AUG 1 4 2002

AccessAED Automatic External Defibrillator

510(k) Summary

Submitter's Name and Address: Access CardioSystems
150 Baker Avenue Extension
Concord, MA 01842

Contact Person: David Barash, M.D.
978-371-4985

Device Name: AccessAED™ Automatic External Defibrillator

Classification: Automatic External Defibrillator
Class III
21 CFR 870.1025

Predicate Devices:

Heartstream FR2 AED (K003565)
Physio-Control Biphasic LifePak 500 (K983393)
Zoll M Series Biphasic Defibrillator (K990762)

Indications for Use:

The AccessAED™ semi-automatic external defibrillator is intended to be used for the treatment of cardiac arrest. The AccessAED should be applied to victims who are unconscious, with absence of breathing, and absence of a detectable pulse.

The AccessALS™ has the capability for manual operation by a user trained in advanced cardiac life support (ALS). In manual mode, the user can select the time for rhythm analysis, device charging, energy level, synchronization, and shock delivery. In the semi-automatic mode, AccessALS functions identically to the AccessAED.

The AccessAED and AccessALS are not currently indicated for children less than 8 years old (less than approximately 25 kgs. or 55 lbs.) The use of the AccessAED and AccessALS should be reviewed after each event and all adverse events should be reported.

AccessAED Automatic External Defibrillator
Contraindications for Use

The AccessAED™ semi-automatic external defibrillator is contraindicated for patients who:

- are conscious
- are breathing
- have a detectable pulse

Training Requirements

The Access AED is intended for use by emergency responders specifically trained in the operation of the Access AED. Users should have, at the minimum, BCLS/AED training equivalent to that recommended by the American Heart Association or American Red Cross or training in other physician-authorized emergency medical response.

Device Description:

The AccessAED™ Automatic External Defibrillator has been designed specifically for the treatment of ventricular tachyarrhythmias in cardiac arrest. The AccessAED delivers a high-energy 200 or 360J biphasic waveform to patients in cardiac arrest resulting from ventricular fibrillation or high rate ventricular tachycardia.

The AccessAED™ features include:

- LED ready indicator
- power button
- shock delivery button
- LCD display with text messaging and ECG display option
- defibrillation pads housed in a tray for rapid application to patient
- disposable Lithium battery system
- rhythm analysis software
- energy selection button (manual mode only)
- synchronization button (manual mode only)
- analysis button (manual mode only)
- charge button (manual mode only)

When the AccessAED™ algorithm software identifies a rhythm that requires defibrillation, the device charges to the required energy level algorithm (200 J or 360 J) as dictated by the internal algorithm. When the device indicates a full charge and instructs the operator to push the shock button, the operator delivers the shock by pressing the shock delivery button.

AccessAED Automatic External Defibrillator
Substantial Equivalence:

The AccessAED™ Automatic External Defibrillator is substantially equivalent to other marketed devices delivering a biphasic waveform, specifically the Zoll M Series Biphasic Defibrillator and the Physio-Control Biphasic Lifepak 500, and the HeartStream FR2. The biphasic waveform in the AccessAED™ delivers a biphasic waveform with characteristics and results similar to both the predicate devices. The operation of this device and any other subtle or minor differences between this device and its predicate devices do not raise any new questions regarding safety and efficacy.

Performance Data:

Performance test data is submitted with the 510 (k) documents. These data demonstrate that the device complies with the applicable sections of AAMI DF2-1989 (Cardiac Defibrillator Devices) and AAMI DF39-1993 (Automatic External Defibrillators). The device was developed under design control, and the hardware was tested in accordance with established industry standards.

The efficacy of the biphasic truncated exponential waveform in this device was demonstrated in a study of swine. The results of this study demonstrate the substantial equivalence of the AccessAED biphasic truncated exponential waveform. Though there are minor differences in the characteristics of the AccessAED biphasic waveform and its predicate device waveforms, these differences do not raise new questions of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2002

David Barash, M.D.
Executive Vice President and Medical Director
Access CardioSystems, Inc.
150 Baker Avenue Extension, Suite 108
Concord, MA 01742

Re: K020984
Trade Name: AccessAED™ Semi-Automatic External Defibrillators
(Models Access AED™ and Access ALS™)
Regulation Number: 21 CFR 870.1025, 21 CFR 870.5300
Regulation Name: Automatic External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ, LDD
Dated: July 2, 2002
Received: July 30, 2002

Dear Dr. Barash:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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

510(k) Number (if known): K020984

Device Name: Access AED

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)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K020984