APR 7 2005

K042007

ZOLL

ZOLL Medical Corporation

Worldwide Headquarters
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U.S.A.

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510(k) Summary:

Submitter's Name and Address:

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269 Mill Road
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Contact Person:

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

Date Summary Prepared:

July 23, 2004

Device:

ZOLL E Series

Classification:

Defibrillator, Low-energy – DC: Class II (21 CFR 870.5300)

Automated External Defibrillator: Class III (21 CFR 870.5310)

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

Electrocardiograph: Class II (21 CFR 870.2340)

External Transcutaneous Cardiac Pacemakers (Non-invasive): Class II (21CFR 870.5550)

Analyzer, Gas, Carbon Dioxide; Class II (21 CFR 868.1400)

Oximeters: Class II (21 CFR 870.2700)

System, Measurement, Blood-Pressure, Non-Invasive: Class II (21 CFR 870.1130)

Description:

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 CO_2, 12-Lead ECG Monitoring, Non-Invasive Blood Pressure measurement and data printing and recording for resting patients in critical care and transport. The ZOLL E Series 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.

Substantial Equivalence: K043007

The features and functions of the ZOLL E SERIES are substantially equivalent to those of the ZOLL M SERIES Biphasic: 510(k) No. k990762, cleared 9/03/1999, the M SERIES SpO_2 Option 510(k) No. K982992, cleared 3/11/1999, the M SERIES End Tidal CO_2 Option: 510(k) No. K993036 cleared 2/28/2000, the M SERIES 12SL Analysis Option 510(k) No. K991556 cleared 10/21/1999, the M SERIES Non-Invasive Blood Pressure measurement Option: 510(k) No. K032363, cleared 10/31/2003, and the ZOLL AED *Plus:* 510(k) No. K033474, cleared 5/21/2004.

Intended Use:

Defibrillation

Use of the E Series products in the manual mode for defibrillation is indicated for converting/terminating ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats. 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.

This product should be used only by qualified medical personnel who are trained and authorized to respond to medical emergencies.

External Pacemaker (Pacer Version Only)

This product may be used for temporary external, demand or non-demand pacing, as an alternative to endocardial stimulation. External cardiac pacing is indicated for use on conscious or unconscious patients in asystole, profound bradycardia or any other conditions determined by a clinician to require external pacing.

ECG Monitoring

The device is indicated for monitoring a patient's electrocardiogram (ECG), via the 3 or 5 lead patient cable, MFE Pads, or through the paddles, for the purposes of identifying and diagnosing cardiac rhythms and dysrhythmias and calculating heart rate.

SpO_2 Option *(if equipped)*

The SpO_2 Option with Masimo Set Technology is indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rate for adult, pediatric and neonatal patients, during both no motion and patient motion conditions, and for patients who are well or poorly perfusing in the hospital or pre-hospital environments.

$EtCO_2$ Option *(if equipped)*

The $EtCO_2$ Option with Respironics Novametrix Technology and Capnostat® is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide ($EtCO_2$) and respiration rate in adult, pediatric and neonatal patient's requiring ventilatory support, transport and anesthesia.

K042007

12SL Analysis Option *(if equipped)*

The 12SL™ Analysis Option using the GE/Marquette 12SL™ Algorithm is useful in the diagnosis of patients with acute myocardial infarction (AMI) and is useful in the interpretation and documentation of other transient cardiac arrhythmias that may occur. The 12-Lead ECG Analysis is indicated for the recording and analysis of 12 Lead ECG signals acquired from adult and pediatric patients in the supine, resting position.

NIBP Option *(if equipped)*

The NIBP Option with SunTech Medical Systems, Inc. Technology is indicated for the noninvasive measurement of arterial blood pressure for resting patients in critical care and transport. The NIBP Option on M Series units is designed to measure blood pressure for adult, pediatric, and neonatal patients.

Comparison of Technological Characteristics

The ZOLL E Series design characteristics are the same as those of the indicated predicate devices; the technology is very similar to that of the ZOLL M Series. The ZOLL E Series acquires and analyzes ECG signals and provides shock advisory determinations for adult and pediatric patients. The ECG Analysis Algorithms are identical to those incorporated into the ZOLL AED *Plus* defibrillator. The ZOLL E Series provides multi-parameter monitoring of patient vital signs, including: ECG Monitoring, Pulse Oximetry, End Tidal CO_2, 12-Lead ECG Monitoring, Non-Invasive Blood Pressure measurement, using technology very similar to those used by the ZOLL M Series.

Performance Testing:

Extensive performance testing ensures that the ZOLL E Series Defibrillator meets all of its functional requirements and performance specifications. Safety testing assures the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL E Series Defibrillator demonstrates that its features, functions and incorporated interpretive algorithm 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
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2005

Zoll Medical Corporation
c/o Mr. Sean Reynolds
Regulatory Affairs Engineer
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105

Re: K042007
Trade Name: Zoll E Series
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: March 11, 2005
Received: March 16, 2005

Dear Mr. Reynolds:

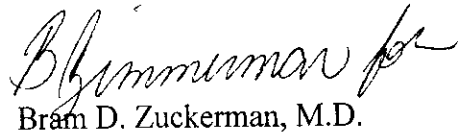
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

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 (301) 443-6597 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): K042007

Device Name: ZOLL E Series

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.

(continued on next page)

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 K042007

Indications for Use
(continued from previous page)

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 (SpO_2), End Tidal CO_2, 12-Lead ECG, and Non-Invasive Blood Pressure (NIBP).

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 measurement of arterial blood pressure for resting adult, pediatric, and neonatal patients.