

AUG 1 2000

K990517

510(k) SUMMARY

- A. Manufacturer:** DMS - DIAGNOSTIC MEDICAL SYSTEMS
Parc de la Mediterranee
District de Montpellier
34470 Perols
France
- Submitted By:** Ferguson Medical
Consultant to DMS
- B. Contact Information:** Phone: +33.467.50.49.00
FAX: +33.467.50.49.09
- C. Classification Name:** System, Imaging, Pulsed Doppler,
Ultrasonic
- Common/usual Name:** Transcranial/Vascular Doppler
- Proprietary Name:** Explorer CVS Transcranial and
Peripheral Vascular Doppler
- D. Classification Number:** 90IYN
- E. Substantial Equivalence:** Rimed Limited Intra-View
Bilateral Transcranial Doppler Device (K974588),
Medasonics, Inc. Neuroguard Transcranial Doppler
Ultrasound System (K962796), Medasonics, Inc.
Cerebrovascular Diagnostic System; CDS (K914862),
Biosound, Inc. Phase 2 Transcranial Probe
(K894163), Acuson Corp. Acuson S228 Transducer For
Transcranial Doppler (K894163), Medasonics, Inc.
Transpect Transcranial Doppler (K872292), and
others.
- F. Device Description:** The Explorer CVS device is a

diagnostic ultrasonic Doppler.

- G. **Intended Use:** The Explorer CVS Doppler device is intended to be used to produce images of intracranial and peripheral vasculature to be analysed by trained medical personnel in the assessment and diagnosis of vascular status and disorders.
- H. **Technological Characteristics:** The Explorer CVS Doppler device utilizes multiple frequencies of transducers to provide high resolution images.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Diagnostic Medical Systems, Inc.
c/o Frank Ferguson
Official Correspondent
Ferguson Medical
P.O. Box 12038
LaJolla, CA 92039

Re: K990517
Explorer CVS Transcranial and Peripheral Vascular Doppler
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Dated: May 15, 2000
Received: May 30, 2000

Dear Mr. Ferguson:

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 Explorer CVS Transcranial and Peripheral Vascular Doppler, as described in your premarket notification:

Transducer Model Number

2 MHz PW-Doppler
4 MHz CW/PW-Doppler
8 MHz CW/PW-Doppler

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 Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David G. Schultz
Daniel G. Schultz, M.D.
Captain, USPHS

Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

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

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

Additional Comments: _____

(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)

David A. Lynn
 (Division Sign-Off)
 F-3 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 310(a) Number K990517

Diagnostic Ultrasound Indications for Use Form

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

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K990517

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 Concurrence of CDH, Office of Device Evaluation (ODE)

David A. Segerson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K990517

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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David A. Reynolds
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K990517

Prescription Use (Per 21 CFR 801.109)