K062537

ZOLL

*Advancing Resuscitation. Today.*

**ZOLL Medical Corporation**

Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105
U.S.A.

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978 421-0025 Main Fax

## 510(k) Summary:

Submitter's Name and Address:

FEB 2 8 2007

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

Contact Person:

Sean Reynolds

(978) 421-9655, Ext. 9386

Date Summary Prepared:

August 1, 2006

Device:

ZOLL M Series with Real CPR Help™

Classification:

Automactic External Defibrillators: Class III (21 CFR 870.5310)

Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)

Description:

The ZOLL M Series with Real CPR Help™ provides 'real-time' user CPR assistance when used in conjunction with ZOLL **CPR-D•**padz™ and **CPR *Stat•padz***™ Multi-function Electrodes. CPR feedback is provided via ZOLL's unique sensor assembly that relays user compression data to the ZOLL M Series. The ZOLL M Series with Real CPR Help™ provides a metronome to encourage rescuers to perform CPR at the AHA/ECR recommended rate of 100 compressions per minute (CPM). The ZOLL M Series additionally provides chest compression performance feedback to the user through displayed symbols, text messages and voice prompts.

The ZOLL M Series Defibrillator is indicated for the defibrillation, Noninvasive Transcutaneous Pacing, 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, CPR performance and data printing and recording for resting patients in critical care and transport. The ZOLL M 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 patient populations in a critical care environment. The device is light weight and easy to carry for transport.

The device is capable of providing Basic Life-Saving (BLS) personnel the option of analyzing a patient's ECG signal via the Advisory feature on the device. The Advisory Algorithm will determine if the acquired heart rhythm is shockable or non-shockable and will prompt the end-user to provide therapy in the event of a shock advised determination. The user will be prompted to re-assess the patient in the event a no shock advised determination is returned.

Intended Use:

The M Series with Real CPR Help™ 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.

Substantial Equivalence:

The features and functions of the ZOLL M Series with Real CPR Help™ are identical to those of the M Series Defibrillator, with the exception of the incorporation of Real CPR Help™. The characteristics, features and functions of the Real CPR Help™ are substantially equivalent to other ZOLL Defibrillators equipped with CPR Feedback.

Comparison of Technological Characteristics

The ZOLL M Series with Real CPR Help™ acquires compression depth and rate signals from the CPR sensor incorporated in the currently marketed ZOLL **CPR-D•**padz™ and **CPR *Stat•padz*™** Multi-function Electrodes. The acquired depth and rate signals are used to provide CPR compression performance feedback to the user through displayed symbols, text messages and voice prompts which are equivalent to other ZOLL defibrillators with user CPR feedback.

Performance Testing:

Extensive performance testing ensures that the ZOLL M Series with Real CPR Help™ 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.

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

Performance and safety testing of the ZOLL M Series with Real CPR Help™ 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.

# SECTION 4 – INDICATIONS FOR USE

**510(k) Number (if known):** _____

**Device Name:** **ZOLL M Series**

## Defibrillator Function

### Intended Use — Manual Operation

Use of the M 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 M 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 M 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

Specifications for the ECG rhythm analysis function are provided at the end of this section

**(continued on next page)**

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**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.

### Intended Use — Real CPR Help™

The ZOLL M Series with Real CPR Help™ is intended to provide visual and audio feedback 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 greater than 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2007

Zoll Medical Corporation
C/O Sean Reynolds Regulatory Affairs Engineer
269 Mill Road
Chelmsford, MA 01824

Re: K062537
Trade/Device Name: M Series with Real CPR Help
Regulation Number: 21 CFR 870.5310
Regulatory Class: Class III
Product Code: MKJ
Dated: February 16, 2007
Received: February 16, 2007

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.

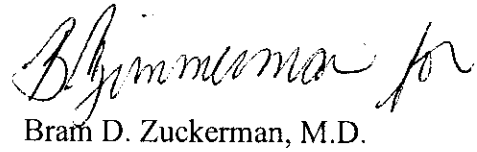
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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

# Indications for Use

510(k) Number (if known):_K062537

Device Name:__M Series with Real CPR Help

Indications For Use: The M Series with Real CPR Help is intended to provide visual and audio feedback to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage the compression depth of greater than 1.5 to 2 inches for adult patients.
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Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062537