



SEP 29 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert W. Titkemeyer
Director Quality Assurance and Regulatory Affairs
Volumetrics Medical Imaging, Inc.
700 West Main Street
Durham, NC 27701

Re: K992378
Model 1.0 Diagnostic Ultrasound System with Contrast Harmonic Imaging
Regulatory Class: II
21CFR892.1550/90 IYN
21CFR892.1560/90 IYO
21CFR892.1570/90 ITX
Dated: September 9, 1999
Received: September 10, 1999

Dear Mr. Titkemeyer

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 Model 1.0, as described in your premarket notification:

Transducer Model Number

214U

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:

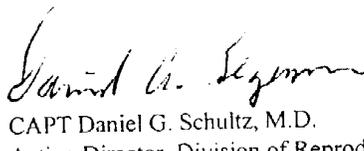
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Paul M. Gammell, 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

Enclosure(s)

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K 992378

THIS PAGE CONTAINS INFORMATION CONFIDENTIAL TO:
VOLUMETRICS Medical Imaging Inc.

Diagnostic Ultrasound Indications for Use Form

Device Name: Model 1.0
Intended Use: Diagnostic Ultrasound

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		(1)	N
Abdominal		P	P	P		P	P		(1)	N
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		(1)	N
Small Organ (specify)		P	P	P		P	P		(1)	N
Neonatal Cephalic		P	P	P		P	P		(1)	N
Adult Cephalic										
Cardiac		P	P	P		P	P		(1)	N
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		(1)	N
Laparoscope										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

- (1) Single B mode or multi-B mode will operate in single combination with M-Mode, or PWD, or color Doppler, or amplitude Doppler (see 4.4.1.1 Transducer Operation table I for a complete listing of combinations).

Small organ (specify) - Testes, adult female breast, and thyroid.

Model 1.0 was previously cleared under 510(k) K963863, K952551, and K982498

Addition of a the following modes:

- 1. Contrast Harmonics mode to optimize the image when using contrast media

Contrast Harmonic modes will utilize second harmonics.

David C. Nguyen
(Division Sign Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K992378

Prescription Use ✓
(Per 21 CFR 801.109)

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