K052316

JAN 3 2006

SECTION 2. SUMMARY AND CERTIFICATION

2.1. 510(k) Summary

Submitter:	Cardiac Science, Inc. 5474 Feltl Road Minnetonka, MN 55343
Contact Person:	Kenneth Olson Phone: (952) 939-2912 Fax: (952) 939-4191
Date Prepared:	August 22, 2005
Trade Name:	Powerheart ECD™
Classification Name and Number:	Automated External Defibrillator Class III, 21CFR 870.5310
Product Code:	MKJ
Predicate Device(s):	The Powerheart ECD™ manufactured by Cardiac Science, Inc is substantially equivalent to Medtronic Physio-Control LIFEPAK® 20 Defibrillator (K012274).
Device Description:	The Powerheart® ECD is a defibrillator/monitor/pacemaker intended for use by personnel trained in its operation. The device is lightweight, portable, easy to use and reliable. It incorporates a 320 x 240 transmissive TFT color display for wide viewing angles in all light conditions. The device operates using either an AC power supply or internal rechargeable Li-Ion battery. The device provides continuous ECG monitoring and three types of therapies: defibrillation, cardioversion and external pacing. Defibrillation can be applied manually or semi-automatically. Pacing therapy can be either fixed or demand. The device employs patented RHYTHMx® software which provides ECG rhythm analysis. STAR® Biphasic waveform delivers impedance-compensated energy ranging from 2-270 Joules. Features and options include external paddles, spoons, disposable pads, 3- and 5-lead ECG, pulse oximetry (SpO_2), built-in 60 mm thermal printer, internal storage of event history and remote synchronization to bedside monitor.
Indications For Use:	The Powerheart ECD defibrillator system is intended to be used by personnel who have been trained in its operation. The Powerheart ECD is indicated for the termination of certain fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and in

	relatively stable patients, ventricular tachycardia. The semi-automatic advisory mode is for use in cardiac arrest in patients of at least 8 years of age. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm. The Powerheart ECD 3-lead and 5-lead ECG monitoring allows for identification or interpretation of cardiac rhythms or dysrhythmias and calculation of heart rate. The Powerheart ECD noninvasive pacing as a therapy is indicated for patients with symptomatic bradycardia or asystole. The Powerheart ECD pulse oximetry is intended for the continuous external monitoring of arterial oxygen saturation and pulse rate and is indicated for use in any patient who is at risk of developing hypoxemia.
Functional and Safety Testing:	Representative samples of the device components underwent system, safety and bench testing on both hardware and software to demonstrate appropriate functional and performance characteristics.
Conclusion:	Based on the results of the testing described above, it is concluded that the Powerheart ECD does not raise any different questions regarding the safety or effectiveness as compared with the predicate device. The Cardiac Science, Inc. Powerheart ECD is substantially equivalent to the Medtronic Physio-Control LIFEPAK 20 in terms of indications for use, features and functions.

2.2. 510(k) Checklist

Traditional 510(k) Premarket Notification Checklist for Class III Device

No.	Item	Included	Location
1	Cover letter clearly identifying submission as "Traditional 510(k)"	Yes	Cover Letter
2	Table of Contents	Yes	TOC
3	Indication for Use	Yes	IFU page
4	Manufacturer name and address	Yes	Section 1
5	Contact person, phone number, fax number	Yes	Section 1
6	Device common name and trade name	Yes	Section 1
7	Establishment registration number	Yes	Section 1
8	Device classification and product code	Yes	Section 1
9	510(k) Summary	Yes	Section 2.1
10	Identification of predicate device	Yes	Section 2.1
11	Truthful and Accurate Statement	Yes	Section 2.4
12	Class III Certification and Summary	Yes	Section 2.5
13	Proposed labeling	Yes	Section 3
14	Description of the device	Yes	Section 4
15	Substantial equivalence comparison	Yes	Section 5
16	Performance testing	Yes	Section 6
17	System Hazard Analysis	Yes	Section 6.1
18	Clinical evaluation	Yes	Section 6.6
19	Biocompatibility data	Yes	Section 7
20	Sterilization information	Yes	Section 8
21	Software documentation	Yes	Section 9
22	Compliance with performance standards	Yes	Section 10

2.3. Premarket Notification Statement

In lieu of a Pre Market Notification Statement, a 510(k) Summary is provided in Section 2.1. of this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 2006

Cardiac Science, Inc.
c/o Mr. Kenneth F. Olson
Chief Technical Officer
5474 Feltl Road
Minnetonka, MN 55343-7982

Re: K052316
Trade Name: Powerheart ECD
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: December 20, 2005
Received: December 21, 2005

Dear Mr. Olson:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Powerheart ECD ™

The Powerheart ECD defibrillator system is intended to be used by personnel who have been trained in its operation.

The Powerheart ECD is indicated for the termination of certain fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and in relatively stable patients, ventricular tachycardia.

The semi-automatic advisory mode is for use in cardiac arrest in patients of at least 8 years of age. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm.

The Powerheart ECD 3-lead and 5-lead ECG monitoring allows for identification or interpretation of cardiac rhythms or dysrhythmias and calculation of heart rate.

The Powerheart ECD noninvasive pacing as a therapy is indicated for patients with symptomatic bradycardia or asystole.

The Powerheart ECD pulse oximetry is intended for the continuous external monitoring of arterial oxygen saturation and pulse rate and is indicated for use in any patient who is at risk of developing hypoxemia.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052316