



January 13, 2017

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

HeartSine Technologies LLC
% Mark Kramer
President
Regulatory Strategies, Inc
808 E. Fox Lane
Fox Point, Wisconsin 53217-2805

Re: P160008

Trade/Device Name: HeartSine Samaritan[®] PAD 350P (SAM 350P)
HeartSine Samaritan[®] PAD 360P (SAM 360P)
HeartSine Samaritan[®] PAD 450P (SAM 450P)
Pad-Pak-01, Pad-Pak-02, and Pad-Pak 07 accessories
Saver EVO[®] software version 1.4.2

Dear Mark Kramer:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its review of your premarket approval application (PMA) and issued an approval order on January 12, 2017. We inadvertently made an error in identifying an incorrect version of the Saver EVO[®] software. The correct version is 1.4.2.

We hope that this error has not inconvenienced you. If you have any questions about this corrective action, please contact Bradley Quinn at 301-796-5575 or Bradley.Quinn@fda.hhs.gov.

Sincerely,

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



January 12, 2017

Food and Drug Administration
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HeartSine samaritan[®] PAD 360P (SAM 360P)
HeartSine samaritan[®] PAD 450P (SAM 450P)
Pad-Pak-01, Pad-Pak-02, and Pad-Pak-07 accessories
Saver EVO[®] software version 1.4.0

Filed: March 21, 2016

Amended: March 21, 2016 (4), March 23, 2016, May 19, 2016, and October 12, 2016

Product Code: MKJ

Dear Mark Kramer:

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 samaritan[®] SAM 350P, SAM 360P, and SAM 450P Public Access Automated External Defibrillators and battery/electrode accessories. These devices are indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation (without a pulse)

The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program.

The devices are indicated for use on patients greater than 8 years old or over 55 lbs. (25 kg) when used with the adult Pad-Pak[™] (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs. (25 kg) when used with the Pediatric-Pak (Pad-Pak-02). We are pleased to inform you that the PMA is approved. You may continue commercial distribution of the device upon receipt of this letter.

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). FDA has determined that this restriction on sale and distribution is 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 the Pad-Pak™ (adult, pediatric, and adult/aviation) accessories of this device has been established and approved at 4.25 years (or 4 years 3 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. 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 (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.

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, 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>.

In accordance with the recall requirements specified in 21 CFR 806.10, 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 you must submit a copy of the final labeling to FDA as an amendment to this PMA submission within 30 calendar days from your receipt of this letter. 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 Luke Ralston at 301-796-6362 or Luke.Ralston@fda.hhs.gov.

Sincerely,

Bram D. Zuckerman -S

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