FEB 1 4 2003

Section 6 510(k) Summary

K023854

Date Summary Prepared:

November 15, 2002

Submitter's Name and Address:

HeartSine Technologies, Inc.
25892 Jamon Lane
Mission Viejo, CA 92691

Contact Person:

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

Device Name:

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

Predicate Device:

The features and functions of the HeartSine Samaritan® AED are substantially equivalent to those of the Phillips Heartstream FR2 (K003565).

Device Description:

The HeartSine Samaritan® AED is a small, portable, battery operated automated external defibrillator (AED) designed to treat victims of a cardiac arrest. The Samaritan® incorporates a simple user interface of voice prompts and text prompts to guide the user. A proprietary ECG analysis algorithm automatically renders a shock or no-shock decision. If a shock is required, the Samaritan® will automatically charge to the appropriate energy level and prompts 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® will pause 60 seconds to allow cardiopulmonary resuscitation to be performed. The Samaritan® AED uses two non-sterile, single use, self-adhesive, conductive adhesive gelled defibrillation/monitoring electrodes to obtain the patient's ECG rhythm and, if required, deliver the defibrillation pulse to the patient.

The Samaritan® AED incorporates the following features:

- Backlight LCD display providing text prompts and ECG display
- Manual override capability to allow manual charging of biphasic energies of 100 J, 150 J, 200 J or 230 J.
- Automated self tests with a separate status indicator display
- Controls for Power On/Off, Shock, Backlight, Contrast & manual override
- Integral event data recording incorporated in the removable battery

A non-rechargeable lithium manganese dioxide battery will operate the Samaritan® AED for 12 hours of continuous ECG monitoring or provide 120 – 200 Joule shocks. The battery also incorporates a memory chip to allow event and incident documentation. 12 hours of continuous ECG as well as incident events time stamped and 60 minutes of audio can be recorded to the battery for post incident review.

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.

Summary of Performance Information:

Testing and performance documentation has been submitted with the 510(k) submission. These data demonstrate that the Samaritan® AED complies with the applicable sections of ANSI / AAMI DF2- 1996 (Cardiac Defibrillator Devices) and ANSI / AAMI DF39 – 1993 Automatic External Defibrillators & Remote Controlled Defibrillators. The efficacy of the biphasic waveform in this device has been demonstrated in animal and human clinical trials.

The information in this 510(k) submission demonstrates that the HeartSine Samaritan® AED is substantially equivalent to the predicate device with respect to safety, effectiveness and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2003

Heartsine Technologies, Inc.
Mr. William J. Smirles
Senior Vice President
25892 Jamon Lane
Mission Viego, CA 92691

Re: K023854
Trade/Device Name: Samaritan® AED
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm.
Regulatory Class: Class III
Product Code: MKJ
Dated: November 15, 2002
Received: November 19, 2002

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

for 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): K023854

Device Name: HeartSine Technologies, Inc. Samaritan® AED

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ashley Boone for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023854

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