K033474

MAY 21 2004

510(K) SUMMARY

Applicant's Name and Address

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824

Contact Person

Paul Dias
(978) 421-9413

Date Summary Prepared

October 17, 2003

Device

ZOLL AED Plus

Device Classification

Automatic External Defibrillator
21 CFR 870.1025 MKJ
Device Class: III

Multifunction Electrocardiograph Electrode
21 CFR 870.2360 MLN
Device Class: III

Device Description

The ZOLL AED Plus is a lightweight, portable, battery powered semi-automatic external defibrillator that uses voice prompts and visual icons to guide a user through a cardiac arrest rescue. The device utilizes the ZOLL Rectilinear Bi-Phasic defibrillation waveform. The device is designed to be used by trained emergency responders for the treatment of cardiac arrest.

When connected with ZOLL AED Plus defibrillation electrodes to a patient, the device will analyze the electrocardiographic (ECG) rhythm of the patient and detect whether the rhythm is shockable or not shockable. If the device detects a shockable rhythm, the device charges the capacitor, enables the treatment button and issues the audio warning "Don't Touch Patient, Press Treatment Button". The user can then press the treatment button to deliver defibrillation therapy to the patient. If the patient is not responsive to treatment, additional shocks may be advised and administered after automatically repeated analyses of the patient's heart rhythm.

The ZOLL AED Plus is lightweight. It can easily be transported to any rescue site. It is designed to hang on the wall in an area where it is easily accessible and ready to use at a moment's notice. The device automatically performs a periodic self-test and continually indicates its state of readiness to the user.

When the ZOLL AED Plus is used in conjunction with the ZOLL AED Plus Pediatric Electrodes the device can be used on patients less than 8 years of age. Labeling and packaging of the electrodes is designed to promote a clear visual distinction between adult and pediatric electrodes.

Indications for Use

The ZOLL AED Plus external defibrillator is intended to be used by personnel who are qualified by training in basic life support, or advanced life support, or other physician-authorized emergency medical response to defibrillate victims of cardiac arrest.

Use the AED when a suspected cardiac arrest victim has an apparent LACK OF CIRCULATION as indicated by:

- Unconsciousness and
- Absence of normal breathing and
- Absence of a pulse or signs of circulation.

When a victim is a child or infant less than 8 years of age, or less than 55 lbs (25kg), the ZOLL AED Plus should be used with the ZOLL AED Plus Pediatric Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

Substantial Equivalence

ZOLL AED Plus and ZOLL AED Plus Pediatric Electrodes are substantially equivalent to other legally marketed AED and pediatric defibrillation electrode combinations. Specifically, the ZOLL AED Plus with the ZOLL AED Plus Pediatric Electrodes is substantially equivalent to the Medtronic Physio-Control Infant / Child Reduced Energy Electrodes used with the LIFEPAK CR Plus or biphasic LIFEPAK 500 AEDs cleared under premarket 510(k) notification k022732.

Performance Data

The ZOLL AED Plus external defibrillator was subject to extensive safety and performance testing prior to release. Final testing for the system included various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety testing was performed to ensure the device complies with applicable sections of the following industry and safety standards.

- EN60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety.
- EN60601-1-2, Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility.
- IEC 601-2-4, Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator-Monitors.
- AAAMI DF39, AED and Remote Control Defibrillators.

In addition the premaket 510(k) notification includes:

- Electrode performance testing,
- Animal testing of defibrillation energy dosing, and
- Rhythm classification algorithm performance testing on a pediatric database.

Conclusion

The information in this premarket notification demonstrates that the ZOLL AED Plus used in conjunction with the ZOLL AEP Plus Pediatric Electrodes is substantially equivalent to the predicate device with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2004

Zoll Medical Corporation
c/o Mr. Paul Dias
Director, Quality Assurance and Regulatory Affairs
World Wide Headquarters
269 Mill Road
Chelmsford, MA 01824

Re: K033474
Trade Name: ZOLL AED Plus
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillators
Regulatory Class: III (three)
Product Code: MLN, MKJ
Dated: April 27, 2004
Received: April 29, 2004

Dear Mr. Dias:

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 (301) 594-4648. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Neil R P O'Toole for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 6 – INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: ZOLL AED Plus

Indications for Use:

Use the AED when a suspected cardiac arrest victim has an apparent LACK OF CIRCULATION as indicated by:

- Unconsciousness and
- Absence of normal breathing and
- Absence of a pulse or signs of circulation.

When a victim is less than 8 years of age, or weighs less than 55 lbs (25kg), the ZOLL AED Plus should be used with the ZOLL AED Plus Pediatric Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

Contraindications:

Do NOT use the AED when patient is:

- Consciousness; or
- breathing; or
- has a detectable pulse or other signs of circulation.

Intended Use:

The ZOLL AED Plus external defibrillator is intended to be used by personnel who are qualified by training in basic life support, advanced life support, or other physician-authorized emergency medical response to defibrillate victims of cardiac arrest.

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033474

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)