SEP 10 2009

III. 510(k) Summary

Submitter:	Cardiac Science Corporation 3303 Monte Villa Parkway Bothell, WA 98021-8969
Contact Person:	Beverly Magrane Phone: (425) 402-2365 Fax: (425) 402-2017
Date Prepared:	June 4, 2009
Trade Name:	Powerheart® AED G3 (Model 9390E) Powerheart® AED G3 Automatic (Model 9390A)
Classification Name and Number:	Automated External Defibrillator Class III, 21CFR 870.5310
Product Code:	MKJ
Predicate Device(s):	The Powerheart® AED G3 manufactured by Cardiac Science, Inc is substantially equivalent to the Cardiac Science Powerheart AED G3, ***K052161*** (10/21/2005) and to the FirstSave™ STAR Biphasic™ AED, ***K010214***, (2/22/2001), manufactured by Survivalink Corporation.
Device Description:	The Powerheart® AED G3 and G3 Automatic are portable, battery operated, automated external defibrillators (AED). After applying the AED's electrodes (pads) to the patient's bare chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to press the button and deliver a shock if needed. The AED uses one button and guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators. For the Powerheart AED G3 Automatic, the AED automatically delivers a shock if needed. The Cardiac Science G3 AEDs may be used in conjunction with an adaptor cable that allows the use of AAMI DF-80 compliant electrodes other than the Cardiac

Science brand. This adaptor cable is provided as an accessory to the Cardiac Science AEDs.

Indications For Use:

The Powerheart AED G3 and the Powerheart AED G3 Automatic devices are 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 ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will change automatically and advise the operator to deliver therapy (G3) or automatically deliver the charge (G3 Automatic).

When the patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the device 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.

Functional and Safety Testing:

Representative samples of the device and adapter cables were tested in accordance with the system, safety, functional and performance specifications. All samples successfully passed.

Conclusion:

Based on the results of the testing described above, it is concluded that the modifications to the Powerheart AED do not raise any new questions regarding the safety or effectiveness as compared with the predicate device. The Cardiac Science, Inc. Powerheart AED is substantially equivalent to the Powerheart AED cleared in K052161 and FirstSave STAR Biphasic AED cleared in K010214 in terms of indications for use, features and functions.

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

SEP 10 2009

Cardiac Science Corporation
c/o Ms. Beverly Magrane
Sr. Manager RA/RC
3303 Monte Villa Pkwy.
Bothell, WA 98021

Re: K091943
Trade/Device Name: 9055 Electrode Adapter Cable
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: August 25, 2009
Received: August 27, 2009

Dear Ms. Magrane:

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.

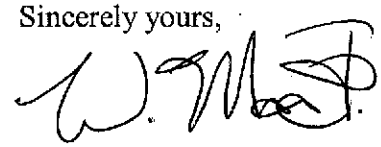
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

Enclosure

K091943

Indications for Use Statement

510(k) Number:

Device Name: Powerheart® AED G3 (Model 9390E), Powerheart® AED G3 Automatic (Model 9390A)

Indications for Use:

The Powerheart AED G3 and the Powerheart AED G3 Automatic devices are 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 ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy (G3) or automatically deliver the charge (G3 Automatic).

When the patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the device 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.

Prescription Use __X__ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091943