K042417

ZOLL

ZOLL Medical Corporation

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

978 421-9655
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OCT 5 - 2004

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:

August 24, 2004

Device:

ZOLL M Series EtCO2 LoFlo™ Option

Classification:

The previously approved EtCO2 Option (K993036) 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 EtCO2 Option would maintain a Class III status due to the same configuration.

Description:

The ZOLL M Series $EtCO_2$ Option with LoFlo™ Sidestream CO_2 is a sidestream sampling system using a 50ml/minute low sampling rate to measure the EtCO2 of non-intubated and intubated infant, pediatric and adult patients using specially designed sampling cannulas and on-airway adapter kits.

The LoFlo™ Sidestream CO_2 module includes Respironics Novametrix CAPNOIII infrared absorption technology. The module is contained in a small plastic enclosure with a short cable that connects to the same M Series connector used by the existing EtCO2 Capnostat 3 sensor. The module uses the same hardware communications interface to the M Series as the existing Capnostat 3 sensor and a slightly expanded software communications protocol.

Substantial Equivalence:

The features and functions of the proposed update to the M Series EtCO2 Option are substantially equivalent to the current features and functions of the EtCO2 Option (K993036), cleared for use on 2/28/2000 and the GE Medical Systems Dash 3000/4000 Patient Monitor (K030431), cleared for use on 2/26/2003.

Intended Use:

The ZOLL M Series EtCO2 LoFlo™ Option is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide ($EtCO_2$) and respiration rate in intubated and non-intubated adult, pediatric and infant patients requiring ventilator support, procedural sedation, transport, anesthesia and other clinical conditions where $EtCO_2$ monitoring is deemed appropriate by the attending care giver. The M Series $EtCO_2$ LoFlo™ Option uses nasal and nasal/oral sampling cannulas and sidestream on-airway adapter kits .

Comparison of Technological Characteristics

The features and functions of the ZOLL M Series EtCO2 LoFlo™ Option are similar to those of the currently marketed ZOLL M Series EtCO2 Option. The LoFlo™ Sidestream feature utilizes the existing CO_2 measurement technology adapted to include a gas sampling system for monitoring the end tidal carbon dioxide and respiration rate in resting adult, pediatric and infant patients using specially designed sampling cannulas and on-airway adapter kits. These sampling cannulas and on-airway adapter kits are the same as those used on the GE Medical Systems Dash 3000/4000 Patient Monitor.

The existing mainstream $EtCO_2$ features, functions and technology will continue to be provided in the M Series in addition to the sidestream option.

Performance Testing:

Extensive performance testing ensures that the ZOLL M Series EtCO2 LoFlo™ Option meets all of its functional requirements and performance specifications. Safety testing assures the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL M Series EtCO2 LoFlo™ Option 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 - 2004

Zoll Medical Corporation
C/O Mr. Sean Reynolds
Regulatory Affairs Engineer
Worldwide Headquarters
269 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K042417
Trade/Device Name: Zoll M Series $EtCO_2$ LoFlo™ Option
Regulation Number: 870.5310, 868.1400
Regulation Name: Automated External Defibrillator, Carbon Dioxide Gas Analyzer
Regulatory Class: III
Product Code: MKJ, CCK
Dated: September 3, 2004
Received: September 8, 2004

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.

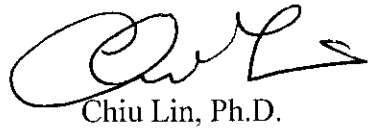
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **ZOLL M Series $EtCO_2$ LoFlo™ Option**

Indications for Use:

The ZOLL M Series $EtCO_2$ Option with Respironics Novametrix technology and Capnostat® sensor is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide ($EtCO_2$) and respiration rate in patients requiring ventilator support, transport, and anesthesia. The M Series $EtCO_2$ Option is designed to monitor adult, pediatric, and neonatal patients.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042417

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)