K022929

JAN 2 7 2003

SECTION 17. 510K 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.

17.1 Adminstrative Information

Name and Address

Submitted by: Cardiac Science Incorporated
16931 Millikan Ave
Irvine, CA 92606

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

Date Prepared: January 15, 2003

17.2 Device Information

Common or Usual Name: Automated External Defibrillator

Trade Name: Powerheart® AED Model 9200/9210
Use with Models 9730 Pediatric Attenuated Defibrillation Electrode.

17.3 Device Classification

Classification Name: Automatic External Defibrillator
21 CFR 870.1025 MKJ
Device Class: III

Multifunctional Electrocardiograph Electrode
21 CFR 870.2360 MLN
Device Class: III

17.4 Device Description

The Powerheart AED is a portable, battery-operated, semi-automatic, low power DC defibrillator. It will diagnose the patient's cardiac rhythm and advise the operator if and

when to deliver the shock energy.

The Model 9730 Pediatric Attenuated Defibrillation Electrodes are specially designed electrodes for operation with only the Powerheart AED biphasic waveform.

The Model 9730 pediatric electrode has been designed to reduce the energy delivered to the patient from a standard biphasic defibrillation waveforms generated by the Powerheart AED to levels applicable for use on children and infants up to 8 yrs of age or weighing less than 55 lbs (25 kg). This is performed though the use of an attenuating circuit that absorbs the excess energy during defibrillation without adversely affecting the electrode's performance during ECG monitoring.

The Model 9730 pediatric electrode is designed as a single use device and is intended for use to defibrillate and monitor of children.

17.5 Indication for use

The Powerheart AED is intended for 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 tachyarrythmia 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 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.

17.6 Identification of Predicate Device

Company	Device	510(k) #	Date Cleared
Agilent Technologies (Philips Medical System)	FR2 AED with Model M3870A Pediatric Attenuated Defibrillation Electrodes.	K003819	May 2, 2001
Survivalink (Wholly Owned Subsidiary of Cardiac Science)	Powerheart AED	K011901	Feb 1, 2002

17.7 Substantial Equivalence

The Powerheart AED with the Model 9730 Pediatric Attenuated Defibrillation Electrodes covered by this submission is substantially equivalent to other legally marketed AED and pediatric attenuated defibrillation electrodes. Specifically, the Powerheart AED with the Model 9730 electrode is substantially equivalent to Agilent Technologies (acquired by Philips Medical System) FR2 AED with model M3870A pediatric attenuated defibrillation cleared under premarket 510(k) notification, K0038198 on May 2, 2002.

17.8 Performance Data

Performance testing was conducted to verify that the Powerheart AED with the Model 9730 Pediatric Attenuated Defibrillation Electrodes has been designed in accordance with industry standards ANSI AAMI DF-39. In addition, biocompatibility assessments were conducted on the components that come into contact with the patient's skin. The Powerheart AED with the Model 9730 electrodes were found to perform as intended.

17.9 Conclusions

Cardiac Science has demonstrated through its evaluation and testing of the Powerheart AED with the model 9730 Pediatric Attenuated Defibrillation Electrodes that the device is equivalent to the predicate device with respect to intended use, technological characteristics, materials, function and safety and effectiveness.

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

JAN 2 7 2003

Cardiac Science Incorporated
Mr. Kenneth Olson
Chief technology Officer
16931 Millikan Avenue
Irvine, CA 92606

Re: K022929
Trade/Device Name: Powerheart AED Model 9200/9210 with Model 9730 Pediatric Attenuated Defibrillation Electrodes
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm.
Regulatory Class: Class III
Product Code: MKJ, MLN
Dated: December 13, 2002
Received: December 16, 2002

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

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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: K022929

Device Name: Powerheart AED Model 9200/9210 with Model 9730 Pediatric Attenuated Defibrillation Electrodes

Indications for Use:

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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022929

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)