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FEB 17 2011

K110168

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

510(k) Summary:

Submitter's Name and Address:

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Contact Person:

Eileen M. Boyle
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Date Summary Prepared: January 14, 2011

Device:

ZOLL E Series® with 2010 AHA Guidelines Software Update

Classification:

Defibrillators, Automatic, External, Class III (21 CFR Part 870.5310)
Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)

Description:

The ZOLL E Series, reviewed and cleared under 510(k) K042007 and K062177, is a portable device designed to be used by trained emergency care personnel in both the hospital and pre-hospital arenas. The ZOLL E Series is designed for all emergent care situations and provides multi-parameter monitoring of patients in critical care and transport. The E Series combines defibrillation, ECG monitoring, noninvasive transcutaneous pacing, pulse oximetry, end tital CO_2, 12-Lead ECG monitoring, non-invasive blood pressure measurement, data printing and recording and CPR feedback in a single instrument.

The recent American Heart Association (AHA) 2010 Guidelines (see attached) changed it's previous recommendation for depth of CPR compressions from 1.5 inches to 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 proposing 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 ZOLL E Series software, which currently supports the American Heart Association's (AHA) Guidelines for CPR 2005, has been revised to optionally support the AHA's Guidelines for CPR 2010. The specific changes include:

- Adding support, in the form of a configuration option, for a minimum CPR target compression depth of at least 2.0 inches (AHA Guidelines for CPR 2005 specified a minimum compression depth of at least 1.5 inches.) as described in Section 7 of the Operator's Guide included in Attachment 11-1.

- Modifying the reference markers associated with the displayed CPR compression bargraph when the CPR target compression depth is configured for 2.0 inches.

- Adding an optional informational message to remind the user to release their hands from the chest between compressions in order to allow the chest to recoil. When the E Series is configured to display this new message, the message FULLY RELEASE will be displayed every 45 seconds, for 5 seconds, as long as CPR compressions are detected.

Substantial Equivalence:

The features and functions of the proposed ZOLL E Series (with 2010 AHA Guidelines software update) are substantially equivalent to the currently marketed ZOLL E Series (K042007, cleared for use on 4/7/2005 and K062177, cleared for use on 12/13/2006)

Defibrillator Function

The E Series products contain a DC defibrillator capable of delivering up to 200 joules of energy. It may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing refer-ence. The unit uses paddles or disposable, pre-gelled, MFE Pads for defibrillation.

The E Series products must be prescribed for use by a physician or medical advisor of an emergency response team.

Intended Use — Manual Operation

Use of the E Series products in the Manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by these three conditions:

- Unconsciousness
- Absence of breathing, and
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

In Manual mode, the E Series unit may also be used for synchronized cardioversion to terminate atrial fibrillation (AF) or ventricular tachycardias (VT) by using the R-wave of the patient's ECG as a timing reference. A qualified physician must decide when synchronized cardioversion is appropriate.

The Advisory function should be used to confirm ventricular fibrillation and wide complex ventricular tachycardia (greater than 150 beats per minute) in patients meeting the three conditions indicating lack of circulation (previously listed).

Intended Use — Semiautomatic Operation (AED)

The E Series AED unit is designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

Use of the device in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation.

Specifications for the ECG rhythm analysis function are provided at the end of this section.

Intended Use — CPR Monitoring

The CPR monitoring function provides visual and audio feedback 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 minimum compression depth of at least 1.5 (3.8 cm) or 2.0 inches (5.0 cm), depending on the configuration, for adult patients.

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

Contraindications for Semiautomatic Operation

Do not use the unit's AED function on patients under 8 years of age.

The rhythm analysis function may not reliably identify ventricular fibrillation in the presence of an implanted pacemaker. Inspection of the electrocar-diogram and clinical evidence of cardiopulmonary arrest should be the basis for any treatment of patients with implanted pacemakers.

Do not use the rhythm analysis function during patient movement on a stretcher or in an ambulance or other conveyance. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement of the stretcher or vehicle prior to analyzing the ECG. If you are using the device in an emergency vehicle, bring the vehicle to a halt before activating the analysis function.

Defibrillator Complications

Inappropriate defibrillation or cardioversion of a patient (e.g., with no malignant arrhythmia) may precipitate ventricular fibrillation, asystole, or other dangerous arrhythmias.

Defibrillation without proper applica-tion of electrode pads or paddle electrolyte gel may be ineffective and cause burns, particularly when repeated shocks are necessary. Erythema or hyperemia of the skin under the paddles or MFE Pads often occurs; this effect is usually enhanced along the perimeter of the paddle or electrode. This reddening should diminish substantially within 72 hours.

Defibrillator Output Energy

The E Series products may deliver up to 200 joules into a 50 ohm impedance. The energy delivered through the chest wall, however, is determined by the patients transthoracic impedance. An adequate amount of electrolyte gel must be applied to the paddles and a force of 10-12 kilograms (22-26.4 lbs) must be applied to each paddle in order to minimize this impedance. If MFE pads are used, make sure that they are properly applied.

External Pacemaker Function (Pacer version only)

Some E Series products may include an optional transcutaneous demand pacemaker consisting of a pulse generator and ECG sensing circuitry. Non-invasive Transcutaneous Pacing (NTP) is an established and proven technique. This therapy is easily and rapidly applied in both emergency and non-emergency situations when temporary cardiac stimulation is indicated.

Proper operation of the device, together with correct electrode place-ment, is critical to obtaining optimal results. Every operator must be thoroughly familiar with these operating instructions.

The output current of the pacemaker is continuously variable from 0 to 140 mA. The rate is continuously variable from 30 to 180 pulses per minute (ppm).

The pacing output pulse is delivered to the heart by specially designed ZOLL MFE Pads placed on the back and the precordium.

The characteristics of the output pulse, together with the design and placement of the electrodes, minimize cutaneous nerve stimulation, cardiac stimulation threshold currents, and reduce discomfort due to skele-tal muscle contraction.

The unique design of the E Series products allow clear viewing and interpretation of the electrocardiogram (ECG) on the display without offset or distortion during external pacing.

Intended Use — Pacemaker

This product may be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

Note: This device must not be connected to internal pacemaker electrodes.

The purposes of pacing include:

- **Resuscitation from standstill or bradycardia of any etiology**

  Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, b-blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other tempo-rary electrodes.

- **As a standby when standstill or bradycardia might be expected**

  Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

- **Suppression of tachycardia**

  Increased heart rates in response to external pacing often suppress ventricular ectopic activity and may prevent tachycardia.

Pacemaker Complications

Ventricular fibrillation does not respond to pacing and requires immediate defibrillation. Therefore, the patient's dysrhythmia must be determined immediately, so that you can employ appropriate therapy. If the patient is in ventricular fibrillation and defibrillation is successful but cardiac standstill (asystole) ensues, you should use the pacemaker.

Ventricular or supraventricular tachycardias may be interrupted with pacing but in an emergency or during circulatory collapse, synchronized cardioversion is faster and more certain. (See "Synchronized Cardioversion" on page 6-1).

Electromechanical dissociation may occur following prolonged cardiac arrest or in other disease states with myocardial depression. Pacing may then produce ECG responses without effective mechanical contractions, and other treatment is required.

Pacing may evoke undesirable repetitive responses, tachycardia, or fibrillation in the presence of generalized hypoxia, myocardial ischemia, cardiac drug toxicity, electrolyte imbalance, or other cardiac diseases.

Pacing by any method tends to inhibit intrinsic rhythmicity. Abrupt cessation of pacing, particularly at rapid rates, can cause ventricular standstill and should be avoided.

Noninvasive Temporary Pacing may cause discomfort of varying intensity, which occasionally can be severe and preclude its continued use in conscious patients.

Similarly, unavoidable skeletal muscle contraction may be troublesome in very sick patients and may limit continuous use to a few hours. Erythema or hyperemia of the skin under the MFE Pads often occurs; this effect is usually enhanced along the perimeter of the electrode. This reddening should substantially lessen within 72 hours.

There have been reports of burns under the anterior electrode when pacing adult patients with severely restricted blood flow to the skin. Prolonged pacing should be avoided in these cases and periodic inspection of the underlying skin is advised.

There are reports of transient inhibition of spontaneous respiration in unconscious patients with previously available units when the anterior electrode was placed too low on the abdomen.

WARNING!: This device must not be connected to internal pacemaker electrodes.

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33lbs / 15kg or less using special ZOLL pediatric MFE Pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Comparison of Technological Characteristics

The technological characteristics of the proposed ZOLL E Series (with 2010 AHA Guidelines software update) are substantially equivalent to the currently marketed ZOLL E Series (K042007, cleared for use on 4/7/2005 and K062177, reviewed and cleared on 12/13/2006)

Performance Testing:

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

Conclusion

Performance testing of the ZOLL E Series 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 Ms. Eileen M. Boyle
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, MA 01824-4105

FEB 17 2011

Re: K110168
Trade/Device Name: Zoll E Series with 2010 AHA Guidelines Software Update
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (two)
Product Code: MKJ
Dated: January 14, 2011
Received: January 20, 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): _____

Device Name: **ZOLL E Series**

Defibrillator Function

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The E Series products must be prescribed for use by a physician or medical advisor of an emergency response team.

Do not use the unit's AED function on patients under 8 years of age.

Intended Use — Manual Operation

Use of the E Series products in the Manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by these three conditions:

- Unconsciousness
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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110168

SECTION 4 – INDICATIONS FOR USE

Intended Use — Semiautomatic Operation (AED)

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They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

Use of the device in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation.

Intended Use — CPR Monitoring

The CPR monitoring function provides visual and audio feedback 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 minimum compression depth of at least 1.5 (3.8 cm) or 2.0 inches (5.0 cm), depending on the configuration, for adult patients.

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