510(k) Summary:

Submitter's Name and Address:

DEC 1 3 2012

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

Contact Person:

Tanmay B. Shukla
(978) 421-9171

Date Summary Prepared:

September, 2012

Device:

ZOLL SurePower Single Bay Charger

Classification:

Automatic External Defibrillators: Class III (21 CFR 870.5310)

Description:

The ZOLL SurePower Charger System was cleared by the agency under 510(k) application K060559. This device is a four bay charger system that contains circuitry to monitor the battery's current, temperature, and voltage to ensure safe and effective battery charging and testing. The charging bays in the SurePower Charger Station are designed to accommodate the following ZOLL rechargable lithium ion battery:

- SurePower Battery Pack
- SurePower II Battery Pack

and the following ZOLL rechargable lead acid batteries:

- Battery Pack PD4410
- Smart Ready Battery
- Smart Battery
- XL Smart Ready Battery
- XL Smart Battery

The batteries communicate with the ZOLL SurePower Charger Station over a serial communication interface utilizing the SMBus communications protocol.

The SurePower Single Bay Charger is a product line extension of the SurePower (four bay) Charger Station currently in production. The following is a comparison summary of the proposed ZOLL SurePower Single Bay Battery Charger when compared to the ZOLL SurePower Charger:

- The SurePower Single Bay Charger is a one bay version of the existing SurePower Charger.
- The SurePower Single Bay Charger charges ZOLL Lithium Ion battery packs only which includes the SurePower and SurePower II battery packs

Intended Use:

The ZOLL SurePower Single Bay Charger is a single-bay unit that can test, recalibrate, and charge a single ZOLL rechargeable defibrillator battery.

The charging bay in the SurePower Single Bay Charger is designed to accommodate the following ZOLL rechargeable lithium ion batteries:
• SurePower Battery Pack
• SurePower II Battery Pack

Substantial Equivalence:

The features and functions of the ZOLL SurePower Single Bay Charger are substantially equivalent to the currently marketed ZOLL SurePower Charger (K060559, cleared for use on 8/17/2006).

Comparison of Technological Characteristics

The technological characteristics of the ZOLL SurePower Single Bay Charger are substantially equivalent to the currently marketed ZOLL SurePower Charger (K060559, cleared for use on 8/17/2006).

Performance Testing:

Extensive performance testing ensures that the ZOLL SurePower Single Bay Charger performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications. Safety testing assures that the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL SurePower Single Bay Charger 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 13 2012

Zoll Medical Corporation
c/o Mr. Tanmay B Shukla
269 Mill Road
Chelmsford, MA 01824

Re: K122839
Trade/Device Name: Zoll SurePower Single Bay Charger
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: November 13, 2012
Received: November 18, 2012

Dear Mr. Shukla:

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.

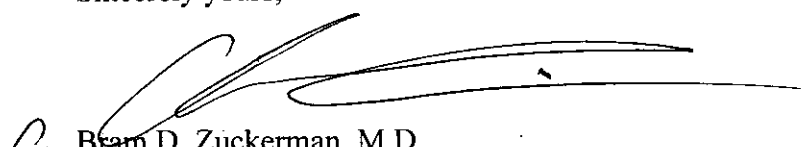
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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, 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): K122839

Device Name: **ZOLL SurePower Single Bay Charger**

The ZOLL SurePower Single Bay Charger is a single-bay unit that can test, recalibrate, and charge a single ZOLL rechargeable defibrillator battery.

The charging bay in the SurePower Single Bay Charger is designed to accommodate the following ZOLL rechargeable lithium ion batteries:

- SurePower Battery Pack
- SurePower II Battery Pack

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)

Owen P. Faris -S
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