K132488

ZOLL®

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Worldwide Headquarters
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Chelmsford, MA 01824
U.S.A.

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APR 0 3 2014

510(k) Summary:

Submitter's Name and Address:

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

Contact Person:

Shannon Duhamel

(978) 421-9574

Date Summary Prepared:

August 6, 2013

Device:

ZOLL Code Writer

Classification:

Classification Product Code:

21 CFR 870.2450. Display, Cathode Ray Tube, Medical. Product code: DXJ. Device Class: 2.

Secondary Product Code:

Software, Transmission and Storage, Patient Data. Product code: NSX. Device Class: Not Classified.

Description:

The proposed ZOLL Code Writer is a software-only product. The primary goal of Code Writer is to provide a reliable and consistent method for Advanced Cardiac Life Support (ACLS) caregivers to electronically record observations and care interventions during cardiac resuscitation events and allow users to view, edit and integrate that data into their medical record systems. The Code Writer system is comprised of two components, Code Writer and Code Writer Service software. Code Writer is a software application that runs on a Microsoft Windows Smart Phone. Code Writer allows users to log code events in real time; code records can be saved to the mobile device for later viewing and modification. The code record can be transferred to a server computer using the wireless

communication capabilities of the mobile device to communicate with the Code Writer Service software which is installed on the server computer. Code Writer Service software enables the uploading of defibrillator data to the code record that is stored in Code Writer.

The minor differences between the Indications For Use for the proposed device and the predicate device merely reflect the more limited application of the proposed device as compared with the predicate device, specifically that the proposed Code Writer device is intended to be used by a very specific type of caregiver (ACLS) responding to very specific types of medical situations (cardiac arrest events) within a hospital environment.

Intended Use:

Code Writer is intended for the collection, storage and display of patient data that is entered by a user (ACLS caregiver) or uploaded from a ZOLL R Series defibrillator/ monitor. Code Writer is intended for use by qualified ACLS caregivers responding to cardiac arrest events in a hospital environment to document the care provided. Code Writer is indicated for use by health care providers whenever there is a need for generation of a record of patient data for cardiac arrest events in a hospital environment. Code Writer should only be used by those whose responsibilities do not include direct delivery of therapy or diagnostic decision making.

Substantial Equivalence:

The features and functions of the proposed ZOLL Code Writer are substantially equivalent to the predicate device, ZOLL RescueNet ePCR (K103473), cleared for use on 05/13/2011.

Comparison of Technological Characteristics:

ZOLL Code Writer System shares similar features and functions as the predicate device, ZOLL RescueNet ePCR. Both products are software applications designed to function on mobile devices that utilize Microsoft Windows. Both ZOLL Code Writer and the indicated predicate device are non-alarming software-only products intended for the collection and storage of patient data that is entered by a user (caregiver). Both software products upload patient data wirelessly from ZOLL defibrillators. After the information is collected on the mobile device, both software products allow the user to transmit the patient data wirelessly to a server computer where the information can be securely accessed by medical personnel for the further review, annotation and retrieval of patient data.

Code Writer is indicated for use by Advanced Cardiac Life Support (ACLS) caregivers in a hospital environment, whereas the indicated predicate is indicated for use by Emergency Medical Services (EMS) personnel engaged in acute or routine pre-hospital care or transport.

No new issues of safety or effectiveness are raised by this premarket notification.

Performance Testing:

Extensive performance testing ensures that ZOLL Code Writer performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications.

Conclusion:

The information provided in this 510(k) submission demonstrates that the features and functions of the proposed ZOLL Code Writer software product are substantially equivalent to the corresponding features and functions 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

Zoll Medical Corporation
c/o Ms. Shannon Duhamel
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, MA 01824-4105

Re: K132488
Trade/Device Names: Zoll Code Writer
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-ray Tube Display
Regulatory Class: Class II (two)
Product Code: DXJ, NSX
Dated: February 24, 2014
Received: February 25, 2014

Dear Ms. Duhamel:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Bram D. Zuckerman -S

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): K132488

Device Name: **ZOLL Code Writer**

Intended Use:

Code Writer is intended for the collection, storage and display of patient data that is entered by a user (ACLS caregiver) or uploaded from a ZOLL R Series defibrillator/ monitor. Code Writer is intended for use by qualified ACLS caregivers responding to cardiac arrest events in a hospital environment to document the care provided. Code Writer is indicated for use by health care providers whenever there is a need for generation of a record of patient data for cardiac arrest events in a hospital environment. Code Writer should only be used by those whose responsibilities do not include direct delivery of therapy or diagnostic decision making.

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)

Bram D. Zuckerman -S
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