OCT 2 1 2005

Premarket Notification (510(k)) Summary

510(k) Number: K052161

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

Common Name: Automated External Defibrillator

Class: III

Submitter's Name: Official Contact: Kenneth F. Olson
Chief Technical Officer
Phone: 952-939-2912
Fax: 952-939-4191

Cardiac Science, Inc.
5474 Feltl Road
Minnetonka, MN 55343-7982

Summary Preparation Date: October 19, 2005

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission for a modification to the Powerheart® AED G3 and Powerheart® AED G3 Automatic devices.

The Powerheart® AED G3 and G3 Automatic devices are portable, battery-operated, automated external defibrillators (AED) indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. The devices were modified to provide enhanced voice prompts.

The modified device is substantially equivalent to the previously cleared Powerheart® AED G3 and Powerheart® AED G3 Automatic devices in intended use, materials, technological characteristics and performance. Validation testing relevant to the enhanced voice prompts further supports a substantial equivalence claim. The collective evidence provides assurance that the modified Powerheart® AED G3 and Powerheart® AED G3 Automatic devices meets the requirements that are considered acceptable for the intended use.

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 the 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 a 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

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

Re: K052161
Trade Name: Powerheart AED G3
Regulation Number: 21 CFR 870.53 10
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: September 20, 2005
Received: September 22, 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,

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

Enclosure

510(k) Number (if known): K052161

Device Name: Powerheart® AED G3, Powerheart® AED G3 Automatic

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.

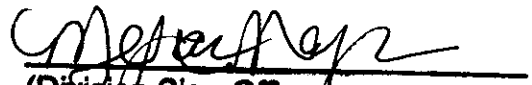
The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy (G3) or automatically deliver the charge (G3 Automatic).

When a 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052161