**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

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

March 27, 2015

Heartsine Technologies, Inc.
% Mark Kramer
President
Regulatory Strategies, Inc.
808 E. Fox Lane
Fox Point, Wisconsin 53217

Re: K142709
Trade/Device Name: Samaritan PAD 450P
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: February 27, 2015
Received: March 2, 2015

Dear Mark Kramer,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

510(k) Number (if known): K142709

Device Name: HeartSine Technologies, Ltd. samaritan® PAD 450P

Indications for Use:

The HeartSine samaritan® PAD 450P (also known as SAM 450P) is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The samaritan® PAD 450P is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support or a physician-authorized emergency medical response training program.

The samaritan® PAD 450P is indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult samaritan® Pad-Pak (Pad-Pak-01 or Pad-Pak-07). The samaritan® PAD 450P is indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the samaritan® Pediatric-Pak (Pad-Pak-02).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ____X_____ or Over-the-Counter Use: _____

Section 5

# 510(k) Summary

**Date Summary Prepared**

18th September 2014

**Submitter's Name and Address**

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**Contact Person**

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**Device Name**

Proprietary Name: HeartSine® samaritan® PAD 450P (also known as SAM 450P)
Common Name: Automated External Defibrillator
Classification Name: Automated External Defibrillator
Classification Regulation: 21 CFR 870.5310
Product Code: MKJ
Classification: Class III

**Predicate Device: HeartSine samaritan® PAD 350P (K123881)**

The features and functions of the HeartSine samaritan PAD 450P (also called the SAM 450P) are substantially equivalent to those of the predicate device, the HeartSine samaritan PAD 350P (K123881), also known as SAM 350P.

As further described below, the SAM 450P and the SAM 350P predicate device differ in that the SAM 450P provides audible and visual cardiopulmonary resuscitation (CPR) compression rate feedback prompts to guide the user to administer CPR at a rate between 100-120 compressions per minute in accordance with current AHA resuscitation guidelines.

## Device Description

Like the SAM 350P predicate device, the SAM 450P is a small, lightweight portable battery operated Automated External Defibrillator (AED) designed to treat victims of a cardiac arrest. The SAM 450P incorporates a simple user interface of voice and text/icon prompts to guide the user in the use of the device.

Like the SAM 350P predicate device, the SAM 450P incorporates an audible metronome to guide the user as to the correct rate at which chest compressions should be administered in accordance with current AHA resuscitation guidelines. However, in addition to the metronome provided in the SAM 350P, the SAM 450P also includes a proprietary impedance cardiogram (ICG) analysis algorithm to determine the rate at which CPR compressions are being administered. The SAM 450P uses the measured CPR compression rate to provide both audible and visual feedback prompts to the user to guide them to administer compressions at a rate within the current AHA resuscitation guidelines (i.e., 100-120 compressions per minute). The SAM 450P's audible and visual feedback prompts take the form of voice prompts such as "Push Faster", "Push Slower", and "Good Speed" and LEDs in red, amber and green being lit on the device cover to indicate if the speed at which the compressions are being delivered is too fast, too slow or within the guideline recommendations.

Like the SAM 350P predicate device, the proprietary SAM 450P ECG analysis algorithm automatically determines whether a victim has a shockable or non-shockable rhythm and advises a shock when appropriate. If a shock is required, the SAM 450P will automatically charge to the appropriate energy level and prompt the user to press the illuminated shock button. This enables the delivery of therapeutic energy to the patient.

Like the SAM 350P predicate device, an escalating, truncated exponential biphasic waveform pulse is delivered to the patient via two disposable defibrillator electrodes. This waveform is known as SCOPE® (Self-compensating Output Pulse Envelope). A 150 Joule, 150 Joule, 200 Joule escalating energy sequence is used in accordance with current AHA resuscitation guidelines.

After initial analysis and shock delivery (if appropriate), the SAM 450P will advise that CPR may be commenced via a number of voice prompts such as "Begin CPR" and "It is safe to touch the patient" in addition to emitting an audible metronome.

Like the SAM 350P predicate device, the SAM 450P records the patient's electrocardiogram (ECG) and the patient's ICG (Impedance Cardiogram). The ECG can be viewed using HeartSine's Saver EVO® software.

The Pad-Pak is a combined battery and electrode unit which is single use. The electrodes used with the SAM 450P are two non-sterile, single-use, self-adhesive, conductive gelled defibrillation electrodes. The Pad-Pak is available in three versions: an adult version, a paediatric version, and an adult version meeting FAA temperature, shock and flammability requirements for use on commercial aircraft. The Pad-Paks are identical to those cleared under K123881 for the SAM 350P.

Like the SAM 350P predicate device, the SAM 450P incorporates the following features:

- Controls for Power ON/OFF and Shock
- Automated charging at escalating energies of 150J, 150J, 200J
- Automated self-tests and LED status indicator
- Combined, disposable battery and electrodes (Pad-Pak™)
- Electrode placement guidance voice prompts and LED/icon indicators
- CPR voice prompts and metronome
- Paediatric function for victims between the ages of 1 and 8 years at non-escalating energy of 50 J
- Integral event data recording

## Indications for Use

The indications for use of the SAM 450P are identical to those cleared under K123881 for the SAM 350P:

The SAM 450P is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The SAM 450P is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support or a physician-authorized emergency medical response training program.

The SAM 450P is indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult samaritan Pad-Pak (Pad-Pak-01 or Pad-Pak-07). The SAM 450P is indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the samaritan Pediatric-Pak (Pad- Pak-02).

## Substantial Equivalence

The SAM 450P is substantially equivalent to the HeartSine samaritan PAD 350P (K123881) in intended use, technological characteristics and performance:

The indications for use of the SAM 450P are identical to the indications for the SAM 350P predicate device.

## Technological Characteristics

The SAM 450P has very similar technological characteristics to the predicate device. Both devices are prescription use AEDs designed to treat victims of a cardiac arrest that incorporate a simple user interface of voice and text/icon prompts to guide the user in the use of the device. The SAM 450P and the predicate device differ in that the SAM 450P provides both audible and visual CPR feedback prompts to guide the user to administer CPR at a rate between 100-120 compressions per minute in accordance with the current AHA resuscitation guidelines.

CPR rate feedback, while new to HeartSine's SAM 450P defibrillator, is present in other legally marketed AEDs and does not raise new types of safety and effectiveness questions. Like the SAM 350P predicate device, the SAM 450P includes a metronome to advise users of the correct CPR speed, and the audible and visual CPR rate feedback prompts are intended to further assist the user in providing CPR compression speed in accordance with the AHA resuscitation guidelines.

## Performance

The 510(k) includes performance testing demonstrating that the SAM 450P has successfully completed comprehensive bench, animal and usability studies as well as software validation appropriate for a major level of concern device. This testing demonstrates the safety and effectiveness of the SAM 450P and that its performance is substantially equivalent and as safe and as effective as the predicate device and other legally marketed AEDs. Below is a summary of the testing provided in support of the 510(k) submission:

## Non-Clinical Testing

Extensive electrical safety, electromagnetic compatibility (EMC) and environmental testing was conducted in accordance with IEC 62366, IEC60601-1, IEC 60601-1-2 and MIL-STD 810F.

Software validation testing was carried out as appropriate for a major level of concern device.

Validation also included testing on key device subassemblies and performance testing of the device as a whole in accordance with device specifications. Although the arrhythmia diagnostic algorithm in the SAM 450P is unchanged from the predicate device, standardised AHA, MIT and CU databases were used to extensively validate the performance of the algorithm in the SAM 450P.

Bench testing was also conducted to verify that the audible and visual CPR rate feedback prompts function as specified.

**Animal Testing**

A GLP animal study was conducted to compare the accuracy and appropriateness of the CPR rate feedback provided by the SAM 450P in comparison to the actual CPR compression rate as determined by video recordings and in comparison to CPR rate feedback provided by another legally marketed device (the Philips MRx defibrillator with Q-CPR functionality).

**Usability Testing**

A Usability Study was conducted to demonstrate the acceptable performance of the SAM 450P with regard to time to first shock and the usability of the new CPR feedback prompts.

The performance testing demonstrates that the SAM 450P is as safe, as effective, and performs as well as the predicate device SAM 350P (K123881).

## Conclusion

The information in this 510(k) submission demonstrates that the HeartSine samaritan PAD 450P is substantially equivalent to the predicate device SAM 350P (K123881) with respect to intended use, technological characteristics and performance.