K081081

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

MAR 9 2009

Contact Person:

Eileen M. Boyle

(978) 421-9655, Ext. 9171

Date Summary Prepared:

April 7, 2008

Device:

ZOLL E Series® with Bluetooth Dial Up Networking 12 Lead Transmission

Classification:

Defibrillators, Automatic, External, Class III (21 CFR Part 870.5310)
Electrocardiograph: Class II (21 CFR Part 870.2340)

Intended Use:

The ZOLL E Series External Defibrillator is indicated for the defibrillation, noninvasive transcutaneous pacing, CPR monitoring, and multi-parameter monitoring of patient vital signs including: ECG monitoring, Pulse Oximetry (SpO2), End Tidal CO2, 12 lead ECG monitoring, and Non Invasive Blood Pressure for resting patients in critical care and transport conditions. It also supports data printing, data recording, and 12 lead data transmission via cellular fax modem, RS232, and Bluetooth.

Description of Modification:

The ZOLL E Series with Bluetooth Dial Up Networking 12 Lead Transmission provides a means of transmitting the 12 lead patient record wirelessly, via Bluetooth, directly to a cellular device. The cellular device then makes an internet connection to a transfer station which redirects the record to a recipient via email or fax.

Substantial Equivalence:

The ZOLL E Series with Bluetooth Dial Up Networking 12 Lead Transmission is substantially equivalent to the predicate E Series product, cleared by the FDA under K042007.

Comparison of Technological Characteristics:

The ZOLL E Series (K042007) currently supports the transmission of the 12 lead patient record to a handheld device or personal computer (PC) via Bluetooth using the serial port profile supported by the embedded Bluetooth module. The handheld device (or PC) then transmits the 12 lead record, via Bluetooth, to a cellular device which makes an internet connection to a transfer station which redirects the 12 lead record to a recipient via email or fax.

The proposed changes to the E Series eliminate the need to transmit the 12 lead patient record to the intermediate handheld device or PC. The E Series will make the connection, via Bluetooth, directly to the cellular device using the Dial Up Networking profile supported by the existing Bluetooth module embedded in the defibrillator. The 12 lead record is then sent directly to the cellular device which makes an internet connection to the transfer station which redirects the 12 lead record to a recipient via email or fax.

Performance Testing:

Extensive performance testing ensures that the E Series with Bluetooth Dial Up Networking 12 Lead Transmission meets all of its functional requirements and performance specifications. 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:

Testing of the E Series with Bluetooth Dial Up Networking 12 Lead Transmission demonstrates that its features and functions are substantially equivalent to that of the indicated commercially distributed device with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2009

Zoll Medical Corporation
World Wide Headquarters
c/o Ms. Eileen M. Boyle
269 Mill Road
Chelmsford, MA 01824

Re: K081081
Trade Name: Zoll E Series with Bluetooth Dial Up Networking 12 Lead Transmission
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: February 20, 2009
Received: February 23, 2009

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.

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Device Name: ZOLL E Series® with Bluetooth Dial Up Networking 12 Lead Transmission

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.

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:

- Unconsciousness
- Absence of breathing
- 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.

Intended Use — Semiautomatic Operation (AED)

The E Series products are 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.

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

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

- Unconsciousness
- Absence of breathing
- Absence of pulse.

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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)

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Division of Cardiovascular Devices
510(k) Number K081081

Indications for Use
(continued from previous page)

Semiautomatic Operation Contraindications for Use

The rhythm analysis function may not reliably identify ventricular fibrillation in the presence of an implantable pacemaker. Inspection of the electrocardiogram and clinical evidence of cardiopulmonary arrest should be the basis for any treatment of patients with implantable 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 via stretcher or vehicle prior to analyzing the ECG. If 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 application 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 substantially lessen within 72 hours.

Intended - Use Real CPR Help®

The Real CPR Help 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)

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.

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

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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 will not respond to pacing and requires immediate defibrillation. The patient's dysrhythmia must therefore be determined immediately, so that appropriate therapy can be employed. If the patient is in ventricular fibrillation and defibrillation is successful, but cardiac standstill (asystole) ensues, the pacemaker should be used.

Ventricular or supraventricular tachycardias may be interrupted with pacing but in an emergency or during circulatory collapse, synchronized cardioversion is faster and more certain.

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 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.

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.

Monitor

Intended-Use Multi-parameter Monitoring

This product may be used for monitoring various patient vital signs, including: electrocardiogram (ECG), Pulse Oximetry (SpO_2), End Tidal CO_2, 12-Lead ECG, and Non-Invasive Blood Pressure (NIBP).

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

SpO_2 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.

$EtCO_2$ monitoring is indicated for the continuous measurement of end tidal carbon dioxide ($EtCO_2$) 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.

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

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