October 2, 2017

Cardiac Designs, Inc.
% Cynthia Pillar
President, Consultant
CJP Consulting, Inc.
5831 N Kostner Ave
Chicago, Illinois 60646

Re: K170506
Trade/Device Name: ECG Check - Universal, ECG Check - Universal Plus
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: September 20, 2017
Received: September 21, 2017

Dear Cynthia Pillar:

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. 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); 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 contact the Division of Industry and Consumer Education (DICE) 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. 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 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 Industry and Consumer Education (DICE) 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,

for

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K170506

Device Name
ECG Check - Universal, ECG Check - Universal Plus

Indications for Use *(Describe)*
The ECG Check Universal family of devices is intended for self-testing by patients at home. These 1-lead cardiac monitors allow remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server.

Specifically, the ECG Check Universal models are indicated for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:
• Skipped Beats
• Pounding Heart (Palpitations)
• Heart Racing or Irregular Pulse
• Lightheadedness or Faintness
• History of Arrhythmias

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## SECTION 5: 510(k) SUMMARY

### TRADITIONAL 510(k) - 510(k) Summary

| | |
|---|---|
| **Date Prepared:** | December 31, 2016 |
| **Submitter:** | Cardiac Designs, Inc.<br>25510 Interstate 45 N, Suite 202<br>Spring, TX 77386<br>Phone: 1 (844) 324-2432<br>Facsimile: 1 (713) 589-7964 |
| **Contact:** | Cynthia J. Pillar, Regulatory Consultant<br>1 (773) 677-8886 |
| **Trade/Proprietary Name of Device:** | ECG CHECK – UNIVERSAL PLUS and<br>ECG CHECK – UNIVERSAL |
| **Common Name of Device:** | Transmitters and Receivers, Electrocardiograph, Telephone |
| **Classification:** | Class II per 21 CFR 870.2920, Telephone electrocardiograph transmitter and receiver, Product Code DXH |
| **Legally Marketed Predicate Device:** | ECG Check (K122184), manufactured by Cardiac Designs, Inc. |

**Description of New ECG CHECK – UNIVERSAL PLUS Device:**

The new ECG CHECK – UNIVERSAL model devices are personal 1 lead ECG Event Monitors specifically designed to operate over the cellular network with iPhone & Android cellular phone handsets. The new ECG CHECK – UNIVERSAL model devices include two models. The ECG CHECK – UNIVERSAL (Model ECG01-U) and the ECG CHECK – UNIVERSAL PLUS (Model ECG01-UPLUS). Both models are designed to capture a user's ECG data and transmit the data via Bluetooth to a cellular device, which will ultimately transmit the ECG data over the cellular network to the ECG Check web center. The difference between the two models is that the new ECG CHECK – UNIVERSAL PLUS allows for the storage of recordings on the device and includes a button for the added capability of transmitting these ECG data trans-telephonically using landlines to the ECG Check web center. The button also provides indication of the number of saved ECG recordings as well as the ability to delete saved recordings. Both new ECG CHECK – UNIVERSAL model

devices will record a preselected amount of user ECG activity, as directed by the user. Typical configuration is to record 30 seconds of ECG per event.

The ECG CHECK – UNIVERSAL model devices are indicated for monitoring symptoms that may suggest irregular or abnormal heart rhythms. The ECG CHECK – UNIVERSAL model devices, when used in conjunction with the ECG Check web center, use standard analysis of ECG by the previously cleared web-based engine for objective assessment of the user in terms similar to a stoplight (Green, Yellow, Red). With a physician prescription, the user will be provided access to be able to trend their results and generate reports to provide to their physician or other caregivers via the application. The symptoms may include: skipped beats, palpitations, racing heart, fainting, lightheadedness, irregular rate, or history of other related heart abnormalities.

As mentioned above, there are two methods for ECG data transmission with the new ECG01-UPLUS model. Both ECG CHECK – UNIVERSAL model devices continue to use the same method for transmission as the predicate. While performing the recording, the results are continuously sent to the cellular phone by secure Bluetooth connection technology and, with a physician prescription, displayed for quality and observation purposes on the cellular phone ECG Check application. Users without a physician prescription will not be able to view the waveform. The data can be stored locally on the cellular device and/or transmitted to the ECG Check web center for analysis and assessment by qualified professionals.

The new ECG01-UPLUS device also stores ECG data on the device and includes a button that allows a user to send these stored recordings with or without connection to the cellular device application. The user can make recordings, which will remain stored on the device. The user can push the button when ready and transmit the ECG data over an analog telephone line whenever the user decides to transmit. The button on the ECG01-UPLUS model will also indicate the number of stored recordings and will allow deletion of stored recordings.

The ECG Check web center provides privacy and protection for user medical information and the ability to interact with Cardiac Designs, Inc. technicians and engineers, as well as with their own caregivers.

The ECG CHECK – UNIVERSAL model devices are intended for users that seek to manage their heart rate and rhythms over long periods of time. Additional features will be added to involve health care professionals in the service, with the intent to ensure that the device remains consumer focused and non-diagnostic.

**Indications for Use of the New Device:**

The ECG Check Universal family of devices is intended for self-testing by patients at home. These 1-lead cardiac monitors allow remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server.

Specifically, the ECG Check Universal models are indicated for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:

- Skipped Beats
- Pounding Heart (Palpitations)
- Heart Racing or Irregular Pulse
- Lightheadedness or Faintness
- History of Arrhythmias

**Comparison of the Technological Features of the New (Modified) Device and Predicate Device:**

The new ECG CHECK – UNIVERSAL model devices indications for use are equivalent to the predicate ECG Check model ECG01-4S. The new ECG CHECK models and the predicate ECG Check model ECG01-4S device have identical patient populations and places of use. In addition, the parameters that are measured by the new ECG CHECK – UNIVERSAL model devices are identical to those measured by the predicate ECG Check model ECG01-4S.

There are few differences between the new ECG CHECK – UNIVERSAL model devices and the predicate ECG Check model ECG01-4S. The main differences are as follows:

1. Redesign of case

The new ECG CHECK – UNIVERSAL model devices case has been redesigned to make it a stand-alone device. The materials of the new ECG CHECK – UNIVERSAL model devices are identical to those used in the predicate.

2. Addition of ‘Offline’ mode:

The new ECG CHECK – UNIVERSAL model devices now include an ‘Offline’ mode for storing ECG data on the cellular device until the user is able to send the transmission.

3. Addition of Trans-telephonic data transmission capability to the ECG CHECK – UNIVERSAL PLUS model:

The new ECG Check model ECG01-UNIVERSAL PLUS device now includes the capability for the user to send the ECG data over regular analog phone lines (TTM). (The new ECG CHECK – UNIVERSAL model transmits using only cellular data connectivity and is therefore equivalent to the predicate device)

4. Addition of a button on the case:

The new ECG CHECK – UNIVERSAL PLUS model includes a button. The button initiates the sending of stored ECG data files trans-telephonically when held down for three (3) seconds. The button also performs the following:

- When pressed for less than three (3) seconds, the LEDs will flash once for each stored recording on the device. This will be accompanied by an audible beep for each stored recording.
- When pressed three (3) times quickly (within one (1) second) the device will delete all stored recordings.

(The new ECG CHECK – UNIVERSAL model does not contain the button and is therefore equivalent to the predicate device)

5. Change from replaceable to rechargeable battery:

Both new ECG CHECK – UNIVERSAL model devices contain an internal rechargeable 3V lithium battery.

6. Compatibility with Android Platform:

The new ECG CHECK – UNIVERSAL model devices can now be used on both iPhone and Android devices.

A more detailed comparison is provided in TABLE 5.1 below:

| ATTRIBUTE | NEW ECG CHECK - UNIVERSAL MODEL DEVICES | PREDICATE: Cardiac Designs ECG Check (K122184) | Variance Explanation |
|---|---|---|---|
| **Indications for Use Statement:** | The ECG Check model ECG01-UNIVERSAL PLUS 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. | The ECG Check model ECG01-4S 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. | Identical |

| | | | |
|---|---|---|---|
| | Specifically, the ECG Check model ECG01-UNIVERSAL PLUS is indicated for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:<br>• Skipped Beats<br>• Pounding Heart (Palpitations)<br>• Heart Racing or Irregular Pulse<br>• Lightheadedness or Faintness<br>• History of Arrhythmias | Specifically, the ECG Check model ECG01-4S is indicated for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:<br>• Skipped Beats<br>• Pounding Heart (Palpitations)<br>• Heart Racing or Irregular Pulse<br>• Lightheadedness or Faintness<br>• History of Arrhythmias | |
| **Place of Use:** | OTC, Home | OTC, Home | Identical |
| **Population of Use:** | Adult | Adult | Identical |
| **Anatomical Sites** | Chest & Fingers | Chest & Fingers | Identical |
| **Usage** | Multi-use | Multi-use | Identical |
| **Technological Characteristics** | **NEW ECG CHECK - UNIVERSAL MODEL DEVICES** | **PREDICATE: Cardiac Designs ECG Check (K122184)** | **Variance Explanation** |
| **Power** | Battery | Battery | Identical |
| **Battery Type** | Internal 3V Lithium Rechargeable Battery | CR2032 3V Lithium Coin Cell | See explanation above |
| **Battery Life** | 8 hours/480 recordings | 8 hours/480 recordings | Identical |
| **Recording Period** | 30 seconds | 30 seconds | Identical |
| **Recording Method** | Automatic | Automatic | Identical |
| **Operating Temperature** | +10° to +40° C | +10° to +40° C | Identical |
| **Transport & Storage Temperature** | -20° to +65° C | -20° to +65° C | Identical |

| | | | |
|---|---|---|---|
| **Humidity** | 30 – 85% noncondensing | 30 – 85% noncondensing | Identical |
| **Dimensions (max.)** | **ECG01-U**: 87 x 49 x 7mm / **ECG01-UPLUS**: 85.95 x 47.95 x 7.2mm | 118 x 62 x 17mm | See explanation above |
| **Weight** | **ECG01-U**: 33 grams<br>**ECG01-UPLUS**: 38 grams | 40 grams | See explanation above |
| **Internal Memory** | **ECG01-U**: No<br>**ECG01-UPLUS**: Yes | No | See explanation above |
| **Features: Button Functions (UPLUS Model Only):** | 1. Initiate send of stored recordings<br>2. Number of stored recordings<br>3. Deletion of stored recordings | No Button | See explanation above |
| **Commun-ications Download/Signal Output Connection** | 1. Bluetooth technology<br>2. Trans-telephonic over analog phone lines (**ECG01-UPLUS** model) | Bluetooth technology | See explanation above |
| **Software Platform** | iOS 5 or Higher/MS Azure or Windows 2008/Android 4.1 or greater | iOS 5 or Higher/MS Azure or Windows 2008 | See explanation above |
| **Device Materials** | **NEW ECG CHECK - UNIVERSAL MODEL DEVICES** | **PREDICATE: Cardiac Designs ECG Check (K122184)** | **Variance Explanation** |
| **Device Casing & Button** | PC Plastic | PC Plastic | Identical |
| **Electrodes** | Copper plated with Ag/Cl | Copper plated with Ag/Cl | Identical |
| **USB Cord (for charging)** | Yes | N/A | See explanation above |
| **Sterilization** | N/A | N/A | Identical |

TABLE 5.1 – TECHNOLOGICAL CHARACTERISTICS COMPARISON

**Clinical Testing:**

No clinical testing was conducted in support of this 510(k) submission.

**Non-Clinical Testing:**

The ECG CHECK device successfully passed safety and essential performance testing as required by:

- IEC 60601-1 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 – Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests
- IEC 60601-1-6 - Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
- IEC 60601-1-11 - Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
- IEC 60601-2-47 - Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.
- IEC 62366:2007 + A1:2014 – Medical Devices – Application of Usability Engineering to Medical Devices

In addition to the testing completed above, the new ECG CHECK – UNIVERSAL model devices were successfully bench tested to performance specifications and in comparison to the performance of the predicate device.

**Conclusion:**

The conclusions drawn from the specifications and performance testing of the new ECG CHECK – UNIVERSAL model devices demonstrate that the new ECG CHECK – UNIVERSAL model devices are at least as safe and as effective and perform as well as or better than the predicate ECG Check model ECG01-4S (K122184). For these reasons, we believe the new ECG CHECK – UNIVERSAL model devices are substantially equivalent to the predicate device.