K042088

SEP - 2 2004

510(k) Summary

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

Contact: William J. Smirles
Senior Vice President, Marketing & Business Development
Phone: 847-317-0926
FAX: 517-809-6748

Proposed Device Identification and Classification:

Proprietary Name:	Samaritan® PAD PAK Defibrillation Electrodes
Common Name:	Disposable Polymer (Hydrogel) External Monitoring and Defibrillation Electrode
Classification Name and Reference:	Automated External Defibrillator § 870.5310
Classification Panel:	Cardiovascular
Product Code:	74 MKJ
Regulatory Class:	III
Performance Standards:	No performance standards have been promulgated under Section 514

Predicate Devices

- Meridian Technologies, PRIME ECG System (K012414)
- Philips Medical Systems, Onsite AED M5066A with M5071A pads (K020715)
- Katecho, Inc., KDP-60A Adult Defib/Pace Multifunction Electrode (K002806)

Substantial Equivalence

The HeartSine Samaritan® PAD PAK defibrillation electrodes are substantially equivalent to the Meridian Medical Technologies, PRIME ECG System electrodes for ECG monitoring, previously cleared under 510(k) # K012414. The Samaritan® PAD PAK electrodes are also substantially equivalent to other legally marketed electrodes for semi-automatic low power DC defibrillators, such as the Philips Onsite Defibrillation pads (Philips Model Number M5071A) as described in the 510(k) submission for the Philips Onsite M5066A Automated External Defibrillator (K020715) and the Katecho, Inc. KDP 60A Adult Multifunction Electrodes (K002806). The Philips and Katecho electrodes are designed for ECG monitoring and defibrillation and are intended for use with a semi-automatic, low power DC defibrillator.

Intended Use

The HeartSine Samaritan® PAD PAK defibrillation electrodes are single use, non-sterile, self-adhesive hydrogel pads, intended to be used for ECG monitoring and external defibrillation. The PAD PAK pads are to be used with the Samaritan® PAD Automated External Defibrillator (K041067) on patients of age 8 years and older.

Device Description

The HeartSine Samaritan® PAD PAK pads are single use, non-sterile, hydrogel polymer self-adhesive electrode pads. The Samaritan® PAD PAK pads will be used in conjunction with Samaritan® PAD low energy semi-automatic external defibrillator (AED). The pads are sealed in a pouch to prevent drying out and to maintain their integrity throughout the duration of the shelf life.

Performance and Biocompatibility Testing

Testing and performance documentation has been submitted with the 510(k) submission. These data demonstrate that the Samaritan® PAD PAK pads comply with applicable FDA guidelines and industry standards. The PAD PAK pads comply with the requirements of AAMI/ANSI DF80, ISO 10993, and FDA Memorandum G95-1, and with HeartSine Technologies, Inc. internal specifications for a single use, ECG monitoring & defibrillation pad. The testing of the PAD PAK pads demonstrate that the PAD PAK Pads function as intended. The results of the testing have also shown the Samaritan® PAD PAK pads do not raise any new questions of safety or effectiveness.

*** * * * * End of 510(k) Summary * * * * ***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2004

Heartsine Technologies, Inc.
c/o William J. Smirles, EMT-P
Senior VP, Marketing & Business Development
940 Calle Amanecer, Suite E
San Clemente, CA 92673

Re: K042088
Trade name: Samaritan® PAD PAK Defibrillation Electrode, Model Spp-301
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: July 30, 2004
Received: August 12, 2004

Dear Mr. Smirles:

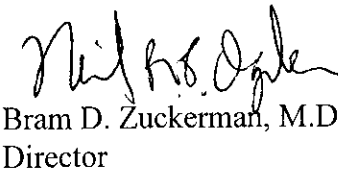
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4648. 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

Indications for Use

510(k) Number (if known): K042088

Device Name: **HeartSine Technologies Samaritan® PAD PAK Defibrillation Pads**

Indications For Use:

The HeartSine Samaritan® PAD PAK defibrillation electrodes are single use, non-sterile, self-adhesive hydrogel pads, intended to be used for ECG monitoring and external defibrillation. The PAD PAK pads are to be used with the Samaritan® PAD Automated External Defibrillator (K041067) on patients of age 8 years and older.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042088