

II. 510(k) Summary of Safety and Effectiveness

CardeaScreen™

General Information

| Criteria | Information |
|------------------|--|
| Trade Name | CardeaScreen™ |
| Model Number | CS-2020 |
| Common Name | Electrocardiograph (ECG) |
| Classification | 21 CFR 870.2340 – Electrocardiograph Class II; product code: DPS |
| 510(k) Submitter | Cardea Associates, Inc. 13720 220 th Place NE Woodinville, WA 98077 USA |
| Contact Person | David M. Hadley, Ph.D. President Cardea Associates, Inc. dave@cardeascreen.com (855) 800-0760 extension 801 (phone) (855) 800-0760 (fax) |

Device Description

The CardeaScreen™, developed by Cardea Associates, Inc. (Cardea), is small, lightweight, portable electrocardiograph, designed for collection of resting (non-ambulatory) electrocardiographic (ECG) data.

The CardeaScreen device system is composed of 2 main components:

- ECG Transmitter - this type of device is also referred to in the medical community as a "ECG recorder", or "ECG data acquisition unit". The CardeaScreen ECG transmitter is about the size of a small paperback book (~6" x 4" x 1.5") and ~11 ounces. The transmitter is battery powered or it can also be powered via AC mains power by using the medical grade power supply supplied as part of the CardeaScreen system.

A patient cable with 10 lead wires is attached to the transmitter. The lead wires terminate in connectors that are attached to commercially available ECG electrodes selected by the clinician for use. The electrodes (not part of the CardeaScreen system) adhere to the

patient's skin in the chest region and are used for detecting a patient's ECG.

- CardeaScreen Software - the software is installed by the clinician on the clinician's personal computer (PC). The software controls the ECG transmitter's use. The transmitter cannot function in any manner to collect ECG, without the software.

Collected ECG data is transferred from the ECG transmitter to the PC using wireless (Bluetooth) transmission. The software can be used for subsequent analysis of the patient's ECG data.

Indications for Use

CardeaScreen records and measures a resting ECG from the adult and pediatric (age ≥ 14) body surface. It provides automatic ECG interpretations which are identified as "Unconfirmed" by the product until they have been over-read and confirmed by a clinician.

CardeaScreen is intended for use on apparently healthy individuals and on symptomatically stable patients with known or potential cardiac conditions.

This device is intended for use under the direct supervision of a licensed health care clinician.

Substantially Equivalent Devices

| Manufacturer | Substantially equivalent devices | 510(k) |
|--|---|---------------|
| Cardiac Science Corporation Bothell, WA | CareCenter MD | K093211 |
| Brentwood Medical Technology Corporation, Midmark Diagnostics Group Versailles, Ohio | IQecg | K103640 |

Substantial Equivalence Comparison

The CardeaScreen has in many instances identical or nearly identical technological characteristics to the substantially equivalent (predicate) ECG devices. The following many *similarities* are noted:

- All devices are electrocardiographs.
- Devices are all classified by FDA as Class II medical devices under regulation 21 CFR 870.2340; code DPS.
- Devices have a common system configuration (e.g., an ECG transmitter (data acquisition unit) and software installed on a clinician's personal computer (PC) for ECG processing/analysis.
- Devices have an identical intended use - all are electrocardiographs used in the collection and analysis of ECG data.
- The devices have very similar wording in terms of indications for use.
- All devices are used for resting ECG data collection.
- All are prescription use devices; no over-the-counter use.
- Devices are used by the same personnel (e.g., healthcare clinicians).
- All devices are used in the same use environment - in hospital/medical settings.
- All devices have the same intended patient population - use in adults and/or pediatrics.
- All devices are not for ambulatory use.
- The CardeaScreen and predicates are all have a common device configuration and the same use mode in that the patient cables (leads) are integrated into the ECG transmitter and the cables terminate in clip/snap connectors that attach to ECG electrodes (applied to the patient's chest by a clinician).
- The CardeaScreen and CareCenter MD predicate ECG have wireless ECG data transfer (via Bluetooth) of the collected ECG data to the clinician's PC. The IQecg is a wired transfer.
- All devices transfer collected ECG data continuously.
- All devices require/are compatible with Microsoft Windows Operating Systems and require a Windows-compatible PC.
- Devices are all capable of interfacing with other equipment (such as servers, electronic medical records, etc.).
- All devices are similarly sized - small and lightweight.
- Devices are all portable.
- Devices are all supplied nonsterile and are reusable.
- Devices are all a standard 12 lead configuration.
- Devices have identical or nearly identical ECG data acquisition characteristics (e.g., frequency response, filters, sensitivity, input impedance, common mode rejection, sample rate for ECG interpretation and analysis, ECG amplifier presence, simultaneous data acquisition from all leads and displayed data of resting ECGs).

- All devices have software that is installed on the user's PC and performs ECG analysis for arrhythmia detection. Such analysis is available to the clinician for use, however the labeling of all the devices notes that device interpretations/analyses are to be confirmed by a clinician.
- All devices have comparable environmental ranges (e.g., temperature and humidity).
- Lastly, the devices all have common safety attributes (e.g., pacemaker and leads off detection features, technical standard conformance, input protection against defibrillation shocks, type CF applied part rating and patient isolation).

Therefore, due to the identical or nearly identical nature of the CardeaScreen, as noted in the numerous similarities itemized above, Cardea believes the CardeaScreen is substantially equivalent to the predicate ECG devices.

Testing

The CardeaScreen underwent extensive testing and related assessments, as listed below. All testing demonstrated acceptable results.

- Design Verification (Safety) testing, including:
 - IEC 60601-1 testing (electrical safety)
 - IEC 60601-1-2 testing (EMC)
 - ANSI/AAMI EC53 testing (patient cable)
- 21 CFR 898 Compliance assessment
- Additional design verification testing
- Firmware/Software (including ECG analysis algorithm) verification/validation testing
- ISO 10993-1 (biocompatibility and equivalent usage in predicate devices)

Summary of Substantial Equivalence

Based on the information provided in this 510(k) and testing completed, the CardeaScreen does not raise any new safety or effectiveness issues and is substantially equivalent to legally marketed electrocardiographs that are in commercial distribution, and have been determined to be substantially equivalent to devices in commercial distribution, prior to May 28, 1976.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 05 2013

Cardea Associates, Inc.
c/o Mr. Jeff D. Rongero
Senior Project Engineer
UL LLC
12 Laboratory Drive,
Research Triangle Park, NC 27709-3995

Re: K123217
Trade/Device Name: CardeaScreen™
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: January 14, 2013
Received: January 15, 2013

Dear Mr. Rongero:

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.

Page 2 – Mr. Jeff D. Rongero

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,


Owen P. Faris -S

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

Enclosure

I. Indications for Use Statement

510(k) Number: **K123217**

Device Name: **CardeaScreen™**

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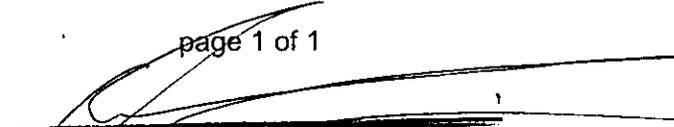
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices