Section 5 510(k) Summary

JUL 1 1 2013

Date Summary Prepared:

November 26, 2012

Submitter's Name and Address:

HeartSine Technologies Ltd.
203 Airport Road West
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BT3 9ED

Contact Person:

James McGuinness, Quality Manager

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Device Name:

Proprietary Name: HeartSine samaritan® PAD 350P (also known as SAM 350P)
Common Name: Automated External Defibrillator
Classification Name: DC-Defibrillator, Low Energy
Product Code: MKJ

Predicate Device:

The features and functions of the HeartSine samaritan® PAD 350P are substantially equivalent to those of the HeartSine samaritan® PAD 300 (K041067) also known as SAM 300 and PAD300P (K052465) also known as SAM 300P.

Device Description:

The HeartSine samaritan® PAD (Public Access Defibrillator) 350P (also called the SAM 350P) is a small, lightweight portable battery operated Automated External Defibrillator (AED) designed to treat victims of a cardiac arrest. The samaritan® PAD 350P incorporates a simple user interface of voice and text/icon prompts to guide the user in the use of the device. The samaritan® PAD 350P also 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.

A proprietary 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 samaritan 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.

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 PAD 350P will advise that CPR (cardiopulmonary resuscitation) may be commenced via a number of voice prompts such as "It is safe to touch the patient" and "Begin CPR" in addition to emitting an audible metronome.

The defibrillator 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 samaritan® PAD 350P are two non-sterile, single-use, self-adhesive, conductive gelled defibrillation electrodes. The Pad-Pak is available in three versions: an adult version, a pediatric version, and an adult version meeting FAA temperature, shock and flammability requirements for use on commercial aircraft.

The samaritan® PAD 350P 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
- Pediatric 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 HeartSine samaritan® PAD 350P is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The samaritan® PAD 350P 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 350P 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 350P 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 PAD 350P is substantially equivalent to the HeartSine PAD Models 300 (K041067) and 300P (K052465) in intended use, technological characteristics and performance:

Indications: The indications for use of the PAD 350P are the same as the indications for the PAD 300P. The PAD 350P indications are also very similar to the PAD 300 indications, except that the PAD 300 was not indicated for pediatric use.

Technological Characteristics: The PAD 350P has very similar technological characteristics to the predicate devices. All three devices are prescription use automated external defibrillators 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 key differences between the PAD 350P and the predicate devices are that the PAD 350P has the following additional features:

1. Addition of CPR coaching prompts
2. Complies with 2010 AHA guidelines, including a CPR metronome that signals rate of chest compressions during the 2-minute CPR period(s) at 110 compressions-per-minute

3. Larger capacity battery which allows longer standby and operating times and the delivery of a greater number of shocks
4. More intuitive LED status indicator
5. A refined arrhythmia analysis algorithm
6. Longer event recording
7. Logging of additional types of event information
8. Addition of a new version of the Pad-Pak (electrode/battery pack) meeting US FAA requirements for use in commercial aircraft
9. Meets current IEC 60601 standards

The above do not raise any concerns of safety and effectiveness for PAD 350P when compared to its predicate devices, HeartSine PAD Models 300 (K041067) and 300P (K052465).

Performance: As summarized in the section below, the 510(k) includes performance testing demonstrating that the PAD 350P and its accessories have successfully completed comprehensive bench, animal and clinical studies as well as biocompatibility evaluation for the patient contacting materials and software validation appropriate for a major level of concern device. This testing demonstrates the safety and effectiveness of the PAD 350P and that its performance is substantially equivalent to the predicate devices and other legally marketed AEDs.

Summary of Performance Information:

Non-Clinical Testing:

Extensive biocompatibility, Usability, EMC and Environmental testing was conducted in accordance with ISO 10993, IEC 62366, IEC60601 (Edition 3) 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. Standardised AHA, MIT and CU databases were used to extensively validate the HeartSine samaritan® PAD 350P algorithm.

Clinical and Usability Testing:

GLP Animal data and Post Marketing Surveillance data were submitted in addition to the referencing of clinical data used to support the 510(k) clearance of the predicate device for the Samaritan AED (K023854). No adverse events or complications were reported. This data demonstrate the safety and efficacy of the HeartSine samaritan® PAD 350P SCOPE® waveform and its substantial equivalence to other automated external defibrillators.

The performance testing demonstrates that the PAD 350P is as safe, as effective, and performs as well as the predicate devices (HeartSine samaritan® PAD 300 (K041067) and PAD300P (K052465)).

Conclusion:

The information in this 510(k) submission demonstrates the HeartSine samaritan® PAD 350P is substantially equivalent to the predicate devices (HeartSine samaritan® PAD 300 (K041067) and PAD300P (K052465)) with respect to intended use, technological characteristics and performance.

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

July 11, 2013

Heartsine Technologies Inc.
c/o Mr. James McGuinness
Quality Manager
Canberra House
203 Airport Road West
Belfast, BT3 9ED
Northern Ireland

Re: K123881
Trade/Device Name: Samaritan PAD 350P AED
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: June 18, 2013
Received: June 19, 2013

Dear Mr. McGuinness:

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 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. 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,

Owen P. Faris -S

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

Enclosure

K123881

Section 4 Indications for Use

510(k) Number (if known): _____

Device Name: HeartSine Technologies, Ltd. samaritan® PAD 350P

The HeartSine samaritan® PAD 350P (also known as PAD 350P and SAM 350P) is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

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The samaritan® PAD 350P 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)

Owen P. Faris -S
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Prescription Use: ✓ or Over-the-Counter Use: _____