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ZOLL Medical Corporation

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ZOLL
Advancing Resuscitation. Today.™

510(k) Summary:

Submitter's Name and Address:

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

JUN 22 2007

Contact Person:

Eileen M. Boyle

(978) 421-9655, Ext. 9171

Date Summary Prepared:

February 14, 2007

Device:

ZOLL AEDPRO® with See-Thru CPR™

Classification:

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

Automatic External Defibrillators have been considered Class III devices by FDA.

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

Description:

The ZOLL AEDPRO with See-Thru CPR enables the user to see a close approximation of the patient's underlying ECG rhythm while performing CPR in conjunction with ZOLL CPR-D•padz™ electrodes in manual mode.

The ZOLL AEDPRO® with See-Thru CPR™ is a portable, battery powered automated external defibrillator (AED) that uses voice prompts and visual messages to provide feedback to a user attempting a cardiac arrest rescue. The AEDPRO acquires and 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.

See-Thru CPR uses a filter that relies on the correlation between CPR compressions, as detected by the ZOLL CPR-D•padz electrodes, and the CPR artifact to remove CPR related artifact from the ECG signal. See-Thru CPR filtering continues as long as the CPR-D•padz electrodes detect compressions. When no compressions are detected, filtering stops, unfiltered ECG signals are displayed, and the unit removes the CPR FLTR message from the LCD screen.

Intended Use:

The functionality (See-Thru CPR) being added to the ZOLL AEDPRO uses a filter to help remove the artifact from the ECG signal.

Substantial Equivalence:

The features and functions of the ZOLL AEDPRO with See-Thru CPR are identical to other ZOLL Defibrillators equipped with this technology.

Comparison of Technological Characteristics

The ZOLL AEDPRO with See-Thru CPR uses a filter that relies on the correlation between the CPR compressions, as detected by the ZOLL CPR-D•padz electrodes, and the ECG signal to remove CPR related artifact from the ECG signal.

Performance Testing:

Extensive performance testing ensures that the ZOLL AEDPRO with See-Thru CPR performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications.

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

Testing of the ZOLL AEDPRO with See-Thru CPR demonstrates that its features and functions are substantially equivalent to that of the indicated commercially distributed device 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

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

JUN 22 2007

Re: K071025
Trade Name: ZOLL AEDPO® with See-Thru CPR™
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: April 13, 2007
Received: May 22, 2007

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 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

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K071025

Device Name: ZOLL AEDPRO® with See-Thru CPR™

Indications for use

Use of the device for defibrillation is indicated on victims of cardiac arrest with apparent ***lack of circulation*** as indicated by:

- Unconsciousness
- Absence of breathing, and
- Absence of pulse and other signs of circulation

When the victim is less than 8 years old or weighs less than 55 lb. (25kg), use ZOLL pedi·padz® II pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

The device is also intended for use when ECG monitoring is indicated to evaluate the patient's heart rate or ECG morphology.

Contraindications for Use

Defibrillation

Never use the AEDPRO unit for defibrillation when the patient:

- Is conscious
- Is breathing, or
- Has a detectable pulse or other sign of circulation

CPR Monitoring

The CPR monitoring function is not intended for use on patients under 8 years of age.

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 K071025