MAR 2 4 2011

5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY of Safety and Effectiveness

1. General Information

Submitter's Name: Address:	Memtec Corporation 68 Stiles Road Unit D Salem, NH 03079
Telephone:	603 893-8080 Ext. 204
Contact Person:	Dennis Garboski
Trade Name:	MobileECG System
Common Name:	Electrocardiograph (per 21 CFR 870.2340)
Class:	II

2. Predicated Devices

The legally marketed predicated devices to which equivalence is being claimed is:

Micromedical, Inc.	Biolog 3000	K974351
Datrix, Inc.	Cardio WiFi and	K053083
	CardioServer	K052883
QRS Diagnostic	EKGCARD SYSTEM	K030535
	Cardioview 32	K083749

3. Description of Device

The MobileECG System is an electrocardiograph consisting of Model 950-12LR HHC module and CardioVu interpretation software.

The Model 950-12LR HHC module is a small, light weight, single battery, wireless module designed to transmit 12Lead electrical heart activity of a patient to a computer. This module will transmit a patient's ECG wirelessly to a laptop, netbook, tablet, or desktop computer containing the CardioVu interpretation software from up to 100 feet away.

Elimination of the cable reduces a source of artifact resulting in high-quality ECG tracings. Wireless dedicated and secure communication links the Model 950-12LR HHC module to CardioVu interpretation software.

The CardioVu software receives, displays, and stores the patients ECG data wirelessly on a laptop, netbook, tablet, or desktop computer in "real time". The software also has the ability to analyze the data using ECG algorithms for review by a physician or other qualified medical professional as an advisory basis only in conjunction with the physician's knowledge of ECG. The wireless feature allows the patient not to be tethered to the computer or a bulky box thus reducing motion artifacts caused by movement of the connecting cables and providing comfort to the patient.

4. Indications For Use

The MobileECG System is intended to provide an interpretation of the resting 12 lead ECG in all situations, whether in a hospital or primary care setting. It is capable of diagnosing all commonly recognized ECG abnormalities such as myocardial infarction (MI), including acute MI, ventricular hypertrophy, abnormal ST-T changes and common abnormalities of rhythm.

The MobileECG System is intended for use in adults and children of any age from birth upwards.

The MobileECG System's interpretation software is not intended as sole means of diagnosis and is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

5. Non-clinical Tests Used in Determination of Substantial Equivalence

Non-clinical tests were performed to compare the MobileECG System to the predicated devices.

The following applicable standards were used to compare the MobileECG System to the predicated devices: ANSI/AAMI EC11, IEC 60601-1-2, IEC 60601-1-1, IEC 60601-1-4, 21 CFR 898, ANSI/AAMI EC53, AND FCC Part 15.247.

6. Conclusions From Non-clinical Testing

After comparing predicated devices to Memtec's MobileECG System, results show that with the intended use, the Model 950-12LR HHC module with CardioVu interpretation software is equivalent in safety and effectiveness. Therefore Memtec supports a claim of substantial equivalence for the MobileECG System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Memtec Corporation
c/o Mr. Dennis Garboski
President
68 Stiles Road Unit D
Salem, NH 03079

MAR 24 2011

Re: K103427
Trade/Device Name: MobileECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 14, 2011
Received: March 16, 2011

Dear Mr. Garboski:

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.

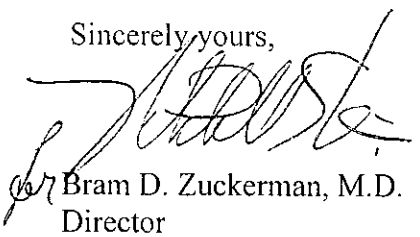
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number(if known) K103427

Device Name: MobileECG System

Indications for Use

The MobileECG System is intended to provide an analysis of rhythm and of detailed morphology of complex cardiac complexes for the resting 12 lead ECG in all situations, whether in a hospital or primary care setting. It is adjunct to the diagnosis of all commonly recognized ECG abnormalities such as myocardial infarction (MI), including acute MI, ventricular hypertrophy, abnormal ST-T changes and common abnormalities of rhythm.

The MobileECG System is intended for use in adults and children of any age from birth upwards.

Prescription Use____X____ and/or Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103427