DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
9200 Corporate Blvd
Rockville, MD 20850

APR 1 8 2008

WARNING LETTER

VIA FEDERAL EXPRESS AND FACSIMILE

Mr. Ian McRoberts
Chief Financial Officer
Heartsine Technologies, LTD.
203 Airport Road West
Belfast, Northern Ireland
United Kingdom

Dear Mr. McRoberts:

During an inspection of your firm located in Belfast, Northern Ireland on November 26 through November 29, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the Samaritan Automatic External Defibrillator (Samaritan AED) and the Samaritan Public Access Defibrillator (Samaritan PAD) devices. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or any function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (cGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received two responses from Gregory D. Cash, President and Chief Executive Officer, dated December 12 and December 14, 2007, respectively, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations that was issued to you. We address these responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for validating the device design to include software validation and risk analysis, as required by 21 CFR 820.30(g). For example, , Software Development Manager, indicated the diagnostic algorithm system for the PAD software was enhanced to version from in September 2007, to include the Arabic and Persian languages. The pediatric capability transfer for the PAD device was conducted on 1/18/07, and 2/19/07. Your validation protocol ( ) failed to document how you validated the software upgrade or how you validated the pediatric capability transfer.

2. Failure to establish and maintain adequate procedures for acceptance of incoming product to include inspection, testing, or other verification as conforming to specified requirements, as required by 21 CFR 820.80(b). For example:

   a) The Heartsine Samaritan AED System Traveler form ( ) indicates that Internal Inspection and In QAT testing was not performed for serial numbers and . Additionally, the required Monitoring Mode for steps through was not performed for serial number ;
   b) The Heartsine Samaritan PAD Unit form ( ) indicates that Internal Inspection and In QAT testing was not performed for serial number ;
   c) The Heartsine Samaritan PAD Page (.) indicates that Inspection and Inspection of were not performed for serial numbers and .

   Your response dated December 14, 2007, is not adequate because it failed to provide documentation of inspection, testing, or other verification that incoming product conforms to specified requirements. Your firm committed to train production operators, supervisors and managers in revised procedures by the end of December 2007, but neither the procedure, nor the documentation of training, was provided with the response. Additionally, there was no retrospective review of device history records for completeness and adherence to the device master record (DMR).

3. Failure to establish and maintain procedures to control labeling activities, as required by 21 CFR 820.120. For example, Heartsine Technologies has no written procedures to control labeling activities.

   Your response dated December 14, 2007, is not adequate because it failed to provide documentation of how labeling activities are controlled, or evidence of its implementation. You committed to establishing instructions for the full labeling cycle by the end of January 2008, but to date, no written procedure to control such labeling activities was provided, nor any information or personnel training to these new procedures.

4. Failure to establish and maintain procedures to ensure that sampling methods are adequate for their intended use, as required by 21 CFR 820.250(b). For example, Heartsine Technologies has no formal sampling method or standard to follow for incoming goods.

   Your response dated December 14, 2007, is not adequate because there is no documentation that a procedure for sampling plans has been implemented. You indicated Heartsine is currently writing a sampling plan procedure to be based on either or a , to be completed by the end of January 2008; however, to date, no sampling plan procedure was provided.

5. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designate unit, as required by 21 CFR 820.198(a). For example, section 3.8 of the Heartsine Complaint Procedure ( ) states, "

." The inspection revealed there were no records to indicate that a reply was sent to 15 complainants regarding the results of the conclusion of the investigation.

   Your response dated December 14, 2007, is not adequate because you have not provided a revised procedure to clearly delineate when replies should be issued and when they should not. You also committed to add a header section or cover letter to the Customer Fault Report by the end of January 2008; however, to date, no documentation of such action has been received.

6. Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example, section of the Heartsine training procedure ( ) requires that all employees be trained in Good Manufacturing Practices and Defects Awareness; however, the inspection revealed that production operators and did not receive this training.

   Your response dated December 14, 2007, is not adequate because there was no documentation that the six employees had been trained in Good Manufacturing Practices or Defects Awareness. Additionally, you committed to retrain (by the end of January 2008), any employee who has not had the required training within the past two years; however, to date, no documentation of such retraining was provided.

A follow up inspection will be required to assure that your corrections are adequate. We will contact the appropriate people and request an establishment re-inspection. An FDA trip planner will be in touch with you to arrange a mutually convenient date for this inspection.

Additionally, the Samaritan PAD is misbranded within the meaning of section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)), in that the labeling of the device fails to bear adequate directions for use because the label of the device fails to contain the required caution statement for prescription devices, as required by 21 CFR 801.109(b).

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed (Section 801(a) of the Act (21 U.S.C. § 381(a)). In addition, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award

of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to CDR Nicole L. Wolanski, Chief, Cardiovascular & Neurological Devices Branch, HFZ-341, Division of Enforcement B, Office of Compliance, 2098 Gaither Road, Rockville, Maryland 20850. If you have any questions about the content of this letter please contact: CDR Wolanski at 240-276-0295 or FAX to 240-276-0325.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health