

K970741

SECTION 21: 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.

OCT 16 1997

21.1 SUBMITTER INFORMATION

- a. **Company Name:** Cardiac Science, Inc.
- b. **Company Address:** 1176 Main Street, Suite C
Irvine, CA 92614
- c. **Company Phone:** (714) 587-0357
Company facsimile: (714) 951-7315
- d. **Contact Person:** Raymond W. Cohen
President and Chief Executive Officer
Cardiac Science, Inc.
- f. **Date Summary Prepared:** February 24, 1997

21.2 DEVICE IDENTIFICATION

- a. **Trade/Proprietary Name:** Powerheart® Automatic External
Cardioverter Defibrillator (AECD®)
- b. **Classification Name:** Automatic External Defibrillator

21.3 IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Laerdal	Heartstart 1000	K883341	September 12, 1988

21.4 DEVICE DESCRIPTION

The Powerheart Automatic External Cardioverter Defibrillator monitors a patient's cardiac electrical activity and treats ventricular tacharrhythmias. The Powerheart senses the ECG signal using one set of electrodes, and delivers cardioversion and/or defibrillation energy through another set of electrodes. The cardioversion/defibrillation electrodes are positioned on the patient either transchest or anterior-posteriorly. The Powerheart uses a combination of rate and (if programmed by the physician) morphology to determine the presence of shockable arrhythmias.

When a shockable arrhythmia is detected, the system selects the appropriate (i.e., as pre-set by the patient's physician) electrical countershock for delivery attempt restoring normal cardiac rhythm. Should the arrhythmia continue, the Powerheart will proceed with subsequent delivery of energy (as pre-set by the patient's physician) after each additional evaluation and charging period. Depending upon the physician programmed parameters, the Powerheart may deliver a maximum of eight pulse sequences. Then, the Powerheart will deliver no further therapy automatically until 60 seconds of consecutive non-shockable rhythm is presented or the device is reset manually.

21.5 SUBSTANTIAL EQUIVALENCE

The Cardiac Science Powerheart AECD is substantially equivalent to other automatic external defibrillators currently in commercial distribution by Laerdal in terms of intended use of achieving a safe and accurate detection and treatment of ventricular tachyarrhythmia of in-hospital patients who are at risk of Sudden Cardiac Arrest.

The fundamental technical characteristics are similar to those of the predicate device and are listed on the comparison chart provided in this 510(k) submission.

21.6 INTENDED USE

The Powerheart AECD system is intended to acquire the electrocardiograph rhythm for the detection of, and to provide treatment for ventricular tachyarrhythmias of in-hospital patients who are at risk of Sudden Cardiac Arrest.

21.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed device is provided within this submission.

21.8 PERFORMANCE DATA

The Powerheart AECD was mechanically and functionally tested to demonstrate conformance with applicable section of the ANSI/AAMI voluntary standard DF39-1993 for Automatic External Defibrillators and Remote Control Defibrillators, the ANSI/AAMI Standard ES1-1993, Safe Current Limits for Electromedical Apparatus, and UL544. The testing demonstrated that the device performs according to its specifications. Documentation to support this performance evaluation has been provided within this submission.

Software for the Powerheart AECD was developed and tested in compliance with the FDA Reviewer Guidance for Computer Controlled Device. The testing demonstrated that the software performs according to its specifications. Documentation to support this performance evaluation has been provided within this submission.

Data from a clinical investigation of the Powerheart AECD demonstrated that the device is able to safely and effectively treat ventricular tachyarrhythmias according to the device specifications. Documentation to support this performance evaluation has been provided within this submission.

21.9 510(K) CHECKLIST

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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT 16 1997

• Mr. Raymond W. Cohen
President and CEO
Cardiac Science, Inc.
1176 Main Street
Building "C"
Irvine, California 92614

Re: K970741
Powerheart® Automatic External Cardioverter
Defibrillator
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: July 17, 1997
Received: July 18, 1997

Dear Mr. Cohen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note:

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this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

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Please be advised that, in the future, FDA may require postmarket surveillance of this device under the authorities granted under section 522 of the Federal Food, Drug and Cosmetic Act. This issue is currently under consideration by FDA and you will be notified of our decision in writing.

Sincerely yours,

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Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

INDICATION FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: Powerheart® Automatic External Cardioverter Defibrillator
(AECED)®

Indications For Use: The Powerheart® Automatic External Cardioverter Defibrillator (AECED)® system is intended to acquire the electrocardiograph rhythm for the detection of, and to provide treatment for, ventricular tacharrhythmias of in-hospital patients who are at risk of Sudden Cardiac Arrest.

(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, Respiratory,
and Neurological Devices
510(k) Number K970741

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)