FEB 12 2014

510(k) Summary

A. Submitter's name, address, telephone number, contact person, and data summary was prepared

Submitter	Cardiac Science Corporation N7 W22025 Johnson Drive Waukesha, WI 53186-1856
Contact Person	Kathleen Roberts Regulatory Affairs Manager Phone: (949) 797-3844 Fax: (949) 797-3801
Date Summary Prepared	September 7, 2012

B. Name of device, including trade name and classification name

Trade/Proprietary Name	Powerheart® G5 AED
Classification Name	Automated External Defibrillator
Classification Number	Class III, 21CFR 870.5310
Product Code	MKJ

C. Identification of the predicate device or legally marketed devices to which substantial equivalence is being claimed

Company	Cardiac Science Corporation
Device	Powerheart® AED G3
Model number	9300A/E, 9390A/E
510(k) number	K102496
Date cleared	June 9, 2011
Device	Defibrillation Electrodes
Model number	9131
510(k) number	K082090
Clearance date	December 12, 2008
Device	Pediatric Attenuated Defibrillation Electrodes
Model number	9730
510(k) number	K022929
Clearance date	September 11, 2002

D. Description of the device

The Powerheart® G5 AED is a portable, battery operated, self-testing defibrillator used to diagnose and treat life threatening ventricular arrhythmias in patients who are unresponsive and not breathing or not breathing normally. This is accomplished by monitoring the patient's ECG and delivering a defibrillation shock if necessary.

The AED is intended to be used by a person designated within a community, locale or building who is the first responder to a medical emergency. This typically includes ambulance, police or fire fighting personnel, emergency response team members, security personnel, and lay persons who have been trained in CPR and in the use of the AED.

The Powerheart® G5 AED guides the user through a rescue using voice or text prompts. Defibrillation pads are used to monitor and defibrillate patients. Adult pads, meant for patients older than 8 years or heavier than 55 lb, are preconnected to the Powerheart G5 AED and placed in two locations on the patient during a rescue. Pediatric pads are connected to the AED when a pediatric patient is involved and meant for use on those patients 8 years or younger, or 55 lb or lighter.

E. Intended use of the device

The Powerheart® Automated External Defibrillator (AED) is intended to be used by persons who have been trained in its operation. The user should be trained in basic life support or other physician-authorized emergency medical response.

An AED is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing or not breathing normally. Post-resuscitation, if the patient 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 a shock, or for an automatic AED, automatically deliver a shock if needed.

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

F. Functional Tests

The Powerheart® G5 AED was subjected to performance hardware and software evaluations in accordance with industry standards. The G5 passed all software and hardware tests and was found to perform as intended.

G. Conclusion

Cardiac Science has demonstrated through evaluation and testing of the Powerheart® G5 AED that the device is equivalent to the Powerheart® AED G3. The proposed device is equivalent with respect to indications for use, technological characteristics, materials, and software algorithm. Based on the results of testing, it is concluded that the Powerheart® G5 AED with Adult Electrodes and Pediatric Electrodes does not raise any new questions regarding the safety or effectiveness as compared with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Cardiac Science Corporation
c/o Ms. Kathleen Roberts
Regulatory Affairs Manager
N7 W22025 Johnson Drive
Waukesha, Wisconsin 53186-1856

Re: K122758
Trade/Device Name: Powerheart G5 AED
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: III
Product Code: MKJ
Dated: November 15, 2013
Received: November 18, 2013

Dear Ms. Roberts:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. 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,

Owen P. Faris -S

for

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

Enclosure

CARDIAC science

Indications for Use

510(k) Number: K122758:

Device Name: Powerheart® G5 AED
Powerheart® G5 Adult Defibrillation Pads
Powerheart® G5 Pediatric Defibrillation Pads

Indications for Use:

The G5 Automated External Defibrillator (AED) is intended to be used by persons who have been trained in its operation. The user should be trained in basic life support or other physician-authorized emergency medical response.

An AED is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing or not breathing normally. Post-resuscitation, if the patient 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 a shock, or for an automatic AED, automatically deliver a shock if needed.

When a patient is a child up to 8 years of age, or up to 25kg (55 lbs), the AED should be used with the Pediatric Defibrillation Pads. 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 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen R. Faris -S
Date: 2014.02.12 08:34:30 -05'00'