February 22, 2019

CardioComm Solutions, Inc.
Jill Turcotte
Quality and Regulatory Manager
259 Yorkland Road, Suite 200
North York, Ontario Canada M2J 0B5

Re: K181310
Trade/Device Name: HeartCheck Cardi Beat ECG Monitor with GEMS Mobile
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: January 21, 2019
Received: January 22, 2019

Dear Jill Turcotte:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Jessica E. Paulsen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181310

Device Name
HeartCheck™ Cardi Beat ECG Monitor (also know as HeartCheck™ Cardi or HeartCheck™ Beat) with GEMS Mobile

Indications for Use *(Describe)*

The HeartCheck™ Cardi Beat ECG Monitor device with the GEMS Mobile software is an over-the-counter device to be used by patients 21 years of age or older. It is intended to record, store and transfer single channel Heart Rhythm signals and display Heart Rhythm waveforms. This 1-lead cardiac monitor allows remote users to display and transmit their ECG data to medical professionals via a communication device to a remote server.

The HeartCheck™ Cardi Beat ECG Monitor combined with GEMS Mobile software is indicated for users who are concerned about their heart rhythms and may have experienced symptoms that may suggest irregular or abnormal heart rhythms. Symptoms may include:

- Skipped beats
- Palpitations
- Racing heart
- Fainting and lightheadedness
- Irregular rate
- History of any related heart abnormalities

The HeartCheck™ Cardi Beat ECG Monitor along with the GEMS Mobile software is not intended to substitute a hospital diagnostic ECG device. Users with an implanted pacemaker or are not recommended to use this device while the implanted device is operational. Users where their pacemaker is operational will not be able to record their ECG under normal sinus rhythm with the pacemaker on.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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CardioComm Solutions, Inc.

HeartCheck™ CardiBeat ECG Monitor with GEMS Mobile

K181310 510(k) Summary

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1 K181310 Summary

Submitter:	CardioComm Solutions, Inc.	
Address:	200-259 Yorkland Road North York, Ontario M2J 0B5	
Phone:	416.977.9425	
Contact Person(s):	Etienne Grima CEO egrima@cardiocommsolutions.com	Jill Turcotte, QA, RA & Infrastructure Manager jturcotte@cardiocommsolutions.com
Date of Summary:	2018-05-01	
Trade/Proprietary Name:	HeartCheck™ CardiBeat ECG Monitor or HeartCheck™ Cardi or HeartCheck™ Beat and GEMS™ Mobile	
Common/Usual Name:	HeartCheck™ CardiBeat ECG Monitor or HeartCheck™ Cardi or HeartCheck™ Beat	
Classification Name	Class II	
Product Code:	DXH	
Regulations:	870.2920	
SE Predicate Device(s):	HeartCheck™ ECG PEN K111159	
SE Reference Device(s):	ECG Check K122184	

1.1 Device Description

The HeartCheck™ CardiBeat ECG Monitor device model HC-WE-01 is an ambulatory and telemedicine based solution that is intended to enable uses to record, store, transfer, and display single channel ECG waveforms. The HeartCheck™ CardiBeat ECG Monitor combined with GEMS™ Mobile enables the user to send their ECG recordings to a medical service for review and interpretation by a qualified health service professional, such as a physician.

The 1 lead ECG Event Monitor is specifically designed to operate with GEMS™ Mobile software, a smartphone software configured to run on mobile devices such as smartphones and tablets. The device will record a pre-selected amount of user ECG activity, as directed by the user. Typical configuration is to record 30 seconds of ECG per event.

The HeartCheck™ CardiBeat ECG Monitor is activated through touch by the user whenever a recording is needed. The recorded data serves as a reliable heart rhythm record that may later be shown to physicians or other health care professionals for confirmation of the presence or absence of an arrhythmia. When a user feels that a cardiac event is occurring, the utilization of the HeartCheck™

CardiBeat ECG Monitor with GEMS™ Mobile has the feature of recording this real time data that would otherwise not be possible to capture.

While performing the recording, data is continuously sent to the smartphone or tablet by secure Bluetooth connection technology. Following an initial physician review, the ECG can be displayed for quality and observation purposes on the GEMS™ Mobile application. Users will not be able to view the waveform without a physician's pre-review from the SMART Monitoring system. This system used the HeartCheck™ ECG PEN and GEMS™ Home system (K111159) with an ECG reading service as a predicate device. The recorded data can be stored locally on the mobile device and/or not transmitted to CardioComm Solutions, Inc.'s SMART Monitoring ECG reading service (powered by GlobalCardio™ K1111320) for analysis and assessment by qualified professionals.

1.2 Indications for Use

The HeartCheck™ CardiBeat ECG Monitor device with the GEMS™ Mobile software is an over-the-counter device to be used by patients 21 years of age or older. It is intended to record, store and transfer single channel Heart Rhythm signals and display Heart Rhythm waveforms. This 1-lead cardiac monitor allows remote users to display and transmit their ECG data to medical professionals via a communication device to a remote server.

The HeartCheck™ CardiBeat ECG Monitor combined with GEMS™ Mobile software is indicated for users who are concerned about their heart rhythms and may have experienced symptoms that may suggest irregular or abnormal heart rhythms. Symptoms may include:

- Skipped beats
- Palpitations
- Racing heart
- Fainting and lightheadedness
- Irregular rate
- History of any related heart abnormalities

The HeartCheck™ CardiBeat ECG Monitor along with the GEMS™ Mobile software is not intended to substitute a hospital diagnostic ECG device. Users with an implanted pacemaker or are not recommended to use this device while the implanted device is operational. Users where their pacemaker is operational will not be able to record their ECG under normal sinus rhythm with the pacemaker on.

1.3 Testing Summary

1.3.1 Nonclinical Testing

Performance evaluation of the features described in the HeartCheck™ CardiBeat ECG Monitor user manual has been successfully completed utilizing hardware and software tests and validations. Hardware qualification is performed using the following industry standards:

Standard Number	Standard Title
IEC 60601-1:2005 + A1:2012	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential Performance
IEC 60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 62304:2006	Medical Devices - Software Development Life Cycle
ISO 10933-1:2009	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process in content
ISO 10933-5:2009	Biological evaluation of medical devices Part 5: Test for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices Part 10: Test for irritation and skin sensitization

Table 1 – Compliant Standards

1.3.2 Clinical Testing

No clinical testing was conducted to support this submission.

1.3.3 Substantial Equivalent (SE) Comparison Summary

Item	Proposed Device (HeartCheck™ CardiBeat) K181310	Primary Predicate Device K111159	Reference Device (ECG Check) K122184
Product Code	DPS/DXH	DPS	DXH
Regulation Number	870.2340/870.2920	870.2340	870.2920
Indications for Use	The HeartCheck™ CardiBeat ECG Monitor device with the GEMS™ Mobile software is an over-the-counter device intended to record, store and transfer single channel Heart Rhythm signals and display Heart Rhythm waveforms. This 1-lead cardiac monitor allows remote users to display and transmit their ECG data to medical professionals via a communication device to a remote server. The HeartCheck™ CardiBeat ECG Monitor combined with GEMS™ Mobile software is indicated for users who are concerned about their heart rhythms and may have experienced symptoms that may suggest	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.	The ECG Check is intended for self-testing by patients at home. This 1-lead cardiac monitor allows remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server. Specifically, the ECG Check is indicated for patients who are concerned about their heart rhythm and experienced the following symptoms that are suggestive of abnormal heart rhythms: • Skipped Beats • Pounding Heart (Palpitations) • Heart Racing or Irregular Pulse

Item	Proposed Device (HeartCheck™ CardiBeat) K181310	Primary Predicate Device K111159	Reference Device (ECG Check) K122184
	irregular or abnormal heart rhythms. Symptoms may include: • Skipped beats • Palpitations • Racing heart • Fainting and lightheadedness • Irregular rate • History of any related heart abnormalities The HeartCheck™ CardiBeat ECG Monitor along with the GEMS™ Mobile software is not intended to substitute a hospital diagnostic ECG device. Users with an implanted pacemaker or are not recommended to use this device while the implanted device is operational. Users where their pacemaker is operational will not be able to record their ECG under normal sinus rhythm with the pacemaker on.	GEMS™ Home is a simple software user interface for managing Heart Rhythm recordings and associated data. Record the Heart Rhythm waveform for an adult. If under the guidance of a qualified Health Care Professional, the software and device can be unlocked to display the Heart Rhythm.	• Lightheadedness or Faintness • History of Arrhythmias
Population	Adult (=> 21 years of age)	Not indicated	Not indicated
Lead	1 lead	1 lead	1 lead
Recording Mode	Automatic, 30 seconds	Automatic, 30 seconds	Automatic, 30 seconds
Measurement Parameters	Heart rate ECG waveform	Heart rate ECG waveform	Heart rate ECG waveform
Display	None	Yes - OLED	None
Power Supply	3.7 V 230 mAh lithium battery 5V 115 mA (for charging only)	3 V (2 AAA alkaline batteries)	3.7 V 230 mAh lithium battery 5V 115 mA (for charging only)
Electrical Safety	The proposed device was tested to demonstrated to comply with IEC 60601-1	IEC 60601-1	IEC 60601-1
EMC	The proposed device was tested to demonstrated to comply with IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2
Patient Contact Material	Metal electrode	Metal electrode	Metal electrode

Table 2- SE Comparison Summary

1.3.4 Conclusion

The applicant device, HeartCheck™ CardiBeat ECG Monitor, indications for use and indications for use are the same as the predicate device HeartCheck™ Pen Handheld ECG Monitor and the reference

device, ECG Check by Cardiac Designs. The new applicant, predicate and reference devices have identical patient populations and places of use. In addition, the parameters that are measured by the new HeartCheck™ CardiBeat ECG Monitor are equal to primary predicate HeartCheck PEN Handheld device with GEMS™ Home and to the reference device, ECG Check by Cardiac Designs.