510(k) Summary K013896 JUN 19 2002

Date Summary Prepared: June 18, 2002

Establishment Registration

Location

Company Name:	Defibtech, LLC
Address 1:	1200 Boston Post Road
Address 2:	Suite 207
City, State, and Zip Code:	Guilford, CT 06437

Contact Information

Name:	Mr. Gintaras Vaisnys
Telephone:	(203) 453-6654 x17
Facsimile:	(203) 453-6657

Trade (Proprietary) Name	*Sentry* Semiautomatic External Defibrillator
Model Number	Defibtech *Sentry*
Common Name	DC-Defibrillator, Low Energy

Trade (Proprietary) Name	Defibrillation Pads or Electrodes
Model Number	DDP-100 Defibrillation Pads
Common Name	External Defibrillation Pads

Substantial Equivalence

Model	*Manufacturer*	*510(k) Number*
ForeRunner	Heartstream, Inc.	K955628
KDP-60	Katecho, Inc.	K981737

Device Description

The *Sentry* is a semiautomatic external defibrillator (AED) designed to be portable and battery powered. It has only two user controls: the ON/OFF and SHOCK buttons. Voice prompts and visual indicators provide a simple interface for the operator. The *Sentry* AED is capable of recording event information including ECG, audio data (optional) and SHOCK/NO SHOCK recommendations.

When connected to a patient who is unconscious and not breathing the *Sentry* AED performs the following tasks:

- Prompts the operator to take necessary actions to enable analysis
- Automatically analyzes the patient's ECG
- Determines whether a shockable rhythm is present
- Charges the defibrillation capacitor if the rhythm is shockable

- Arms the SHOCK button and prompts the operator to press the SHOCK button when the device is ready and a shock is recommended
- Delivers a shock if the user presses the SHOCK button and the device has determined that a shock is required

The *Sentry* AED will *NOT* shock a patient automatically; it will only advise the operator. The SHOCK button is only enabled when a shockable rhythm is detected and the device is charged and ready to shock. Charging occurs automatically when the device detects a shockable rhythm. The operator must press the SHOCK button to initiate defibrillation.

The *Sentry* AED uses two non-sterile self-adhesive defibrillation/monitoring pads to monitor ECG signals and, if necessary, to deliver defibrillation energy to the patient. These pads (also known as electrodes) are provided as a single patient use, packaged, disposable assembly.

The *Sentry* AED determines proper pad-to-patient contact by monitoring the impedance between the two pads. Visual and audio prompts inform the operator of possible problems with patient contact. Voice prompts and visual indicators communicate the status of the AED and of the patient to the operator. The *Sentry* AED has two push-button controls and several LED indicators.

Defibrillation energy is delivered as a biphasic truncated exponential waveform. The device delivers 150 Joules into a 50-ohm load. Energy delivered does not change significantly with patient impedance, although the duration of the generated waveform will vary. The Defibtech AED is designed to deliver up to 150J of defibrillation energy through a patient impedance range of 25 – 150 ohms.

Defibrillation and AED operating power is supplied by a replaceable (non-rechargeable) Lithium/Manganese Dioxide Battery Pack. Battery Packs are available in several configurations that are optimized for use in specific applications. Each Pack is marked with an expiration date.

The *Sentry* AED records event documentation internally and optionally, on Defibtech Data Cards (DDC). The optional DDC enables the AED to record event documentation, and audio, if enabled. Audio recording is available only for units with Defibtech Data Cards installed. Event documentation stored internally can be downloaded onto a DDC for review.

Intended Use

The *Sentry* AED is indicated for use on victims of sudden cardiac arrest (SCA) when the patient is:

- Unconscious and unresponsive
- Not breathing
- At least eight years old

The *Sentry* AED must be used by or on the order of a physician.

The DDP-100 defibrillation pads are used in conjunction with the Defibtech *Sentry* semiautomatic external defibrillator and act as a conductive interface between the Sentry and the patient's skin. The disposable electrodes are non-sterile and for single patient use only. The pads are intended for external defibrillation and ECG monitoring in combination with a Defibtech defibrillator.

Conclusion Summary of Safety and Effectiveness

Testing and performance evaluations demonstrate that the safety and effectiveness of the Defibtech *Sentry* is substantially equivalent to the predicate device. Performance testing was performed in accordance with established industry standards (ANSI/AAMI DF39 - *Automatic external defibrillators and remote-control defibrillators*: 1993) and recommendations (American Heart Association - Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety: October 1996).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2002

Defibtech, LLC
c/o Mr. Gintaras Vaisnys
1200 Boston Post Road
Suite 207
Guilford, CT 06437

Re: K013896
Sentry Semiautomatic External Defibrillator (AED)
Regulation Number: 870.1025
Regulation Name: Automated External Defibrillator
Regulatory Class: III (three)
Product Code: MKJ
Dated: March 20, 2002
Received: March 21, 2002

Dear Mr. Vaisnys:

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.

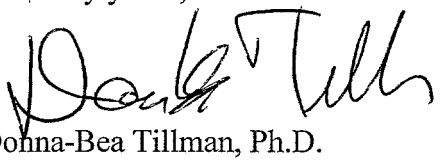
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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). 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: Defibtech, LLC

510(k) Number (if known): K013896

Device Name: *Sentry* Semiautomatic External Defibrillator ("AED")

Indications For Use:

The *Sentry* AED is indicated for use on victims of sudden cardiac arrest ("SCA") when the patient is:

- Unconscious and unresponsive
- Not breathing
- At least eight years old

The *Sentry* AED must be used by or on the order of a physician.

Contraindications For Use:

The *Sentry* AED should not be used if the patient shows any of the following signs:

- Conscious and/or Responsive
- Breathing
- Has a detectable pulse
- Is younger than eight years old

Refer to User's Manual for Operator Training Requirements.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices (801.109)

510(k) Number K013896

(Optional Format 1-2-96)