetal)
P339 (5 MHz Vascular)

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,

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

Enclosure

Diagnostic Ultrasound Indications for Use Form

System with Fetal Probe - Model T334 or System with Vascular Probe - Model T335

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					N					
Abdominal										
Intraoperative (specify)										
Intraoperative										
Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The system consists of a 5.1 MHz unfocused CW transducer for peripheral vascular applications, and a 2.3 MHz unfocused CW transducer for fetal heart rate detection. Only one transducer can be used with the speaker unit at a time

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991441

Diagnostic Ultrasound Indications for Use Form
2 MHz Fetal Probe - Model P338 (probe only)

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					N					
Abdominal										
Intraoperative (specify)										
Intraoperative										
Neurological										
Pediatric										
Small Organ (specify)										
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: The above is a 2.3 MHz unfocused CW transducer for fetal heart rate detection

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991441

Diagnostic Ultrasound Indications for Use Form
5 MHz Vascular Probe - Model P339 (probe only)

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)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The above is a 5.1 MHz unfocused CW transducer for peripheral vascular applications

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991441