510(k) Summary K071028

Summary preparation date: 04/09/07

MAY - 1 2007

1.0 Device Trade Name

Device Trade Name	Device Classification
ViewMate® System	II

2.0 Establishment Address and Registration

EP MedSystems Inc.
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293 USA

Larry Picciano
Telephone: 856-753-8533, x221
Fax: 856-753-8544
E-mail: lpicciano@epmedsystems.com

US Food and Drug Administration Establishment Registration No.: 2248049

3.0 Device Classification

Classification	Product Code	Device Classification Name	Regulation Number	Classification Number	Performance Standard(s)
Primary	IYN	System, Imaging, Pulsed Doppler, Ultrasonic	892.1550	II	None
Subsequent	ITX	Transducer, Ultrasonic	892.1570	II	None
Subsequent	IYO	System, Imaging, Pulsed Echo, Ultrasonic	892.1560	II	None

4.0 *Predicate Devices / Technology

Product Description	510 (k) No.	Date
ViewMate® System	031066	10/17/03

* This application describes a modification to the ViewMate® System's catheter called ViewFlex™.

5.0 Labeling and Intended Use

The following labeling is contained within **Appendix 4**.

5.1 Proposed Product Labeling
5.2 Proposed Marketing Literature
5.3 Proposed Instructions for Use
5.4 **Intended Use**

The ViewMate® System is intended to be used to visualize cardiac structures and blood flow within the heart.

6.0 Indications for Use

Note: A copy of the original Diagnostic Ultrasound Indications for Use Form, which is not affected by this notification, is provided in **Appendix 6-18**.

Indications for Use Statement

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

7.0 Device Description

7.1 **Background of the ViewMate® System with the ViewFlex™ Catheter:** The ViewMate® cardiac ultrasound imaging console in combination with the ViewFlex™ ultrasound catheter was cleared for US marketing on October 17, 2003 (K031066). As of this writing, there have been no significant modifications to any element of the ViewMate® System; therefore, there have been no additional notifications to FDA (the agency). On August 18, 2006 EPMedSystems' ViewFlex™ catheter was cleared for US marketing with Philips Medical Systems' (PMS) HD-11 Ultrasound System (K062247). There have been no other US filings regarding the ViewMate® console or the ViewFlex™ catheter.

7.2 **Product Numbering Change Notice:** In an effort to make it easier for customers to order catheters and to clarify product identification, EPMedSystems, Inc., (the company) is modifying the way it refers to the ViewFlex™ catheter. This is strictly a nomenclature change. The company currently uses VF-PA9F64E2D to represent the ViewFlex™ catheter model number, the transducer (model) number, the product code and the part number. Moving forward EPMedSystems will refer to the ultrasound product as follows in **Table 1**.

Number Description	Former Number	New Number
Catheter Model Number[1]	VF-PA9F64E2D	VF-01
Ultrasonic *Transducer Model* Number[2]	VF-PA9F64E2D	204
Catheter Part Number	VF-PA9F64E2D	VF-PA9F64E2DW[3,4]
Product Code	VF-PA9F64E2D	VF-PA9F64E2DW[3,4]

Table 1: Product Code Modification

Notes: (1) "Catheter" and "Transducer" are not used synonymously. (2) "Transducer" model refers to the active ultrasonic element commonly referred to as a piezoelectric crystal contained within the catheter - there is no change to this component, it is the same as that cleared under K032066. (3) "W" indicates wire added as part of the redesign; this differentiates the product by design. (4) Units of former design will also be sold during a phase in period as VF-PA9F64E2D.

7.3 **General Description of the ViewMate® System with the ViewFlex™ Catheter:** The ViewMate® cardiac ultrasound imaging system (K031066) is intended to be used to visualize cardiac structures and blood flow within the heart; it is indicated for use in adult and adolescent pediatric patients. The ViewMate® system's imaging capability can be used by physicians to: assess overall cardiac performance and size, determine the presence and location of electrophysiology catheters, aid in electrophysiology procedures, and visualize blood flow through cardiac arteries. Cardiac electrophysiology (EP) procedures are complex diagnostic tests that enable physicians to look at electrical signals from within the heart to determine if an abnormality (arrhythmia) exists. Use of the ViewMate® system in EP studies offers significant advantages in that it enables physicians to locate and accurately place EP catheters and to identify physiologic and blood flow anomalies.

7.4 The ViewMate® System is a portable, computerized, ultrasound imaging system used to display and capture intracardiac ultrasound images. The ViewMate® System illustrated in **Figure 1** is comprised of three components: ViewMate® console, patient isolation module and the ViewFlex™ ultrasound catheter.

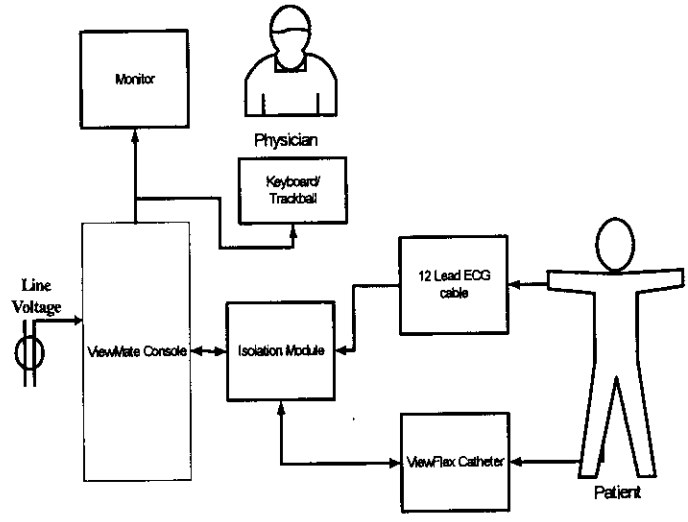


Figure 1: ViewMate® System

7.5 The ViewMate® console comprises a personal computer (PC), ultrasound imaging beam former and a digital frame grabber with storage. The system software is used to control imaging modes, image quality, image acquisition, storage, and retrieval of patient records (i.e., images, ECG, and notes). The system software enables multiple imaging modes: two dimensional (B mode and color Doppler) and time-motion mode (spectral Doppler/pulse wave Doppler and M Mode). Additional software functionality includes zoom, labeling, image storage, retrieval and review. ViewMate® may be used in interventional cardiology, specifically in the interventional EP laboratory.

7.6 **Description of ViewFlex™ Catheter:** ViewMate® employs an ultrasound catheter called ViewFlex™ inserted into the heart though intravascular access. The ViewFlex™ catheter, illustrated in **Figure 2**, is a single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. ViewFlex™ mechanical properties are as follows: The catheter shaft is 9 French, approximately 110 cm long, constructed of radio-opaque tubing. The catheter offers bi-directional steerability that can easily be manipulated with one hand. A minimum of a 10 French introducer is recommended for use with this catheter for insertion into the femoral or jugular veins. ViewFlex™ imaging properties are as follows: The catheter consists of a 64-element linear phased array, wideband transducer with an imaging frequency range of 4.5 MHz to 8.5 MHz, 86° viewing angle, and user-selectable magnification.

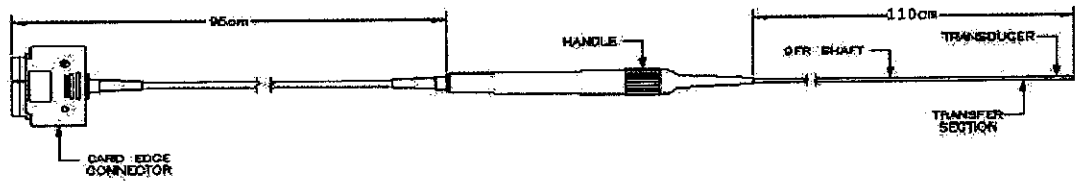


Figure 2: ViewFlex™ Catheter

7.7 **Change Scope and Description:** The intent of this submission is to provide premarket notification of modifications to the mechanical design of the ViewFlex™ catheter; intended use and indications for use are not affected. No changes have been made to the ultrasound or electronics design of the catheter; the ultrasound transducer and its performance is not affected by the proposed changes. Similarly, no changes have been made to the ViewMate® console. The modification is intended to improve production yield and throughput, to improve curvature distribution and bond strength of the transfer (bending) section, and to stabilize the steering (deflection) range. EPMedSystems employed design controls, verification and validation in the design change process. The changes are explained in Engineering Change Request – Change Description (ECRCD) 004 located in **Appendix 6** and in the supporting documentation provided. The following table summarizes the changes.

ECR 004 Change #	Change Classification	Change Description
1	Finished product, external material change	Replace PEBAX® with silicone in distal transfer section
1	Finished product, internal material change	Change transfer section adhesive to silicone adhesive Med1511
1	Production process, material change	Add silicone expander OS-10 for assembly with silicone
1	Finished product, internal material change	Addition of Nitinol round wire (0.018 in.) in main shaft to maintain length and avoid kinking
1	Production process change	Modify manufacturing steps to add and secure Nitinol wire; included is disassembly and assembly of catheters
2	Finished product, internal material change	Addition of Nitinol flat wire (0.005 x 0.020 in.) in distal bending section to maintain curvature after many deflections
2	Production process change	Modify manufacturing steps to add and secure Nitinol wire; included is disassembly and assembly of catheters

Table 2:ViewFlex™ Catheter Change Summary

End of document

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2007

EPMedSystems
c/o Larry Picciano
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293

Re: K071028
Trade/Device Name: ViewMate® System
Regulation Numbers: 21 CFR 892.1550; 21 CFR 892.1560; and, 21 CFR 892.1570
Regulation Names: Ultrasonic pulsed doppler imaging system; Ultrasonic pulsed echo imaging system; and, Diagnostic ultrasonic transducer;
Regulatory Class: Class II
Product Codes: IYN; IYO; and, ITX
Dated: April 10, 2007
Received: April 11, 2007

Dear Mr. Picciano:

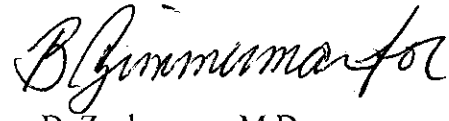
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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.

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 letter will allow you to begin marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

EPMedSystems

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Tel: (856)753-8533
Fax: (856)753-8544

K071028

Indications for Use

Device Name: ViewMate® System (K031066)

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

Prescription Use ____√____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Gunneman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031066

File: VF-01 Sp 510(k) Indcations for Use 040907

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