



OCT 17 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EP MedSystems
c/o Mr. John J. Talarico
VP of QA/Regulatory Affairs
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NY 08091

Re: K031066
Trade Name: ViewMate® System
Regulation Number: 21 CFR 892.1550, 892.1560, and 892.1570
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer
Regulatory Class: Class II (two)
Product Code: IYN, IYO, and ITX
Dated: July 28, 2003
Received: July 29, 2003

Dear Mr. Talarico:

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 ViewMate® System, as described in your premarket notification:

Transducer Model Number VF-PA9F64E2D

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.

Page 2 - Mr. John J. Talarico

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>".

Page 3 - Mr. John J. Talarico

If you have any questions regarding the content of this letter, please contact Sharon Lappalainen at (301) 443-8913.

Sincerely yours,



for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form

ViewMate (Console) Ultrasound Imaging System (Model #VM-01)

Intended Use: The ViewMate® System is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity	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	-	-	-	-	-	-	-	-	-	-
Laparoscopic	-	-	-	-	-	-	-	-	-	-
Musculo-skeletal Conventional	-	-	-	-	-	-	-	-	-	-
Musculo-skeletal Superficial	-	-	-	-	-	-	-	-	-	-
Other- Intracardiac	-	N	N	N	-	N	-	-	-	-

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)

Maureen May
 (Division Sign-Off)
 Division of Cardiovascular Devices

File 3283a-ViewMate

510(k) Number 15031066

000120

Diagnostic Ultrasound Indications for Use Form

ViewFlex™ Ultrasound Catheter (Model # VF-PA9F64E2D)

Intended Use: The ViewMate® System is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.

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

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)

Megan C. Mar
 (Division Sign-Off)

Division of Cardiovascular Devices file 3283a-ViewFlexCatheter

510(k) Number K031066

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