K111159

DEC 2 2 2011

510(k) SUMMARY
(as required by 807.92(c))

Regulatory Correspondent: AJW Technology Consultants, Inc.
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Submitter of 510(k): CardioComm Solutions, Inc.
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Date of Summary: March 31, 2011

Trade/Proprietary Name: HeartCheck Pen Handheld Heart Rhythm with GEMS Home

Classification Name: Class II

Product Code: DPS

Regulation: 870.2340

Intended Use:

The HeartCheck™ Pen Handheld device with GEMS Home software is an over-the-counter device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The HeartCheck™ Pen Handheld device along with GEMS Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.

Device Description:

The applicant device of HeartCheck Pen is a handheld device, which can record cardiac event data. As delivered to the end user, Heart Rhythm recordings are made on the HeartCheck™ Pen Heart Rhythm device and uploaded to GEMS Home, but the Heart Rhythm Waveform itself is not visible to or accessible by the user. GEMS Home allows the user to manage their personal information, their Heart Rhythm recordings and upload their Heart Rhythm recordings for Physician Review. Once the end user is under the guidance of a qualified Health Care Professional (e.g. Physician, Trained Technician, etc.), the Health Care Professional can use the access-controlled "Physician Review" section of the existing CardioComm Solutions Rx Only devices to initiate a process to "unlock" the GEMS Home Software and the HeartCheck™ Pen Heart Rhythm device to allow the end user to see their Heart Rhythm Waveforms in the GEMS Home software and on the device. Access to the "Physician Review" component of the existing CardioComm Solutions Rx Only devices is restricted to Health Care Professionals. The "unlock" feature is not accessible to anyone other than qualified Health Care Professionals and can only be initiated once the user has uploaded their collected HR Data from the GEMS Home.

The Heart Rhythm Monitor is made up of signal input unit, signal amplify unit, CPU, Display unit, power unit and storage chip. They are all in one PCB that is designed and made by our manufacturing partner Beijing Choice Electronic Technologies.

The HeartCheck™ Pen Heart Rhythm device is activated by the user whenever symptoms are experienced. The recorded data serves as reliable evidence and can be later uploaded for review by qualified Health Care Professionals for confirmation of these symptoms.

The applicant device has a "data upload" function which is controlled by hardware; it can transmit the data measured by the device to a computer via the USB port. The "GEMS Home" software is used to store and review the data collected by the HeartCheck Pen Heart Rhythm Monitor. The "GEMS Home" software is installed onto the computer from a CD ROM by the user. The "GEMS Home" software CD ROM is an accessory of the applicant device.

The applicant device has low battery voltage indication function. 2 AAA batteries supply the power for the monitor.

Predicate Device(s): Handheld ECG Monitor MD100 (K093872)
Read My Heart Model RMH 2.0 (K052303)

Substantial Equivalence:

The proposed device is substantial equivalent to the Handheld ECG Monitor MD100 (K093872) and Read My Heart Model RMH 2.0 (K052303) devices. The proposed device has a similar intended use, technological, and design characteristics as the predicate device. Any minor differences do not introduce new issues of safety or effectiveness.

Performance Testing:
The device complies with IEC60601-1, IEC 60601-1-2 and AAMI EC38 standards. A Low Voltage Indication Validation Test, Shock Test, Random Vibration Test, Sinusoidal vibration Test, Heart Rate Accuracy Test (Shelf Life) and High, low temperature & humidity Test were all performed on the applicant device to validate its performance.

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

DEC 22 2011

Cardio Comm Solutions, Inc.
c/o Jonathan Ward
President
AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Re: K111159
Trade Name: HeartCheck Pen Handheld ECG with GEMS Home
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: December 16, 2011
Received: December 19, 2011

Dear Mr. Ward:

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

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

Indications for Use K111159

510(k) Number (if known):

Device Name: HeartCheck Pen Handheld Heart Rhythm with GEMS Home

The HeartCheck™ Pen Handheld with GEMS Home software is an over-the-counter device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The HeartCheck™ Pen Handheld device along with GEMS Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 807 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) 12/22/2011

Division of Cardiovascular Devices

510(k) Number K111159