ZOLL Medical Corporation

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

978 421-9655
978 421-0025 Main Fax

ZOLL
Advancing Resuscitation. Today.™

510(k) Summary: K072430

Submitter's Name and Address:

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

NOV 06 2007

Contact Person:

Sean Reynolds
(978) 421-9386

Date Summary Prepared:

August 23, 2007

Device:

ZOLL ***pedi***•pad***z***™ Reduced Energy Electrode

Classification:

Electrode, Electrodcardiograph, Multi-Function; Class II (21 CFR 870.2360)

Substantial Equivalence:

The features and functions of the ZOLL ***pedi***•pad***z***™ Reduced Energy Electrode are substantially equivalent to those of the ZOLL ***pedi***•pad***z***™ Multifunction Electrode K915159A, cleared 02/07/1992, and the Cardiac Science Model 9730 Pediatric Attenuated Defibrillation Electrodes K022929, cleared 01/27/2003.

Description:

The disposable ZOLL ***pedi***•pad***z***™ Reduced Energy Electrode is specifically designed for use with ZOLL M Series and ZOLL E Series AED products on children less than 8 years of age or weighing less than 55 lbs (25 kg), to reduce the energy delivered by the device to levels within the range that has been identified as acceptable for the indicated patient population.

The ZOLL M Series and ZOLL E Series Defibrillator products are portable, battery-powered devices indicated for the defibrillation (manual and AED), 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.

When analyzing a patient's heart-rhythm using the incorporated interpretive algorithm, the device analyzes an adult or pediatric patient's ECG signal and, if a shockable rhythm is detected, recommends delivery of a defibrillation shock via voice and visual prompts.

Indications for Use

The ZOLL ***pedi***padz™ Reduced Energy Electrode is intended for defibrillation, ECG monitoring and noninvasive pacing of pediatric patients less than 8 year of age or weighing less than 55 lbs (25 kg).

The ZOLL ***pedi***padz™ Reduced Energy Electrode is intended for use only with ZOLL M Series and ZOLL E Series Biphasic AED Defibrillator products. The ZOLL M Series AED and ZOLL E Series AED Defibrillator products are intended to be used by personnel who have been trained on the device operation and in basic life support or other physician authorized emergency medical response system.

The ZOLL M Series AED and ZOLL E Series AED Defibrillator products are indicated for use on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

Comparison of Technological Characteristics

The ZOLL ***pedi***pad***z***™ Reduced Energy Electrode in conjunction with ZOLL E Series or ZOLL M Series AED products maintain performance characteristics, features and functions that are very similar to those of the Cardiac Science Model 9730 Pediatric Attenuated Defibrillation Electrodes (K022929) with the Cardiac Science PowerHeart® Automated External Defibrillator, Model 9200/9210.

Testing

Extensive testing of the ZOLL ***pedi***pad***z***™ Reduced Energy Electrode with the ZOLL M Series and ZOLL E Series AED ensures that these products meet all functional requirements and performance specifications with regard to safety and effectiveness.

Conclusion

Based on the results of the usability testing, the ZOLL ***pedi***pad***z***™ Reduced Energy Electrode has demonstrated 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

NOV 0 6 2007

ZOLL Medical Corporation
c/o Mr. Sean Reynolds
Regulatory Affairs Engineer
269 Mill Road
Chelmsford, MA 01824

Re: K072430
ZOLL *pedi*·padz™ Reduced Energy Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: MLN
Dated: August 28, 2007
Received: August 29, 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,

FOR 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): K072430

Device Name: ZOLL *pedi*•padz™ Reduced Energy Electrode

Indications for Use

The ZOLL *pedi*•padz™ Reduced Energy Electrode is intended for defibrillation, ECG monitoring and noninvasive pacing of pediatric patients less than 8 year of age or weighing less than 55 lbs (25 kg).

The ZOLL *pedi*•padz™ Reduced Energy Electrode is intended for use only with ZOLL M Series and ZOLL E Series Biphasic AED Defibrillator products. The ZOLL M Series AED and ZOLL E Series AED Defibrillator products are intended to be used by personnel who have been trained on the device operation and in basic life support or other physician authorized emergency medical response system.

The ZOLL M Series AED and ZOLL E Series AED Defibrillator products are indicated for use 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072430