December 7, 2018

Cardiac Science Corporation
Christine Thomas
Vice President of Regulatory Affairs
500 Burdick Parkway
Deerfield, Wisconsin 53531

Re: P160033
Trade/Device Name: Powerheart® AED G3, Powerheart® AED G3 Plus, and Powerheart® AED G5
Product Code: MKJ
Filed: August 8, 2016
Amended: February 27, 2017; September 19, 2017; June 8, 2018, and December 3, 2018

Dear Christine Thomas:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Powerheart® AED G3 (Model 9300A and 9300E), including the Intellisense® Lithium Battery (Model 9146), Intellisense™ Defibrillation Pad – Adult (Model 9131), and Intellisense™ Defibrillation Pad – Pediatric (Model 9730); Powerheart® AED G3 Plus (Model 9390A and 9390E), including the Intellisense® Lithium Battery (Model 9146), Intellisense™ Defibrillation Pad – Adult (Model 9131), and Intellisense™ Defibrillation Pad – Pediatric (Model 9730); and the Powerheart® AED G5 (Models G5A-80A, G5A-80C, G5S-80A, and G5S-80C), with the Intellisense® Lithium Battery (Model XBTAED001A), Intellisense™ Defibrillation Pad – Adult (Model XELAED001A), Intellisense™ Defibrillation Pad – Pediatric (Model XELAED003A), and Intellisense™ Defibrillation Pad – ICPR Adult (Model XELAED002B).

The Powerheart® AED G3 is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,
- not breathing normally, and
- without pulse.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs. (25kg), the device should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The Powerheart® AED G3 is intended to be used by personnel who have been trained in its operation.

The Powerheart® AED G3 Plus is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,

- not breathing normally, and
- without pulse.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs. (25kg), the device should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The Powerheart® AED G3 Plus is intended to be used by personnel who have been trained in its operation.

The Powerheart® AED G5 is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are:

- unresponsive,
- not breathing normally, and
- without pulse.

When a patient is a child up to 8 years of age, or up to 25kg (55 lbs.), the AED should be used with the Intellisense™ Defibrillation Pad – Pediatric. The therapy should not be delayed to determine the patient's exact age or weight.

The G5 Automated External Defibrillator (AED) is intended to be used by persons who have been trained in its operation.

When used with the optional Intellisense™ Defibrillation Pad – ICPR, the device offers CPR performance feedback to aid a trained rescuer by providing compression rate and depth performance feedback through audio prompting. The Intellisense™ Defibrillation Pad – ICPR is indicated-for use on cardiac arrest patients 8 years of age or older, or who weigh more than 25 kg (55 lbs.).

We are pleased to inform you that the PMA is approved. You may continue commercial distribution of the device upon receipt of this letter. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for Intellisense® Lithium Battery (Model 9146) has been established and approved at a 4-year shelf life plus 1-year stand-by after installation. Expiration dating for Intellisense™ Defibrillation Pad – Adult (Model 9131) has been established and approved at 27 months. Expiration dating for Intellisense™

Defibrillation Pad – Pediatric (Model 9730) has been established and approved at 30 months. Expiration dating for Intellisense® Lithium Battery (Model XBTAED001A) has been established and approved at 4-year shelf life plus 1-year stand-by after installation. Expiration dating for Intellisense™ Defibrillation Pad – Adult (Model XELAED003A) has been established and approved at 27 months. Expiration dating for Intellisense™ Defibrillation Pad – Pediatric (Model XELAED003A) and Intellisense™ Defibrillation Pad – ICPR Adult (Model XELAED002B) has been established and approved at 30 months.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have agreed to provide the following non-clinical information as part of the annual report, which may be followed by a PMA supplement where applicable.

1. The number of devices returned to the applicant for cause from domestic sources, with a breakdown into:
    a. Those returned for normal end-of-life.
    b. Those returned with any alleged failures or malfunctions, including a summary of root causes and the frequency of occurrence for each identified root cause.

2. The number of replacement defibrillation pads and replacement batteries issued to customers domestically for all causes.

3. A summary of information available to you related to individual domestic uses of your device that may include, but is not limited to:
    a. Defibrillation success and the number of shocks required for success.
    b. Identification of any error codes or malfunctions during use and their related MDR number.

4. A listing of any safety alerts, technical service bulletins, user communications, or recalls for devices under this PMA.

You have also agreed to provide the following non-clinical information:

FDA notes that you have implemented some cybersecurity controls in the Powerheart® AED G5 (Model G5A-80A, G5A-80C, G5S-80A, and G5S-80C). In addition, you have described additional controls you intend to implement but have not yet done so. In order to assure that this device is sufficiently secured from end-to-end, i.e., from the server to the AED itself, you must address this condition of approval. Specifically,

you must develop and implement a plan, with FDA's approval, to address end-to-end security of this device. Further, you may not distribute the Powerheart® AED G5 (Model G5A-80A, G5A-80C, G5S-80A, and G5S-80C), until you have been notified by FDA that this condition has been satisfied, including but not limited to the items listed below.

1. You must provide a proposed plan to address this condition of approval no later than January 15, 2019. This plan should include at least the following information:
    a. A description of the controlled measures that have been or will be implemented to provide end-to-end security of the subject device.
    b. A timeline for all activities planned to address this condition of approval.

2. You must have a finalized plan to address this condition of approval that FDA deems acceptable no later than March 1, 2019.

3. You must provide to FDA the following no later than April 1, 2019:
    a. A comprehensive cybersecurity risk management plan.
    b. A comprehensive threat model that identifies all critical assets (e.g. firmware and backend servers), threats, and design information for the protection control measures for each identified asset.

4. You must have implemented the controlled measures to provide end-to-end security of the subject device as outlined in the finalized plan no later than September 3, 2019. Note that these controlled measures may require FDA approval prior to implementation.

Please note, future submissions should incorporate these items into the PMA submission as part of the premarket review prior to device approval.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm and on combination product postmarketing safety reporting is available at (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when

accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Loriano Galeotti at 301-796-5279 or Loriano.Galeotti@fda.hhs.gov.

Sincerely,

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