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K040438

SECTION 16: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

16.1: ADMINSTRATIVE INFORMATION

Name and Address

Submitted by: Cardiac Science Incorporated
5474 Feltl Road
Minnetonka, MN 55343

Contact Person: Kenneth F. Olson
Telephone No.: 952-939-4181
Facsimile No.: 952-939-4191
Email: kolson@cardiacscience.com

Date Prepared: February 16, 2004

16.2: DEVICE INFORMATION

Common or Usual Name: Automatic External Defibrillator

Trade Name: Powerheart® Automatic External Defibrillator G3A

16.3: DEVICE CLASSIFICATION

Classification Name: Automated External Defibrillator
21 CFR 870.5310 MKJ
Device Class: III

16.4: DEVICE DESCRIPTION

The Powerheart® AED G3A is a portable, battery-operated, fully-automatic, low power DC defibrillator. The device is designed to diagnose and monitor the patient's cardiac rhythm and deliver the shock energy as required. The Powerheart® AED device in this submission is equivalent to the current Powerheart® AED and accessories in commercial distribution that was cleared under premarket 510(k) notifications K022929, K011901, K982710 and K031987. The reason for this premarket notification is to introduce a fully –automation version of the device.

16.5: INDICATION FOR USE

The Powerheart® AED G3A is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the Powerheart® AED G3A should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. The therapy should not be delayed to determine the patient's exact age or weight.

16.6: IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Cardiac Science	Powerheart AED	K031987	07/30/2003
Survivalink	FirstSave Biphasic AED	K022929	01/27/2003
Corporation	(renamed Powerheart AED)	K011901	02/01/2002
(Cardiac Science)		K982264	01/25/1999
Medtronic Physio-Control Corp.	LIFEPAK CR PLUS AED	K011144	12/03/2001

16.7: SUBSTANTIAL EQUIVALENCE

The Powerheart® AED G3A covered by this submission is substantially equivalent to other legally marketed automatic external defibrillators. Specifically, the Powerheart® AED G3 that is the subject of this premarket notification is equivalent to the current Powerheart® AED in commercial distribution with the exception of being a fully-automatic AED. The Powerheart AED G3A is substantially equivalent to the Medtronic Physio-Control LIFEPAK CR PLUS fully-automatic AED.

16.8 PERFORMANCE TESTING

The Powerheart® AED G3A was subjected to performance software evaluations in accordance with FDA guidelines and industry standards. The results of the testing showed that the device modifications had no affect on the safety or effectiveness of the device. The Powerheart® AED G3A passed all software tests and was found to perform as intended.

16.9 CONCLUSIONS

Cardiac Science has demonstrated through its evaluation and testing of the Powerheart® AED G3A that the device is equivalent to the current Powerheart® AED and the Physio-Control LIFEPAK CR PLUS AED. The proposed Powerheart® AED G3A is identical with respect to indications for use, technological characteristics, materials, and software algorithm as the current commercially distributed Powerheart® AED. This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K040438
Trade Name: Powerheart® Automatic External Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automatic External Defibrillator
Regulatory Class: III (three)
Product Code: MKJ
Dated: May 21, 2004
Received: May 24, 2004

Dear Mr. Olson:

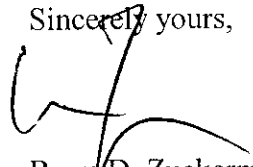
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Powerheart® Automatic External Defibrillator G3A

Indications for Use: The Powerheart® AED G3A is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040438