K041067

MAY 2 5 2004

Section 6 510(k) Summary

Date Summary Prepared:

April 21, 2004

Submitter's Name and Address:

HeartSine Technologies, Inc.
940 Calle Amanecer, Suite E
San Clemente, CA 92673

Contact Person:

William J. Smirles, EMT-P
Telephone: 1.847.317.0926
Facsimile: 1.517.809.6748

Device Name:

Proprietary Name: HeartSine Samaritan® PAD
Common Name: Automated External Defibrillator
Classification Names: DC-Defibrillator, Low Energy

Device Description:

The HeartSine Samaritan® PAD is a small, lightweight portable, battery operated automated external defibrillator (AED) designed to treat victims of a cardiac arrest. The Samaritan® PAD incorporates a simple user interface of voice prompts and visual graphic prompts to guide the user. A proprietary analysis algorithm automatically renders a shock or no-shock decision. The Samaritan® PAD analysis algorithm is identical to the Samaritan® AED model which is in commercial distribution and which has been premarket cleared under K023854. The Samaritan® PAD functions identical to the earlier model Samaritan® AED. If a shock is required, the Samaritan® PAD will automatically charge to the appropriate energy level and prompt the user to press an illuminated shock button - to deliver the therapeutic energy to the patient. A low energy, escalating truncated exponential biphasic waveform pulse is delivered. A 100 Joule, 150 Joule, 200 Joule escalating energy sequence is used. After three consecutive shocks have been administered, the Samaritan® PAD will pause 60 seconds to allow cardiopulmonary resuscitation to be performed. The Samaritan® PAD uses two non-sterile, single use, self-adhesive, conductive adhesive gelled defibrillation/monitoring electrodes to obtain the patient's heart rhythm and, if required, deliver the defibrillation pulse to the patient.

The Samaritan® PAD incorporates the following features:

- An LED graphic display providing visual graphic prompting to the user
- Automated self tests with an LED flashing status indicator
- Integral event data recording

The Samaritan® PAD uses a disposable, non-rechargeable lithium manganese dioxide battery to operate the Samaritan® PAD for a minimum of 3 hours of continuous operation or provide a minimum of 30 – 200 Joule shocks. The disposable battery is housed in a plastic tray with the disposable defibrillation pads. By housing the battery in the same rigid plastic tray as the electrodes, this will greatly assist the end user in keeping the device in a state of readiness. This will also help eliminate the chance that the end user would respond to an incident with a good battery but expired electrodes, as could happen with many other AEDs currently.

Event details are recorded internally in the Samaritan® PAD for later retrieval on a computer. 1.5 hours of continuous ECG as well as incident events time stamped are recorded. Event and incident data can be viewed, printed, annotated and forwarded using the HeartSine SAVER software program. The Samaritan® PAD incorporates a USB communication port that allows for downloading event details to the SAVER software program. This USB port also allows for changing language settings for the Samaritan® PAD voice prompts and allows for customizing the factory settings.

Samaritan® PAD also incorporates a training module which converts the Samaritan® PAD into a training device. The training module will automatically disable the Samaritan® PAD energy delivery capability. This training module will allow the user to select training scripts, which simulate different rescue and demonstration scenarios.

Indications for Use:

The HeartSine Samaritan® AED is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The Samaritan® AED 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® AED is not currently indicated for use on children less than 8 years old.

Predicate Device:

HeartSine Technologies, Inc.	Samaritan® AED	(K023854)
Phillips Medical	Onsite M5066A	(K020715)

Substantial Equivalence:

The HeartSine Samaritan® PAD is substantially equivalent to those of the previously cleared HeartSine Samaritan® AED (K023854) and the Phillips Onsite M5066A (K020715). The Samaritan® PAD does not raise any new issues of safety and effectiveness.

Summary of Performance Testing:

Testing and performance documentation has been submitted with the 510(k) submission. These data demonstrate that the Samaritan® PAD complies with the applicable FDA guidelines and industry standards. The Samaritan® PAD was developed under extensive design controls. The hardware and software were tested in accordance with established industry standards and found to perform as intended. The efficacy of the HeartSine SCOPE biphasic waveform in this device has been demonstrated in animal and human clinical trials.

The results of the testing have shown the Samaritan® PAD does not raise any new questions of safety or effectiveness.

Conclusion:

The information in this 510(k) submission demonstrates that the HeartSine Samaritan® PAD is substantially equivalent to the predicate device with respect to safety, effectiveness and performance and does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2004

Mr. William J. Smirles
Senior Vice President, Marketing & Business Development
HeartSine Technologies, Inc.
940 Calle Amanecer, Suite E
San Clemente, CA 92673

Re: K041067
Samaritan® PAD
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm Defibrillator, AED
Regulatory Class: Class III
Product Code: MKJ
Dated: April 21, 2004
Received: April 30, 2004

Dear Mr. Smirles:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Section **3**

Indications for Use

510(k) Number (if known): K041067

Device Name: HeartSine Technologies, Inc. Samaritan® PAD

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041067

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