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K110526

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

510(k) Summary:

Submitter's Name and Address:

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

Contact Person:

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(978) 421-9655, Ext. 9171

Date Summary Prepared:

February 11, 2011

Device:

ZOLL AED Pro® with 2010 AHA Guidelines Software Update

Classification:

Defibrillator, Low-energy – DC: Class III (21 CFR 870.5310)

Automatic External Defibrillators have been considered Class III devices by FDA.

Cardiac Monitors (including Cardiotachometers and Rate alarms):
Class II (21 CFR 870.2300)

Description:

The ZOLL AED Pro® is a portable, battery powered automated external defibrillator (AED) that uses voice prompts and visual messages to provide feedback to a user attempting a cardiac arrest rescue. The AED Pro acquires and analyzes an adult or pediatric patient's ECG signal and, if a shockable rhythm is detected, recommends delivery of a defibrillation shock via voice and visual prompts.

The recent 2010 American Heart Association Guidelines for CPR and ECC changed previous recommendations from 1.5"-2.0" inches compression depth to a depth of at least 2.0". The Guidelines also advise caregivers to allow full recoil of the patient's chest during CPR. As a result, we are proposing modifying the device's software to prompt caregivers to perform CPR in accordance with the new AHA guidelines.

Description of Software Changes

The ZOLL AED Pro software, which currently supports the 2005 American Heart Association Guidelines for CPR and ECC, has been revised to optionally support the 2010 American Heart Association Guidelines for CPR and ECC. The specific changes include:

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- 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 rescuer to "Fully Release" the patient's chest during CPR

Intended Use

The AED Pro unit is intended to defibrillate victims of ventricular fibrillation or pulseless ventricular tachycardia, for ECG monitoring, and for CPR monitoring of patients. The CPR monitoring function provides a metronome designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a compression depth of at least 2 inches (5 cm) for adult patients.

Indications for Use

Use of the device for defibrillation is indicated on victims of cardiac arrest with apparent ***lack of circulation*** as indicated by

- Unconsciousness
- Absence of breathing, and
- Absence of pulse and other signs of circulation.

When the victim is less than 8 years old or weighs less than 55 lb. (25 kg), use ZOLL ***pedi•padz®*** **II** pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

The device is also intended for use when ECG monitoring is indicated to evaluate the patient's heart rate or ECG morphology.

Contraindications for Use
Defibrillation

K110526

Never use the AED Pro unit for defibrillation when the patient

- Is conscious
- Is breathing, or
- Has a detectable pulse or other sign of circulation.

CPR Monitoring
The CPR monitoring function is not intended for use on patients under 8 years of age.

Intended Users
In semiautomatic mode, the AED Pro unit is intended to be used by rescuers and emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the operator controls delivery of shocks to the patient. In manual mode, the AED Pro unit is intended to be used only by qualified medical personnel trained in Advanced Life Support skills.

In ECG monitoring mode, the AED Pro unit is intended to be used by personnel who are qualified by training in the use of the AED Pro device, basic life and/or advanced life support, or other physician-authorized emergency medical training.

Substantial Equivalence:

The features and functions of the proposed ZOLL AED Pro (with 2010 AHA Guidelines software update) are substantially equivalent to the currently marketed ZOLL AED Pro (K041892, cleared for use on 2/4/2005).

Comparison of Technological Characteristics

The technological characteristics of the proposed ZOLL AED Pro (with 2010 AHA Guidelines software update) are substantially equivalent to the currently marketed ZOLL AED Pro (K041892, cleared for use on 2/4/2005).

Performance Testing:

Extensive performance testing ensures that the ZOLL AED Pro Defibrillator meets all of its functional requirements and performance specifications.

Conclusion

Performance testing of the ZOLL AED Pro Defibrillator demonstrates that its features and functions are substantially equivalent to that of the indicated commercially distributed predicate devices 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

ZOLL Medical Corporation
c/o Mr. Chuck Kolifrath
Regulatory Affairs Manager
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105

MAR 25 2011

Re: K110526
Trade/Device Name: ZOLL AED Pro with 2010 AHA Guidelines
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: January 26, 2011
Received: February 24, 2011

Dear Mr. Kolifrath:

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): K110526

Device Name: ZOLL AED Pro with 2010 AHA Guideline Update

Indications for Use
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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)

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110526