July 2, 2018

Physio-Control. Inc.
Paula Lank
Vice-President, Regulatory and Clinical Affairs
11811 Willows Road NE
Redmond, Washington 98052

Re: P160026
Trade/Device Name: LIFEPAK® 1000 Defibrillator, LIFEPAK® 1000 Defibrillator Lithium-Ion Rechargeable Battery, LIFEPAK® 1000 Defibrillator Non-Rechargeable Battery, LIFEPAK® 20 Defibrillator/Monitor (Refurbished), LIFEPAK® 20e Defibrillator/Monitor, LIFEPAK® 15 Monitor/Defibrillator, LIFEPAK® Lithium-ion Rechargeable Battery (for use with the LIFEPAK® 15 Monitor/Defibrillator)
Filed: July 25, 2016
Amended: December 13, 2016; December 28, 2016; March 10, 2017; March 20, 2017; May 18, 2017; June 19, 2017; June 22, 2017; July 11, 2017; August 28, 2017; October 4, 2017; October 5, 2017; October 23, 2017; November 8, 2017; December 6, 2017; December 18, 2017; December 19, 2017; February 12, 2018; February 13, 2018; February 20, 2018; February 28, 2018; March 1, 2018; March 8, 2018; May 11, 2018; May 30, 2018; and June 26, 2018
Product Code: MKJ

Dear Paula Lank:

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 LIFEPAK® 1000 Defibrillator, LIFEPAK® 1000 Defibrillator Lithium-ion Rechargeable Battery, LIFEPAK® 20 Defibrillator/Monitor (Refurbished), LIFEPAK® 20e Defibrillator/Monitor, LIFEPAK® 15 Monitor/Defibrillator, and LIFEPAK® Lithium-ion Rechargeable Battery (for use with the LIFEPAK® 15 Monitor/Defibrillator) These devices are indicated for use as follows:

LIFEPAK® 1000 Defibrillator
Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia.

The defibrillator is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation.

The defibrillator may be used with standard defibrillation pads (QUIK-COMBO® Electrodes with REDI-PAK) only on adults and children who are 8 years old or more or who weigh more than 25 kg (55 lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.

LIFEPAK® 20/20e Defibrillator/Monitors
The AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm.

In AED mode, the LIFEPAK® 20 and LIFEPAK® 20e defibrillator/monitor is not intended for use on pediatric patients less than 8 years old.

LIFEPAK® 15 Defibrillator/Monitors
AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK® 15 monitor/defibrillator is not intended for use on pediatric patients less than 8 years old.

We are pleased to inform you that the PMA is approved. You may continue commercial distribution of the device in accordance with the conditions of approval described below.

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 these devices has been established and approved as follows:

LIFEPAK® 1000 Defibrillator Non-Rechargeable Battery – 5 years
LIFEPAK® 1000 Defibrillator Lithium-Ion Rechargeable Battery – 30 months
LIFEPAK® Lithium-ion Rechargeable Battery (for use with the LIFEPAK® 15 Monitor/Defibrillator) – 24 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. Two copies of 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. 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.

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, 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; and
    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; and
    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.

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 copies 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 in 6 copies, 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
PMA 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 Shawn Forrest at 301-796-5554 or Shawn.Forrest@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