OCT 3 1 2003

Section 3

510(k) Summary:

Submitter's Name and Address:

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:

July 30, 2003

Device:

ZOLL M-Series NIBP Option

Classification:

System, Measurement, Blood-Pressure, Non-Invasive: Class II (21 CFR 870.1130)

The previously approved NIBP Option (k002029) was established as a Class III device due to its combination with the ZOLL Defibrillator/Pacer/Monitor which was classified as being Class III under 510(k) application number k972241. The proposed update to the NIBP Option would maintain a Class III status due to the same configuration.

Description:

The ZOLL M Series NIBP Option non-invasively measures arterial blood pressure and pulse rate in resting adult, neonate and pediactric patients. By incorporating the SunTech Medical Instruments Advantage OEM BP™ Model 2 Module into the M Series Defibrillator/Monitor/Pacemaker devices, the option facilitates the ability to monitor and assess the physiological characteristics of the indicated patient populations.

The ZOLL M Series products (K972241) combine a defibrillator, ECG display, Noninvasive Transcutaneous Pacing, Pulse Oximetry (K982992), End Tidal CO_2 (K993036), 3-, 5- and 12-Lead ECG Monitoring (K991556), Non-Invasive Blood Pressure measurement (K002029) and Invasive Blood Pressure and Temperature (K011865), data printing and recording in a single instrument.

Substantial Equivalence:

The features and functions of the proposed update to the M Series NIBP Option (k002029) are substantially equivalent to those of the Protocol Systems, Inc. Propaq CS Vital Signs Monitor: 510(k) no.k012451, cleared 8/20/2001.

Indications for Use:

The ZOLL M Series NIBP Option is indicated for the noninvasive measurement of arterial blood pressure for resting patients in critical care and transport. The NIBP Option on M Series units is designed to measure blood pressure for adult, pediatric, and neonatal patients.

Summary of Performance Information:

The 510(k) includes documentation related to the performance of the incorporated NIBP module and compliance with the applicable AAMI, CEN, and IEC automated noninvasive blood pressure, defibrillator and monitor standards.

- ANSI/AAMI SP-10-1992, Electronic or Automated Sphygmomanometers.
- EN 1060-1:1996, Non-invasive sphygmomanometers - Part 1: General requirements
- EN 1060-3:1997, Non-invasive sphygmomanometers - Part3: Supplementary requirements for electro-mechanical blood pressure measuring systems
- EN 60601-1;1990; Amd 1 1992; Amd 2 1995; Amd 13 1995, Medical Electrical Equipment – Part 1: General Requirements for Safety.
- IEC 60601-1-2; 2001, Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility.
- IEC 60601-2-4; 2001, Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator-Monitors.
- EN 60601-2-30; 2000, Medical Electrical Equipment – Part 2: Automatic Cycling Indirect Blood Pressure Monitoring Equipment.
- AAMI DF2; 1996, Cardiac Defibrillator Devices.
- AAMI DF39; 1993, AED and Remote Control Defibrillators.

The information in this 510(k) demonstrates that the proposed update to the M Series NIBP Option (k002029) 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

OCT 31 2003

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

Re: K032363
Trade Name: ZOLL M Series NIBP Option
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 17, 2003
Received: September 23, 2003

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 (301) 594-4646. 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,

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

Enclosure

510(k) Number (if known): K032363

Device Name: ZOLL M Series NIBP Option

Indications For Use:

The ZOLL M Series NIBP Option is indicated for the noninvasive measurement of arterial blood pressure for resting patients in critical care and transport. The NIBP Option on M Series units is designed to measure blood pressure for adult, pediatric, and neonatal patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032363

(Optional Format 3-10-98)