

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Corcam's 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Corcam Heart Monitor is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device(s).

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Date Prepared: March 3, 2014
Proposed Class: II
Proprietary Name: Corcam Heart Monitor
Common Name: Arrhythmia Detector and Alarm
Classification Name: Arrhythmia Detector and Alarm
Regulation Number: 21 CFR 870.1025
Product Codes: DSI

Predicate Device(s):

Manufacturer	Device Name	Procode	Common Name	Class
CardioNet, Inc.	CardioNet ECG Monitor with Arrhythmia Detection	DSI	Arrhythmia Detector and Alarm	II
Preventice, Inc.	Body Guardian	MHX, DSI	Patient Physiological Monitor, Arrhythmia Detector and Alarm	II
Applied Cardiac Systems	CORE™ ECG Monitor	DSI, DSH, DPS	Arrhythmia Detector and Alarm	II

Indication for Use

The Corcam Heart Monitor is a portable device intended to continuously monitor a patient's cardiac condition for early signs of arrhythmia.

1. Adult patients who have demonstrated a need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.
2. Adult patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: dizziness or lightheadedness; syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and dyspnea (shortness of breath).
3. Adult patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Adult patients who require outpatient monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).

Device Description

The Corcam Heart Monitor is a battery operated, non-invasive, portable device intended to continuously monitor a patient's cardiac condition for early signs of arrhythmia. The device allows for autonomous remote monitoring via a Global System for Mobile Communications/General Packet Radio Service (GSM/ GPRS). The device is connected to the patient via four commercially available electrodes (Derivations I, II, III, and ground) and is equipped with an accelerometer to detect patient falls, GPS for geographical and accurate location of the user, and a speaker system to allow communication to or with the Monitoring Center. A vibrating mechanism and lights, when activated, provide physical and visual signals to the user. Indicator lights also show the operating status of the unit. An SOS/ Help button can be pressed by the user to send a help signal to the monitoring center. In addition to the transmission of patient data to the monitoring center, the monitoring center or clinician at any given moment can conditionally request a new exam on demand allowing for actual and accurate tracking of a cardiac event. Once the monitor detects an irregular heartbeat, the device generates an electrocardiogram (ECG) and sends it to the monitoring center. A clinician in the monitoring center carries out an analysis on the received ECG. Depending upon the analysis of the ECG, the clinician can check the symptoms of the patient, request another ECG transmission, or initiate immediate assistance for the patient in the form of an ambulance/ emergency services.

Performance Data (Non-Clinical)

The Corcam Heart Monitor meets the requirements of the following standards:

- NBR IEC 60601-1:1994, Electromedical Equipment - Part 1 – General Safety Prescriptions
- NBR IEC 60601-1, Amendment 1: 1997
- ABNT NBR IEC 60601-1-2:2006, Electromedical Equipment - Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and tests.
- ABNT NBR IEC 60601-2-27:1997, Medical Electrical Equipment - Part 2: Particular Requirements For the Safety of Electrocardiographic Monitoring Equipment
- NBR IEC 60601-2-27:1997, Part 2: Specific Prescriptions for the Equipment Safety for the Electrocardiogram Software
- IEC 62209-01: 2005, Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices- Human models, instrumentation, and procedures - Part 1: Procedure to determine the specific absorption rate (SAR) for hand-held devices used in close proximity to the ear (frequency range of 300 MHz to 3 GHz)
- IEC 62209 – 02: 2010, Procedure to determine the Specific Absorption Rate (SAR) in the head and body for 30 MHz to 6 GHz Handheld and Body-Mounted Devices used in close proximity to the Body
- IEEE Std 1528, IEEE Recommended Practice for Determining the Peak Spatial- Average Specific Absorption Rate (SAR) in the Human Head from Wireless Communications Devices: Measurement Techniques
- ETSI TS 151 010-1 V6.5.0 (2005-11) - (3GPP TS 51.010-1 version 6.5.0 Release 6), Digital cellular telecommunications system (Phase 2+); Mobile Station (MS) conformance specification; Part 1: Conformance specification
- AAMI / ANSI EC38: 2007, Medical Electrical Equipment – Part 2-47: Particular Requirements for the safety, including essential performance, of ambulatory electrocardiographic systems. (Cardiovascular)
- AAMI/ANSI EC 57 1998/(R) 2003 – Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms

Performance Data (Clinical)

A cross-sectional observational study was designed to assess the accuracy of this monitor as compared to that of conventional ECG (gold standard) as a screening tool for the detection of arrhythmias and myocardial ischemia. From May to August 2012, 152 consecutive patients were included in the study. Patients were inpatients or outpatients with established clinical diagnoses (as reported in medical records) and ECGs meeting the eligibility criteria of the study. Inclusion criteria were patients over 18 years of age with cardiac arrhythmias or myocardial ischemia and an established diagnosis of atrial fibrillation, acute coronary syndromes, or ventricular arrhythmias or bradyarrhythmias. All patients underwent conventional electrocardiography and had an electrocardiogram (ECG) generated by the Corcam device. For the Corcam Heart Monitor ECGs, the device was installed onto the patient and automatically generated and sent an ECG to the Central Monitoring Station without human intervention, either from the patient or the investigator. Both tests were performed within a 10-minute window. There were no adverse

events. Results showed that in 92% of the cases evaluated, the Central Monitoring Station received the ECGs automatically generated by the Corcam device within 3 minutes. ECGs that took between 4 and 5 minutes to send were generated at peak times, when there is greater data traffic over the cellular network. The study concluded that the Corcam Heart Monitor has the ability to detect relevant ECG changes and generate an electrocardiogram and transmit it automatically (without human intervention) within minutes to a Central Monitoring Station.

Technological Characteristics and Substantial Equivalence

The Corcam Heart Monitor has the same indications for use and similar design features as compared with the predicate arrhythmia detectors. Additionally, both the Corcam device and the predicate CORE™ ECG Monitor use an accelerometer to detect accelerated motion. The bench testing along with the clinical data demonstrate that the performance characteristics of the Corcam Heart Monitor is equivalent to those of other legally marketed arrhythmia detectors, and therefore supports a determination of Substantial Equivalence for the proposed indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 23, 2014

Corcam Technologia, SA
% Ms. Jennifer Daudelin
Consultant for Corcam
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575 Eighth Ave, Ste 1212
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Re: K140548
Trade/Device Name: Corcam Heart Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm
Regulatory Class: Class II
Product Code: DSI
Dated: March 25, 2014
Received: March 26, 2014

Dear Ms. Jennifer Daudelin:

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.

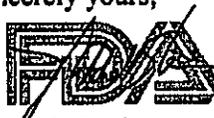
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 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>. 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 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,

A stylized signature of Bram D. Zuckerman, M.D., written in a bold, blocky font. The letters are interconnected and have a textured, almost 3D appearance.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K140548

Device Name: Corcam Heart Monitor

Indications for Use:

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3. Adult patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Adult patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).

Prescription Use AND/OR
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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