DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 25, 2014

Zeller Power Products
Mr. Doug Austin, Owner
Battery Beast, LLC Medical Division
3975 West Post Road
Las Vegas, Nevada 89118

Re: K141231
Trade/Device Name: ZP9141, ZP9146Y, ZP9146W Non-Rechargeable Battery Pack
Regulatory Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (Three)
Product Code: MKJ
Dated: October 6, 2014
Received: October 16, 2014

Dear Mr. Austin:

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,

Melissa A. Torres -S

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K141231

Device Name: ZP9141, ZP9146Y, ZP9146W Non-Rechargeable Battery Pack

Indications for Use:

The ZP9141 is a disposable non-rechargeable battery pack for use in the Cardiac Science PowerHeart® Non-G3 Model 9100 and 9200, or Survivalink Non-G3 9100 and 9200 AED's and is designed to replace the Cardiac Science Model / Part Number 9141-001 battery pack. This battery pack has a shelf life of 5 years from the date of manufacture.

The ZP9146Y (or W) is a disposable non-rechargeable battery pack for use in the Cardiac Science PowerHeart® Non-G3 Model 9300A and 9300E AED's and is designed to replace the Cardiac Science Model / Part Number 9146-001 battery pack. This battery pack has a shelf life of 5 years from the date of manufacture.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K141231

510(k) Summary
(Per 21 CFR 807.92)

Submitter: Zeller Power Products
Battery Beast, LLC Medical Division
3975 West Post Road
Las Vegas, Nevada USA 89118

Contact Information Douglas Austin / Owner
Tel: 702-609-9213
Fax: 208-752-1291
Email: doug@batterybeast.com

Date Prepared January 22, 2014

Device Information

Trade/Proprietary Name:	ZP9141, ZP9146Y, ZP9146W Non-Rechargeable Battery Pack
Common/Generic Name:	Box, Battery
Classification Name:	Box, Battery, Non-Rechargeable
Regulatory Class:	III
Product Code:	MKJ

Classification	Cardiovascular Panel	Class
21 CFR 870.5310	Automated External Defibrillator	III (3)

Identification of Predicate Devices

- Cardiac Science battery packs 9141-001 and 9146-001
- Approved under K031987 and K040438 for their associated Cardiac Science PowerHeart® or Survivalink AED devices.

Legally Marketed Predicate Devices

The ZP9141 is the same as the Cardiac Science replacement battery Model 9141-001 for use in the Cardiac Science PowerHeart® AED Non-G3 Model 9100 and 9200, or Survivalink Non-G3 9100 and 9200 AED cleared under 510(k) notification K031987 and K040438.

The ZP9146Y (or W) is the same as the Cardiac Science replacement battery Model 9146-001 for use in the Cardiac Science PowerHeart® AED Non-G3 Model 9300A and 9300E cleared under 510(k) notification K031987 and K040438.

The Cardiac Science batteries were bundled in the original submission(s) as accessories.

Device Description - Overview

Non-rechargeable battery packs are utilized as a primary direct current (d-c) power source or as a standby or backup d-c power source for portable as well as stationary medical equipment. These devices provide a means of supplying electrical power through chemical reaction. The energy provided depends upon the voltage and capacity rating of a particular pack and the amount of current used by the device into which they are installed. The performance and life span of these batteries depends on operating conditions of temperature, current drain, and the discharge method. These parameters are taken into account in designing such batteries. The goal is to develop battery packs that maintain capacity for as high and as long as possible under a specified range of environmental conditions.

The Zeller Power Products ZP9141 / ZP9146 battery packs utilize Saft LO26SHX, 3.0 Vdc / 7.5 Ah (amp-hour) primary lithium sulfur dioxide (Li-SO2) D- size spiral cells wired in series (4 cells) which produces a total maximum output of 12Vdc @ 7.5Ah. Two (2) additional cells in the ZP9146 provide 6Vdc for auxiliary functions.

Diodes are included to prevent recharging by blocking current into the cells while allowing current out of the cells. Thermal fuses (thermistors) are utilized to cut-off current flow should the battery packs overheat. Ceramic slow-blow fuses protect the pack from short circuits.

A proprietary IC is utilized as an Identification (ID Sensor) chip which signals the appropriate Cardiac Science AED that the battery pack is the correct model.

The only difference between the ZP9146Y and ZP9146W is the case color and label in order to accommodate end user preference.

Indications for Use

The ZP9141 is a disposable non-rechargeable battery pack for use in the Cardiac Science PowerHeart® Non-G3 Model 9100 and 9200, or Survivalink Non-G3 9100 and 9200 AED's and are designed to replace the Cardiac Science Model / Part Number 9141-001 battery pack. This battery pack has a shelf life of 5 years from the date of manufacture.

The ZP9146Y (or W) is a disposable non-rechargeable battery pack for use in the Cardiac Science PowerHeart® Non-G3 Model 9300A and 9300E AED's and are designed to replace the Cardiac Science Model / Part Number 9146-001 battery pack. This battery pack has a shelf life of 5 years from the date of manufacture.

Substantial Equivalence

The design components and functionality of the ZP9141 and ZP9146Y (or W) replacement battery packs are substantially equivalent to other legally marketed predicate devices. Cell chemistry and type are identical; sealed (vented) Lithium Sulfur Dioxide (LiSO2) as well as all safety components and hardware.

Reference:
- Specifications and Comparison Data, 510(k) Summary Pages 3 thru 6.
- Substantial Equivalence Comparison Chart, Executive Summary.

Specifications and Comparison Data

Zeller Power Products ZP9141
Battery Pack, 12.0 Volt / 7.5 Amp-Hours

Device Name / Intended Use

Name:	Replacement Battery Pack for Cardiac Science PowerHeart® Non-G3 Model 9100 and 9200 or Survivalink Non-G3 9100 and 9200 AED's.
Manufacturer/OEM:	Cardiac Science, Inc. (Survivalink is a subsidiary of Cardiac Science)
Classification:	Class III Device, 21 CFR 870.5310 – Automatic External Defibrillator
General:	Extended Life Lithium Battery (5-year), PowerHeart® AED or SurvivaLink® AED.

Predicate or After-Market Device(s)

Predicate Device: Cardiac Science P/N: 9141-001
- K031987 (approved 07/30/2003)
- K040438 (approved 07/01/2004)
- Battery pack bundled / included with AED device submissions.

Predicate Device Comparison Data of Technological Characteristics

Basic Technology / Chemistry

Predicate:	Replacement:
- Cells used: Four (4) Saft LO26SHX 3.0 V / 7.5 Ah D Cells, Non-Rechargeable	Identical
- Chemistry: Sealed Lithium Sulfur Dioxide (LiSO2)	Identical
- Internal diodes, thermistors, fuse	Identical

Physical / Mechanical Characteristics

Predicate:	Replacement:
- Cell case material: Rigid ABS plastic.	Equivalent
- Connector location, Internal PC board, contacts	Identical

Electrical Characteristics

Predicate:	Replacement:
- Nominal Amp-hour rating at 7.5 Amp @ Ambient Room temp. of 25 Deg. C	Meets or exceeds specifications
- Minimum voltage maintained during Discharge at required current: 11.50 Volts	Meets or exceeds specifications

Specifications and Comparison Data

Zeller Power Products ZP9146
Battery Pack, 12.0 Volt / 7.5 Amp-Hours

Device Name/Intended Use

Name:	Replacement Battery Pack for the PowerHeart® Non-G3 Model 9300A or 9300 E Automatic AED's.
Manufacturer/OEM:	Cardiac Science, Inc.
Classification:	Class III Device, 21 CFR 870.5310 – Automatic External Defibrillator

Predicate or After-Market Device(s)

Predicate Device: Cardiac Science P/N: 9146-001
- K031987 (approved 07/30/2003)
- K040438 (approved 07/01/2004)
- Battery pack bundled / included with AED device submissions.

Predicate Device Comparison Data of Technological Characteristics

Basic Technology/Chemistry

Predicate:	Replacement:
- Cells used: Six (6) Saft LO26SHX 3.0 V / 7.5 Ah D Cells, Non-Rechargeable	Identical
- Chemistry: Sealed Lithium Sulfur Dioxide (LiSO2)	Identical
- Internal diodes, thermistors, fuse	Identical

Physical/Mechanical Characteristics

Predicate:	Replacement:
- Cell case material: Rigid ABS plastic	Equivalent
- Connector location, Internal PC board, contacts	Identical

Electrical Characteristics

Predicate:	Replacement:
Nominal Amp-hour rating at 7.5 Amp @ Ambient Room temp. of 25 Deg. C	Meets or exceeds specifications
Minimum voltage maintained during Discharge at required current: 11.50 Volts	Meets or exceeds specifications

Summary of Performance and Safety Testing

Voltage and capacity:

The predicate and replacement battery packs are tested using a Cadex Electronics Battery Analyzer Model C7000 in the “Auto Mode”. This exercises both devices in order to identify performance characteristics.

Target capacity is the percentage of the battery capacity compared to nominal capacity and serves as a threshold. A threshold setting of 80% maintains batteries by providing a balance between adequate energy reserves and long service life.

Target capacity is a pass/fail mark and our replacement device must pass this threshold prior to final Quality Control inspection.

All Battery Packs are tested 100% for voltage prior to shipment. Those devices that fail are rejected and quarantined.

Proper use, discharging, and maintenance procedures for maximum performance of the predicate battery pack are generally provided by the manufacture of the equipment into which it is installed. This would apply equally to our replacement since both are electrically identical and similar in construction. The OEM Operator, User, Maintenance Manual must be referenced.

Shelf life is based on data sheets supplied by the battery manufacturer for the specific cell(s) utilized in the replacement. Since the cells are the same or equivalent to the predicate, shelf life should be also.

Replacement batteries are expected to perform as well as the predicate under the same environmental conditions since the cells are the same or equivalent.

These devices are intended for use by qualified medical personnel and are typically installed by Biomedical Technicians or Maintenance Engineers in a hospital or medical clinic or service setting. Other than misuse by the end user, the only potential problem would be a bad cell lot from the cell manufacturer.

Additional battery pack testing included drop, temperature vs. energy, and life cycle as outlined under the Performance Testing – Bench section.

Conclusions

Zeller Power Products / Battery Beast, LLC has demonstrated through its continued evaluation and testing of the ZP9141 and ZP9146 replacement battery packs, and that these devices are substantially equivalent to the current Cardiac Science AED non-rechargeable battery packs, as outlined in this submission and indicated by internal testing, comparison analysis, and feedback from end users. Differences are generally cosmetic in nature and do not affect form, fit, or function.

The proposed ZP9141 and ZP9146 non-rechargeable battery packs are substantially equivalent with respect to indications for use, technological characteristics, and materials to those currently distributed commercially. This notification contains all information required by 21 CFR 807.87