K082090

III. 510(k) Summary

Submitter:	Cardiac Science Corporation 3303 Monte Villa Parkway Bothell, WA 98021-8969 DEC 12 2008
Contact Person:	Beverly Magrane Phone: (425) 402-2365 Fax: (425) 402-2017
Date Prepared:	December 10, 2008
Trade Name:	9131 Defibrillation Electrode 9133 Defibrillation Electrode
Common Name:	External defibrillation electrodes
Classification Name and Number:	Automated External Defibrillator accessory (Electrode) Class III, 21CFR 870.5310
Product Code:	MKJ
Predicate Device(s):	The 9131 and the 9133 Defibrillation Electrodes manufactured by Cardiac Science, Inc are substantially equivalent to the Survivalink-9130 Defibrillation Electrode, ***K971149***, (6/23/1997)
Device Description:	The model 9131 and the 9133 Defibrillation Electrodes consists of a pair (2 each) of hydrogel polymeric self adhesive electrode pads of equal dimension. The outer dimension for each pad is 4.88in (12.4cm) by 4.88in (12.4 cm). Each electrode pad has a conductive hydrogel polymeric area of at least $50cm^2$ to comply with the AAMI DF-80 (AAMI DF-39) specifications. The total surface area of the two electrodes is greater or equal to $150cm^2$. The electrodes pads are packaged in such a way that the two conductive hydrogel surfaces are in electrical contact. This feature enables the Cardiac Science AED to run diagnostic checks on the electrodes by checking the inter-electrode impedance when the electrode package is connected to and stored in the device. The Cardiac Science 9133 defibrillation electrodes may be used in conjunction with adaptor cables that allow the electrodes to be used with compliant AEDs other than the Cardiac Science brands. These adaptor cables are

	provided as accessories to the Cardiac Science defibrillation electrodes.
Indications For Use:	Cardiac Science 9131 Defibrillation Electrodes are single use and intended to be used in conjunction with Cardiac Science automatic external defibrillators (AED) to monitor and deliver defibrillation energy to the patient. Cardiac Science 9133 Defibrillation Electrodes are single use and intended to be used in conjunction with compatible automatic external defibrillators (AED) from Zoll or Physio-Control to monitor and deliver defibrillation energy to the patient, via brand-specific adapters. The brand-specific adapters are available for the AEDs specified in the product labeling. The electrodes are intended for short term use (<8 hours) and must be used before the expiration date listed on the packaging. The AED electrodes are used for emergency treatment of cardiac arrest patients over 8 years of age or greater than 55 pounds. The user assesses the patient's condition and confirms that the patient is unconscious, pulseless and is not breathing prior to applying the electrodes to the skin.
Functional and Safety Testing:	Representative samples of the electrodes were tested in accordance with the system, safety, functional and performance specifications. All samples successfully passed.
Conclusion:	Based on the results of the testing described above, it is concluded that the modifications to the Cardiac Science, Defibrillation Electrode do not raise any new questions regarding the safety or effectiveness as compared with the predicate device. The Cardiac Science 9131 and the 9133 Defibrillation Electrodes are substantially equivalent to the Defibrillation Electrode cleared in K971149 in terms of indications for use, features and functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2008

Cardiac Science Corporation
c/o Ms. Beverly Magrane
Sr. Manager RA/RC
3303 Monte Villa Parkway
Bothell, WA 98021-8969

Re: K082090
Trade/Device Name: 9131 and 9133 Defibrillation Electrode
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: November 10, 2008
Received: November 12, 2008

Dear Ms. Magrane:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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 Statement

510(k) Number: K082090

Device Name: 9131 Defibrillation Electrode

Indications for Use:

Cardiac Science 9131 Defibrillation Electrodes are single use and intended to be used in conjunction with Cardiac Science automatic external defibrillators (AED) to monitor and deliver defibrillation energy to the patient.

Cardiac Science 9133 Defibrillation Electrodes are single use and intended to be used in conjunction with compatible automatic external defibrillators (AED) from Zoll or Physio-Control to monitor and deliver defibrillation energy to the patient, via brand-specific adapters. The brand-specific adapters are available for the AEDs specified in the product labeling.

The electrodes are intended for short term use (<8 hours) and must be used before the expiration date listed on the packaging.

The AED electrodes are used for emergency treatment of cardiac arrest patients over 8 years of age or greater than 55 pounds. The user assesses the patient's condition and confirms that the patient is unconscious, pulseless and is not breathing prior to applying the electrodes to the skin.

Prescription Use __X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082090