K092598

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
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

DEC - 3 2009

Contact Person:

Eileen M. Boyle
(978) 421-9655, Ext. 9171

Date Summary Prepared:

August 21, 2009

Device:
ZOLL E Series® with SpCO/SpMet Option

Classification:

Defibrillators, Automatic, External, Class III (21 CFR Part 870.5310)
Oximeters: Class II (21 CFR 870.2700)

Description:

The ZOLL E Series® Defibrillator, which was originally reviewed and cleared by the FDA under premarket notification K042007, is designed for all emergent care situations and provides multi-parameter monitoring of patients in critical care and transport. The ZOLL E Series combines defibrillation, CPR feedback, ECG monitoring, noninvasive transcutaneous pacing, pulse oximetry (SpO_2), end tidal CO_2 ($EtCO_2$), 12-Lead ECG monitoring, non-invasive blood pressure measurement (NIBP), and data printing and recording in a single instrument.

The proposed enhancement, the ZOLL E Series® with SpCO/SpMet Option, is intended to provide personnel trained in its use with the ability to monitor carbon monoxide

concentration in arterial blood and oxidized hemoglobin concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

Substantial Equivalence:

The ZOLL E Series with SpCO/SpMet Option is equivalent to the existing E Series device cleared under 510K K042007. The new option (SpCO/SpMet) is achieved by incorporating the same technology that was previously reviewed and cleared by the FDA under 510K number K061204 for the Masimo SET® Radical 7 Pulse CO-Oximeter in the E Series device.

Intended 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 emergecy 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.

Indications for Use

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 (SpO_2), Carboxyhemoglobin (SpCO), Methemoglobin (SpMet), End Tidal CO_2, 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.

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.

SpCO monitoring is indicated for detecting carbon monoxide concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

SpMet monitoring is indicated for detecting oxidized hemoglobin concentration in arterial blood 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 or other cardiac arrhythmias.

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

Comparison of Technological Characteristics

The ZOLL E Series (K042007) currently supports the monitoring of the saturation of oxygen in arterial hemoglobin (SpO2) via the integration of the Masimo SET® technology (using the measurement circuit and measurement software based on the Masimo SET® 2000, 510K K990966).

The proposed change to the E Series will replace the existing Masimo SET® technology with Masimo Rainbow™ SET® technology as reviewed and cleared by the FDA under 510K K061204. Using Rainbow™ SET® technology, the E Series will now be able to monitor carbon monoxide concentration in arterial blood (SpCO) and oxidized hemoglobin concentration in arterial blood (SpMet) in addition to SpO2.

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 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 W-O66-0609
Silver Spring, MD 20993-0002

DEC - 3 2009

Zoll Medical Corporation, World Wide Headquarters
c/o Ms. Eileen M. Boyle
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, MA 01824-4105

Re: K092598
Trade/Device Name: Zoll E Series with SpCO/SpMET
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ, DQA
Dated: November 24, 2009
Received: November 25, 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 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): K092598

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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 K092598

Indications for Use
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