ZOLL
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K110154

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A

510(k) Summary:

Submitter's Name and Address:

FEB 17 2011

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Eileen M. Boyle
(978) 421-9171

Date Summary Prepared:

January 14, 2011

Device:

ZOLL AED Plus with 2010 AHA Guidelines Software Update

Classification:

Automatic External Defibrillators: Class III (21 CFR 870.5310)

Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)

Description:

The ZOLL AEDPlus was cleared by the agency under 510(k) application K033474. The device is a lightweight, portable, battery-powered semi-automatic external defibrillator that uses voice prompts and visual icons to guide a user through a cardiac arrest rescue. The device utilized the ZOLL Rectilinear Bi-Phasic defibrillation waveform. The device is designed to be used by trained responders for the treatment of cardiac arrest.

When connected with ZOLL AED Plus defibrillation electrodes to a patient, the device will analyze the electrocardiographic (ECG) rhythm of the patient and detect whether the rhythm is shockable or non-shockable. If the device detects a shockable rhythm, the device charges the capacitor, enables the treatment button and prompt the user to deliver the defibrillation energy to the patient. If the device detects a non-shockable rhythm, the device will prompt the user to begin CPR. The electrodes used with the device incorporates an accelerometer that mesures the depth of CPR compressions. This information is used by the device to provide feedback to the user and encourage

the user to administer CPR in compliance with the American Heart Association (AHA) Guidelines. The device provides feedback in the form of a metronome (to encourage the proper CPR frequency of 100 compressions per minute) and a visual depth indicator on the display (to encourage the recommended compression depth).

The recent American Heart Association (AHA) 2010 Guidelines (see attached) changed it's previous recommendation for a minimum depth of CPR compressions from 1.5 inches to a depth of at least 2.0 inches. The Guidelines also advise caregivers to allow full recoil of the patient's chest during CPR. As a result we are modifying the device's software from it's current CPR depth monitoring of 1.5" to at least 2.0" and provide an additional text user prompt to remind users to fully release the patient's chest during CPR.

The specific changes include:

- changing the depth indicator on the device screen from 1.5 inches to 2.0 inches
- prompting the user to "push harder" when compressions are less than 2.0 inches instead of less than 1.5 inches in the previous release
- adding a text prompt to remind the user to "Fully Release" the patient's chest during CPR

Intended Use:

Use the AED when a suspected cardiac arrest victim has an apparent LACK OF CIRCULATION as indicated by:

- Unconsciousness and
- Absence of normal breathing and
- Absence of a pulse or signs of circulation

When a victim is less than 8 years of age, or weighs less thank 55 lbs (25kg), the ZOLL AED Plus should be used with the ZOLL AED Plus Pediatric Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

Substantial Equivalence:

The features and functions of the proposed ZOLL AED Plus (with 2010 AHA Guidelines for CPR software update) are substantially equivalent to the currently marketed ZOLL AED Plus (K033474, cleared for use on 5/21/2004).

Comparison of Technological Characteristics

The technological characteristics of the proposed ZOLL AED Plus (with 2010 AHA Guidelines software update) are substantially equivalent to the currently marketed ZOLL AED Plus (K033474, cleared for use on 5/21/2004).

Performance Testing:

Extensive performance testing ensures that the ZOLL AED Plus (with 2010 AHA Guidelines software update) performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications. Safety testing assures that the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL AED Plus (with 2010 AHA Guidelines software update) demonstrates that its features and functions are substantially equivalent to those of the indicated commercially distributed predicate device with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Eileen M. Boyle
Regulatory Affairs Specialist
Zoll Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105

FEB 17 2011

Re: K110154
Trade/Device Name: Zoll AED Plus with 2010 AHA Guidelines Software Update
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: January 14, 2011
Received: January 19, 2011

Dear Ms. Boyle:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

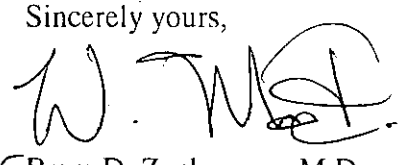
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K110654

Device Name: **ZOLL AED Plus**

Use the AED when a suspected cardiac arrest victim has an apparent LACK OF CIRCULATION as indicated by:

- Unconsciousness and
- Absence of normal breathing and
- Absence of a pulse or signs of circulation

When a victim is less than 8 years of age, or weighs less thank 55 lbs (25kg), the ZOLL AED Plus should be used with the ZOLL AED Plus Pediatric Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110654