

K982710

AUG 10 1998

Attachment D

**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.

**Submitter Information**

- a. Company Name: Cardiac Science, Inc.
- b. Company Address: 1176 Main Street, Suite C
- c. Company Phone: (949) 587-0357
- d. Company Facsimile: (949) 951-7315
- e. Contact Person: Stan Tillman, RAC, CQM, CQE, CQA  
Director of Regulatory Affairs and Quality Assurance
- f. Date Prepared: July 16, 1998

**Device Identification**

- a. Trade/Proprietary Name: Automatic External Cardioverter Defibrillator (AECD)<sup>®</sup>  
Arrhythmia Detection Software<sup>®</sup>
- b. Classification Name: Defibrillators, Automatic, External

**Identification of Predicate Device**

<u>Company</u>	<u>Unmodified Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Cardiac Science	Powerheart <sup>®</sup> AECD <sup>®</sup>	K970741	Oct. 16, 1997

**Device Description**

The Cardiac Science, Inc., AECD Arrhythmia Detection Software is simply the "arrhythmia detector" software program which is the primary component of the unmodified Powerheart AECD (K970741).

This is a computer software program which analyzes the patient's ECG waveform and determines whether the patient exhibits a non-shockable or shockable rhythm, based upon the physician programmed parameters for the patient.

This software is not a standalone medical software device. The AECD Arrhythmia Detection Software will be marketed as a component intended to enhance the performance of defibrillators and/or patient monitors by adding this functionality to those products.

**Substantial Equivalence.**

The AECD Arrhythmia Detection Software is substantially equivalent to the unmodified Powerheart AECD cleared under 510(k) K970741 on October 16, 1997. The software which is the subject of this submission is virtually unchanged from the previously cleared version. The

difference between this submission and the previously cleared device is that this submission is for the arrhythmia detection software only and does not include hardware.

**Intended Use**

The AECD Arrhythmia Detection Software, when loaded into the Powerheart AECD 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.

**Performance Data**

The AECD Arrhythmia Detection Software is the same proprietary arrhythmia detector 510(k) cleared in the Powerheart AECD submission (K970741). The detector was subjected to pre-clinical, clinical and software validation testing as the primary component of the 510(k) cleared Powerheart AECD submission (K970741). Bench testing was performed using standard ECG databases prior to the clinical trials. Testing demonstrated that the software performs according to its specifications. Documentation to support the performance evaluation, including clinical data resulting from IDE Application G920078, was provided in the Powerheart AECD submission (K970741).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 10 1998

Mr. Stan Tillman  
Cardiac Science, Inc.  
1176 Main Street  
Building "C"  
Irvine, CA 92614

Re: K982710  
AECD® Arrhythmia Detection Software®  
Regulatory Class: III (three)  
Product Code: 74 MKJ  
Dated: August 3, 1998  
Received: August 4, 1998

Dear Mr. Tillman:

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 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). 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.

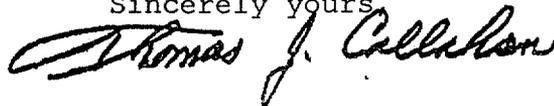
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Stan Tillman

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/dsma/dsmamain.html>".

Sincerely yours



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

Enclosure

Attachment C

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**Indications for Use**

510(k) Number (if known): K982710

Device Name: AECD® Arrhythmia Detection Software®

**Indications for Use:**

The AECD Arrhythmia Detection Software, when loaded into the Powerheart AECD 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.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Mark Kramer*  
*Prescription Use ✓*

(Optional Format 3-10-98)