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ZOLL Medical Corporation

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U.S.A.

978 421-9655
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510(k) Summary:

Submitter's Name and Address:

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

DEC 13 2006

Contact Person:

Sean Reynolds
(978) 421-9655, Ext. 9386

Date Summary Prepared:

December 11, 2006

Device:

ZOLL E Series with Real CPR Help™

Classification:

Automatic External Defibrillators: Class III (21 CFR 870.5310)

Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)

Description:

The ZOLL E Series with Real CPR Help™ provides 'real-time' user CPR assistance when used in conjunction with ZOLL CPR-D•padz™ Multi-function Electrodes. CPR feedback is provided via ZOLL's unique sensor assembly that relays user compression data to the ZOLL E Series. The ZOLL E Series with Real CPR Help™ provides a metronome to encourage rescuers to perform CPR at the AHA/ECR recommended rate of 100 compressions per minute (CPM). The ZOLL E Series additionally provides chest compression performance feedback to the user through displayed symbols, text messages and voice prompts.

The ZOLL E Series External Defibrillator is indicated for the defibrillation, Noninvasive Transcutaneous Pacing and multi-parameter monitoring of patient vital signs, including: ECG Monitoring, Pulse Oximetry, end tidal CO₂, 12-Lead ECG monitoring, non-invasive blood pressure measurement, CPR performance and data printing and recording for resting patients in critical care and transport. The ZOLL E Series is intended for use by qualified medical personnel who are trained and authorized to respond to medical emergencies, to facilitate the ability

to monitor and assess the physiological characteristics of the indicated patients in a critical care environment. The device is light weight and easy to carry for transport.

The device is capable of providing Basic Life-Saving (BLS) personnel the option of analyzing a patient's ECG signal via the Advisory feature on the device. The Advisory Algorithm will determine if the acquired heart rhythm is shockable or non-shockable and will prompt the end-user to provide therapy in the event of a shock advised determination. The user will be prompted to re-assess the patient in the event a no shock advised determination is returned.

Indications for Use:

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 reference. 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.

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 compression depth of 1.5 to 2 inches (3.8 to 5.0 cm) for adult patients.

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

External Pacemaker (Pacer Version Only)

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 temporary 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.

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.

Monitor

Intended-Use Multi-parameter Monitoring

This product may be used for monitoring various patient vital signs, including: electrocardiogram (ECG), Pulse Oximetry (SpO₂), End Tidal CO₂, 12-Lead ECG, and Non-Invasive Blood Pressure (NIBP).

ECG monitoring is performed by connecting the patient to the unit via the 3 or 5 lead patient cable, MFE Pads, or through the paddles.

SpO₂ monitoring is indicated for detecting arterial oxygen saturation of blood and pulse rate for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

EtCO₂ monitoring is indicated for the continuous measurement of end tidal carbon dioxide (EtCO₂) and respiration rate for adult, pediatric and neonatal patients.

12 Lead ECG analysis is indicated for the diagnosis and treatment of adult and pediatric patients with acute myocardial infarction or other cardiac arrhythmias.

NIBP monitoring is indicated for the measurement of arterial blood pressure for resting adult, pediatric, and neonatal patients.

Substantial Equivalence:

The features and functions of the ZOLL E Series with Real CPR Help™ are identical to those of the E Series Defibrillator, with the exception of the incorporation of Real CPR Help™. The characteristics, features and functions of the Real CPR Help™ are substantially equivalent to other ZOLL Defibrillators equipped with CPR Feedback.

Comparison of Technological Characteristics

The ZOLL E Series with Real CPR Help™ acquires compression depth and rate signals from the CPR sensor incorporated in the currently marketed CPR-D•padz™ Multi-function Electrodes. The acquired depth and rate signals are used to provide CPR compression performance feedback to the user through displayed symbols, text messages and voice prompts which are equivalent to other ZOLL defibrillators with user CPR feedback.

Performance Testing:

Extensive performance testing ensures that the ZOLL E Series with Real CPR Help™ performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications. Safety testing assures the device complies with applicable sections of recognized industry and safety standards.

Functional testing of the device's features and functions was conducted to ensure that the modifications to the software did not degrade or impact other product features, functions or performance specifications.

Conclusion

Performance and safety testing of the ZOLL E Series with Real CPR Help™ demonstrates that its features and functions are substantially equivalent to that of the indicated commercially distributed device with regard to performance, safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2006

ZOLL Medical Corporation
c/o Sean Reynolds
Regulatory Affairs Engineer
269 Mill Road
Chelmsford, MA 01824-4105

Re: K062177

Trade/Device Name: ZOLL E Series Defibrillator with Real CPR Help
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LIX
Dated: November 13, 2006
Received: November 29, 2006

Dear Mr. Reynolds:

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.

Page 2 – Mr. Reynolds

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K062177

Device Name: **ZOLL E Series**

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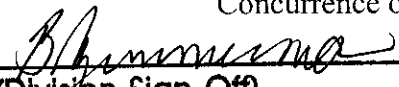
Prescription Use X
(Part 21 CFR 801 Subpart D)

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 K062177

Indications for Use (continued from previous page)

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