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MAR 10 2009

510(k) Summary of Safety and Effectiveness

Date:12/09/08

Submitter:
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Device Name:
Trade Name: CardioView 32 Review Module
Common Name: ECG Interpretive Software
Classification Name: System, ECG Analysis
Classification: Listed as Class III (510(k)) Considered Unclassified Pre-amendment
Panel Code: LOS
Regulation Number: N/A

Identification of Legally Marketed (Unmodified) Device (Predicate Device):

Name of Predicate	Manufacturer	Use	510K)	Date Cleared
CardioView 3000	MicroMedical, Inc	ECG Analysis	K974352	9/8/1998

Device Description:

Indications for Use

CardioView32 Review Module is a Window's based program intended to be called from a host application/database in a Hospital or in a Physician's Office. CardioView32 Review Module receives, analyzes, displays, stores and prints ECG *.scp files generated from a standard 12-lead ECG recording. CardioView 32 Review Module provides interpretive statements for which the physician renders his/her own medical opinion.

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- Patient Population: Male/Female, Adults
- Environment of Use: Hospital and Clinic
- Prescription Device by a Physician

Technological Comparison to (Unmodified) Predicate Device:

The following summary table of comparisons compares the Modified CardioView 32 Review Module Device to the Previously Cleared CardioView 3000 Device.

#	Area	Modified Device (CardioView 32 Review Module)	Previously Cleared Device CardioView 3000	Same	Different
Indications for Use					
1	Patient Population	Male/Female Adult	Male/Female Adult	X	
2	Environment of Use	Hospital, Clinic, Home Use	Hospital, Clinic, Home Use	X	
Fundamental Scientific Technology					
3	SCP Files	• Receipt of SCP File from Software • Re-analyze/Interpret • Store • Display • Print	• Acquires/Generates SCP File from Hardware • Receipt from Software • Analyze/Interpret • Stores • Display • Print		X
4	Interpretation Algorithm	Cardionics Algorithm	Cardionics Algorithm	X	
5	Device Components	• Computer with Windows OS • Software	• Computer with Windows OS • Software	X	
Contraindications					
6	Contraindications	No contraindications	No contraindications	X	
Sterility/Expiration Dating					
7	N/A	N/A	N/A	X	
Energy Type					
8	Based upon computer utilized	N/A	N/A	X	
Environmental Specifications					
9	Based upon computer utilized	N/A	N/A	X	
Performance Standards					
10	AAMI EC11-1991	Meets	Meets	X	

#	Area	Modified Device (CardioView 32 Review Module)	Previously Cleared Device CardioView 3000	Same	Different
		AAMI EC11-1991 Requirements	AAMI EC11-1991 Requirements		
Algorithms					
11	ECG Algorithm Executable	Updated to include Japanese Translation	Japanese Translation not available		X
12	Cardionics ECG Algorithm DLL (MMISYS32.dll)	MMISYS32.dll Update to eliminate need for user to have "write permission" to C:\ in order to analyze an ECG.	User must have "Write" permission to C:\ in order to analyze an ECG		X
13		Changed writing of the temp file to work with Vista. OS'	ECG Analysis was not supported on Vista OS'		X
14		Recompiled MMISYS32.dll to not include a diagnostic log file.	MMISYS32.dll includes diagnostic log file		X
15		Added Interpretation statement numbers to correlate with Physician's Guide	Interpretation codes listed in Physician's guide not presented to user in software		X
Software					
16	Micro Processor	32 Bit Application	16 Bit Application		X
17	Hosting Program (shell around application)	C++ DLL written in VS2005(ECG.dll)	Based on VB3 framework		X
18	Review Window	Cardioview32 has three different color choices in review screen	One color scheme		X
19	Review Window	Lead order can be changed in Cardioview32	Lead order cannot be changed		X
20	Interpretive Module	SCP file is read through MMISCP.dll, and then the results are sent to MMISYS32.dll	Application wrapper (Analysis.exe) used to read SCP file, and send the results to MMISYS32.dll		X
21	Review Window	Rhythm strip can be moved to the bottom of the screen in 12 lead view	Rhythm strip always at the top.		X
22	Review Window	Numeric values for	Only text is shown for		X

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#	Area	Modified Device (CardioView 32 Review Module)	Previously Cleared Device CardioView 3000	Same	Different
		the interpretation codes are available.	interpretation codes.		
23	Review Window	Review window is launched from a standalone application.	Review window is launched within Office Medic		X
24	Review Window	Print preview is available	No print preview		X
25	Review Window	Interpretation/measurements can be viewed on the main review screen	Interpretation and measurements are on a new window.		X
26	Review Window	Patient details can be viewed on the main review screen	Patient details come up on a new window.		X
27	Review Window	Menus and toolbars have a different order.			X
28	Review Window	Print to file is available inside of the review window	Print to file is initiated from Shell Application		X
29	Review Window	Strips view can show 2,3, 6, 9, and 12 leads at a time	Strips view only shows 3 leads at a time.		X
31	Review Window	X axis and Y axis controlled by radio buttons on the right	X axis and Y axis are controlled by buttons below the traces.		X
31	Review Window	The icon in the upper left is a heart	The icon is a picture of a computer with an ECG trace.		X
32	ECG Trace viewing module	This is written in Microsoft Visual C++ using microsoft libraries(MMIECG32.ocx)	This is written using a 1995 compiler, Borland C.(MMIECG200.VBX)		X
33	SCP File reading and writing module	This is written in Microsoft Visual C++ using microsoft libraries(MMISCP32.ocx)	This is written using a 1995 compiler, Borland C.(MMSCP200.dll)		X
34	Languages	Strings are only in English	Strings are translated into French, German, Italian		X

#	Area	Modified Device (CardioView 32 Review Module)	Previously Cleared Device CardioView 3000	Same	Different
35	Printed reports	Grid is printed in red	Grid is only available in black.		X
36	Printed reports	PDF reports can have minor grids showing	16 bit software does not allow for minor grids in PDF reports due to quality problems with 16 bit software		X
37	Printed reports	This is written in Microsoft Visual C++ using microsoft libraries(MMIPRN32 .dll)	Printed reports part of MMIECG200.vbx		X

Summary of Performance Testing:
The modified CardioView 32 Review Module has been tested or found otherwise to comply with applicable sections of the following standards:

- AAMI EC11-1991 (R/2007)– Diagnostic Electrocardiographic Devices

Conclusions:
The results of the tests discussed above, indicate that the modified QRS Diagnostic CardioView 32 Review Module is as safe, as effective, and performs as well as or better than the non-modified device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2009

Primary Care Physician Platform, LLC
dba QRS Diagnostic, LLC
c/o Ms. Amy Ptak
Operations Manager
14755 27th Avenue North
Plymouth, MN 55447

Re: K083749
Trade Name: Cardioview32 Review Module
Regulation Number: Unclassified
Regulation Name: ECG Analysis System
Product Code: LOS
Dated: February 3, 2009
Received: February 13, 2009

Dear Ms. Ptak:

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 (301) 594-4646. 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" (21CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

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Indications for Use

510(k) Number (if known): *To be determined*

Device Name: CardioVew 32 Review Module

Indications for Use:

CardioView32 Review Module is a Window's based program intended to be called from a host application/database in a hospital or in a Physician's Office. CardioView32 Review Module receives, analyzes, displays, stores and prints ECG *.scp files generated from a standard 12-lead ECG recording. CardioView 32 Review Module provides interpretive statements for which the physician renders his/her own medical opinion.

- Patient Population: Male/Female, Adults
- Environment of Use: Hospital and Clinic
- Prescription Device by a Physician

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 3/10/09
Division of Cardiovascular Devices
510(k) Number K083749