K081574

SEP 1 8 2008

510(k) Summary:

Submitter's Name and Address:

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

Contact Person:

Eileen M. Boyle
(978) 421-9171

Date Summary Prepared:

May 30, 2008

Device:

ZOLL R Series® WiFi Option

Classification:

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

Automatic External Defibrillators: Class III (21 CFR 870.5310)

Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)

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

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

Oximeters: Class II (21 CFR 870.2700)

Description:

The ZOLL R Series® External Defibrillator is indicated for the defibrillation, Noninvasive Transcutaneous Pacing, multi-parameter monitoring of patient vital signs, including: ECG Monitoring, Pulse Oximetrey, CPR performance and data printing and recording for resting patients in critical care and 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:

The ZOLL R Series with WiFi Option is intended to be used by qualified medical professionals for the wireless transmission of data files, such as Summary Reports, Full Disclosure Waveforms and Device Logs between the R Series to a network server or handheld device.

Substantial Equivalence:

The features and functions of the proposed R Series with WiFi Option are substantially equivalent to the current features and functions of the R Series (K060559) , cleared for use on 8/17/2006.

Comparison of Technological Characteristics

The ZOLL R Series with WiFi Option utilizes the same interpretive features and functions to those of the currently marketed ZOLL R Series (K060559). The device will transmit information between the defibrillator and a wireless network or wireless device.

Performance Testing:

Extensive performance testing ensures that the ZOLL R Series with WiFi Option 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.

Conclusion

Performance and safety testing of the ZOLL R Series with WiFi Option demonstrates that its features and functions are substantially equivalent to those 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

SEP 1 8 2008

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

Re: K081574
ZOLL R Series AED with WiFi Wireless feature
Regulation Number: 21 CFR 870.5310
Regulation Name: Automatic External Defibrillator
Regulatory Class: Class III (three)
Product Code: LDD
Dated: September 12, 2008
Received: September 15, 2008

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,

Donna R. Vachey

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): K081574

Device Name: ZOLL R Series

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 Operatio (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 involing 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

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)

Donna R. Kostis

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K081574