K110742

BIO-DETEK
INCORPORATED

APR 13 2011

510(k) Summary: Rev. 5

Submitter's Name and Address:
Bio-Detek, Inc.
A Division of **ZOLL**® Medical Corporation
525 Narragansett Park Drive
Pawtucket, RI 02861
Tel. (401) 729-1400

Contact Person:
Robert Morse
Director, Regulatory Affairs
Tel. (866) 639-0060 x. 224

Date Summary Prepared:
February 23, 2011

Device Name:
OneStep™ Adult Multi-Function Electrode (MFE)

Classification Name:
Electrode, Electrocardiograph, Multi-Function with CPR Sensor;
Accessory to an Automated External Defibrillator

Substantial Equivalence:
The **OneStep** Electrode Family is substantially equivalent to **ZOLL ready-padz OneStep** Electrodes that were FDA cleared on 510(k), K060559. In addition, the **OneStep** Electrode is substantially equivalent to the originally cleared **ZOLL stat·padz *MWP*** identified on 510(k), K051076. The intent is to show that the **OneStep** Electrodes will assist in providing therapy for Defibrillation, Cardioversion, External Noninvasive Pacing, ECG Monitoring and CPR Sensor comparable to the previously cleared devices, for use with **ZOLL** Defibrillators. All of the cleared devices are in the Regulatory Class III category.

Description of Device:
The **OneStep** Electrode System is intended for use with **ZOLL** R Series and M Series for ECG Monitoring, Defibrillation, External Noninvasive Pacing, Cardioversion and CPR Sensor of adult patients in either the hospital or pre-hospital environment.

Through part number selection you can choose the full featured Complete model down to the Basic version which offers fewer therapy options. The **OneStep** Adult Electrodes consist of 5 versions related to the combination of features included with the electrodes. The chart below contains the versions and their features:

OneStep Electrode Versions:

Version	MFE	CPR	MWP	Self Test	ZOLL Part Number
OneStep Complete	x	x	x	x	8900-0214-01
OneStep CPR AA	x	x		x	8900-0217-01
OneStep CPR AP	x	x		x	8900-0213-01
OneStep Pacing (MWP)	x		x	x	8900-0212-01
OneStep Basic	x			x	8900-0211-01

MFE – Multi-Function Electrode
CPR - CPR Sensor
(Cardiopulmonary Resuscitation Aid)
MWP – Imbedded ECG Electrodes in front pad for pacing
(MWP = Monitor While Pace)
AA – Optimized for Anterior / Anterior Placement
AP – Anterior / Posterior Placement

The system is comprised of a single use, disposable electrode made of solid hydrogel with a pure tin electrical conductive element having a polyethylene terephtalate (PET) backing with an adhesive perimeter suitable for coupling to patient skin during rescue and/or treatment. By product selection it is determined whether all therapy providing options are available or a reduced choice is made as applicable to caregiver needs.

Indications for Use
Device Name: OneStep™ Adult Multi-Function Electrode

Intended Use:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- ECG Monitoring
- CPR Sensor

For use with **ZOLL**® Defibrillators:

- R Series
- M Series

By Trained Personnel only, Including:

- Physicians
- Nurses
- Paramedics
- Emergency Medical Technicians
- Cardiovascular Laboratory Technicians

The OneStep Adult Electrodes are not indicated for use on a patient less than 8 years of age or weighs less than 55 Lbs. (25Kg).

Comparison of Technological Characteristics:
The intended use of the OneStep Multi-Function Electrodes as described in the indications for use, and labeling has not changed as a result of this submission. For the connection of the **OneStep** Family of Electrodes in this submission to the ZOLL defibrillator cables are similar to the predicate devices with the addition of the M Series utilizing an adaptor for CPR Monitoring functionality which can be procured under ZOLL part number 8000-0599. The **OneStep** MFE's within this submission as compared to the two ZOLL predicate electrode devices using the same hydrogel, acrylic adhesive closed cell foam and have a conductive area of the same dimensional size that meet/exceed National and International Standards ANSI/AAMI DF80 and EN 60601-2-4 respectively.

Nonclinical Testing & Clinical Service:
The **OneStep** Electrode System has been subjected to extensive performance testing to ensure the device meets all of its functional requirements and performance specifications as defined in applicable National/International recognized standards. The ZOLL **OneStep** Electrode Family has been in clinical service since the latter part of October, 2006 through a substantial equivalence determination by FDA for clearance to distribute through a Traditional 510(k) process. This Special 510(k) has been compiled to address the relocation of the self test continuity circuit from the opening process of the pouch to two disconnect points on each electrode. Upon electrode removal from the release liner material, exposed when the pouch is opened, the self test circuit will disengage allowing therapy to be carried-out. It is our intent to present a safer and more reliable circuit disconnects to enhance the effectiveness of the self test process.

Validation Project Number (VPN) 0730 addresses design validation to ensure the safety and effectiveness considerations have been successful in integrating the **OneStep** electrode with previously stated ZOLL defibrillators and performs as well and/or better than the legally marketed predicate devices. Applicable standards are defined in Form FDA 3514, VPN 0730 and Section 2, Device Description, within this premarket submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zoll Medical Corporation
c/o Mr. Robert Morse
Bio-Detek, Inc.
525 Narragansett Park Drive
Pawtucket, RI 02861

APR 13 2011

Re: K110742
Trade/Device Name: Onestep Adult Multi-function Electrode
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, DRO, DQA, LDD, LIX
Dated: March 17, 2011
Received: March 18, 2011

Dear Mr. Morse:

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,

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

510(k) number (if known): K110742

Device Name: OneStep™ Adult Multi-Function Electrode

Intended Use:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- ECG Monitoring
- CPR Sensor, (Optional)

For use with **ZOLL®** Defibrillators:

- R Series
- M Series

By Trained Personnel only, Including:

- Physicians
- Nurses
- Paramedics
- Emergency Medical Technicians
- Cardiovascular Laboratory Technicians

The OneStep Adult Electrodes are not indicated for use on a patient less than 8 years of age or weighs less than 55 Lbs. (25Kg).

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K110742

(Division Sign-Off)
for Division of Cardiovascular Devices

510(k) Number K110742

Prescription Use ☒ OR Over the Counter Use ☐

(Per 21 CFR 801.109)

Rev. 4