DEC 2 1 2011

II. 510(k) Summary of Safety and Effectiveness K113176

mySense™ Heart

General Information

Criteria	*Information*
Trade Name	*mySense™ Heart*
Model Number	none assigned
Common Name	Ambulatory electrocardiograph (ECG)
Classification	21 CFR 870.2800 – Medical magnetic tape recorder Class II; product code: DSH
510(k) Submitter	Cardiac Science Corporation 3303 Monte Villa Parkway Bothell, WA 98021 USA
Contact Person	Neil Sheller Senior Regulatory Affairs Engineer Cardiac Science Corporation nsheller@cardiacscience.com 425-402-2156 (phone) 425-402-2017 (fax)

Substantially Equivalent Devices

Manufacturer	*Substantially equivalent devices*	*510(k)*
iRhythm Technologies, Inc. San Francisco, CA	Zio patch *Example model*: Z100	K090363
Braemar Corporation Burnsville, MN	Holter recorder *Example model*: Model DXP1000 (model is now called the Vision 5L)	K993618

Device Description

The mySense™ Heart, developed by Cardiac Science Corporation (CSC), is small, lightweight, patch-style cardiac monitor, designed for ambulatory collection of electrocardiographic (ECG) data continuously for up to 24 hours. The device system is composed of 2 main components:

- *Recorder* - The mySense Heart recorder is about the size of a large band-aid and contains 2 electrodes that are used for sensing and detecting a patient's ECG. The recorder has an adhesive pad so that it can be attached to the patient's skin in the chest region for ECG collection.

- *Recorder Processing Software (RPS)* - The RPS is installed on a computer where the patient's ECG data on the recorder will be downloaded for subsequent analysis by ECG technicians/clinicians.

Indications for Use

The mySense Heart is indicated for use with patients who experience transient symptoms such as syncope, palpitations, shortness of breath or chest pains.

Testing

The mySense Heart device underwent extensive testing, including testing listed below. All testing demonstrated acceptable results.

- Design verification testing
- Software verification and validation testing
- IEC 60601-1 testing (Electrical safety)
- IEC 60601-1-2 testing (EMC)
- ISO 10993-1 testing (biocompatibility)
- ANSI/AAMI EC12 testing (disposable ECG electrodes), including adhesive testing in humans in a clinical trial.
- Clinical trial - Comparative testing against a commercially available Holter ECG monitor (predicate device) in 50 cardiac subjects.

Summary of Substantial Equivalence

Based on the information contained in this 510(k) Notification, Cardiac Science Corporation determined that the mySense Heart 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 Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 1 2011

Cardiac Science Corporation
c/o Mr. Neil Sheller
Senior Regulatory Affairs Engineer
3303 Monte Villa Parkway
Bothell, WA 98021

Re: K113176
Trade/Device Names: mySense™ Heart
Regulatory Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (Two)
Product Code: DSH
Dated: October 25, 2011
Received: October 28, 2011

Dear Mr. Sheller:

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.

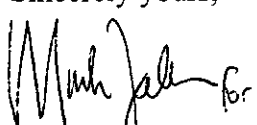
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,



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 (if known): K113176

Device Name: ***mySense™ Heart***

Indications for Use:

The mySense Heart is indicated for use with patients who experience transient symptoms such as syncope, palpitations, shortness of breath or chest pains.

(Division Sign-Off) for Bram Zuckerman Director DCD
Division of Cardiovascular Devices

510(k) Number K113176

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)