K090985

510(k) Summary: SEP 23 2009

Submitter's Name and Address:

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Date Summary Prepared:

March 24, 2009

Device:

ZOLL R Series® NIBP and $EtCO_2$ Options

Classification:

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

Automatic External Defibrillators: Class III (21 CFR 870.5310 - MKJ)

Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200 - DRM)

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

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

Oximeters: Class II (21 CFR 870.2700 - DQA)

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

Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase: Class II (21 CFR 868.1400 - CCK)

Description:

The ZOLL R Series® External Defibrillator is intended for the defibrillation, Noninvasive Transcutaneous Pacing, multi-parameter monitoring of patient vital signs, including ECG Monitoring, Pulse Oximetry, Non-Invasive Blood Pressure measurement (proposed), End Tidal CO_2 (proposed), CPR performance and data printing and recording for resting patients in critical care and in-hospital transport. The ZOLL R

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 design facilitates table top use while still providing a light weight and easy to carry device for transport.

Intended Use:

Defibrillator Function

Intended Use — Manual Operation

Use of the R 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.

In manual mode, the unit can also be used for synchronized cardioversion of certain atrial or ventricular arrhythmias. A qualified physician must decide when synchronized cardioversion is appropriate.

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

Intended Use – Semiautomatic Operation (AED)
The R 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.

Use of the R Series 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

Specifications for the ECG rhythm analysis function are provided in the section, "ECG Rhythm Analysis Algorithm Accuracy" on page A-29.

When the patient is less than 8 years of age or weighs less than 55lbs (25Kg), you must use ZOLL pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

Intended Use – ECG Monitoring

The unit is intended for use when ECG monitoring is indicated to evaluate the patient's heart rate or ECG morphology. In ECG monitoring mode, the unit is intended to be used by personnel who are qualified by training in the use of the R Series defibrillator, basic life and/or advanced life support, or other physician authorized emergency medical training.

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

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 33lb. (15kg) or less using ZOLL pediatric hands-free therapy electrodes. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Intended Use - SpO2 Monitoring

The R Series pulse oximeter, with the Masimo® SET® technology and the LNCS® series of oximeter sensors, is indicated for the continuous, noninvasive monitoring of arterial oxygen saturation (SpO2) and pulse rate during both no motion and patient motion conditions for adult patients, and no motion conditions for pediatric and neonatal patients in a hospital or prehospital environment.

Intended Use – NIBP Monitoring

The ZOLL R Series NIBP option is indicated for the non-invasive measurement of arterial blood pressure for resting patients in critical care and in-hospital transport.

The R Series NIBP option is designed to measure blood pressure for adult patients (21 years of age and older) and for pediatric patients, as described in the following table:

Pediatric Subpopulation	Approximate Age Range
Newborn (neonate)	Birth to 1 month of age
Infant	1 month to 2 years of age
Child	2 to 12 years of age
Adolescent	12-21 years of age

Intended Use – EtCO2 Monitoring

The ZOLL R Series EtCO2 option with Respironics Novametrix technology is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide (EtCO2) and respiration rate in patients requiring ventilator support, in-hospital transport, or anesthesia.

This option uses the CAPNOSTAT 5 Mainstream CO2 sensor attached to an airway adapter that connects to an endotracheal tube, mask or disposable mouthpiece.

The R Series EtCO2 option is designed to monitor adult, pediatric, and neonatal patients.

The following substances can influence CO2 measurements made with the CAPNOSTAT 5 CO2 sensor:

- elevated oxygen levels
- nitrous oxide
- halogenated agents

The R Series EtCO2 option provides settings for high oxygen and/or nitrous oxide compensation. Halogenated anesthetic agents alter CO2 readings, but the R Series unit will monitor CO2 within specifications when these agents are present at normal clinical levels. The presence of Desflurane in the exhaled breath beyond normal values (5%) may positively bias measured carbon dioxide values.by up to an additional 3 mmHg.

The R Series EtCO2 option is intended for use only with the ZOLL/Respironics Novametrix CAPNOSTAT 5 Mainstream CO2 Sensor and mainstream airway adapters.

The R Series EtCO2 option can be used on adult patients (21 years of age and older) and on pediatric patients, as described in the following table:

Pediatric Subpopulation	Approximate Age Range
Newborn (neonate)	Birth to 1 month of age
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Substantial Equivalence:

The features and functions of the proposed ZOLL R Series NIBP and $EtCO_2$ Options are substantially equivalent to the ZOLL E Series NIBP and $EtCO_2$ Options (K042007, cleared for use on 4/7/2005).

Comparison of Technological Characteristics

The ZOLL R Series with NIBP and $EtCO_2$ Options features design characteristics that are very similar to those of the indicated predicate device, and utilizes the same interpretive features and functions as those of the currently marketed ZOLL R Series (K081574). The ZOLL R Series NIBP and $EtCO_2$ Options utilize technologies very similar to those used by the ZOLL E Series.

Performance Testing:

Extensive performance testing ensures that the ZOLL R Series with NIBP and $EtCO_2$ Options performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications. Safety testing assures that the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL R Series with NIBP and $EtCO_2$ Options demonstrates that its features and functions are substantially equivalent to those of the indicated commercially distributed predicate device 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

SEP 28 2009

Zoll Medical Corporation
Worldwide Headquarters
c/o Mr. Charles W. Kolifrath
Regulatory Affairs Manager
269 Mill Road
Chelmsford, MA 01824-4105

Re: K090989
Trade/Device Name: Zoll R Series with NIBP & EtCO2 Options
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ, LDD, DRM, DRT, DRO, DQA, DXN, CCK
Dated: September 4, 2009
Received: September 8, 2009

Dear Mr. Kolifrath:

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): K090989

Device Name: ZOLL R Series

Defibrillator Function

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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 K090989

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The R Series EtCO2 option is intended for use only with the ZOLL/Respironics Novametrix CAPNOSTAT 5 Mainstream CO2 Sensor and mainstream airway adapters.

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