K033144

NOV 1 3 2003

Section E – 510(k) Summary

Date of Submission: September 26, 2003

Establishment Registration

Location

Company Name:	Defibtech, LLC
Address 1:	753 Boston Post Road
Address 2:	Suite 102
City, State, and Zip Code:	Guilford, CT 06437

Contact Information

Name:	Mr. John L. Rogers
Telephone:	(203) 453-6654 x13
Facsimile:	(203) 453-6657

Trade (Proprietary) Name	*Defibtech Electrode Adapter*
Model Number	*DAC-300 Series*
Common Name	*Defibrillation Electrode Adapter*

Classification

FDA Panel	Cardiovascular
Class	Class III
Regulation	21 CFR 870.1025 - Arrhythmia detector and alarm

Substantial Equivalence

Model	*Manufacturer*	*510(k) Number*
Heartstream Electrode Adapter	Heartstream, Inc.	K972418

Device Description

The Defibtech Electrode Adapter provides an interface between Defibtech electrodes and various automatic and manual external defibrillators. Each adapter is reusable and is either a stand-alone accessory or can be preattached to a Defibtech electrode package.

Intended Use

Intended for use with Defibtech electrodes to monitor, pace and defibrillate (up to 360 Joules) with automatic and manual defibrillators.

Conclusion Summary of Safety and Effectiveness

Testing and performance evaluations demonstrate that the safety and effectiveness of the Defibtech Electrode Adapter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2003

Defibtech, LLC
c/o Mr. John L. Rogers
Director, Medical Device Compliance
753 Boston Post Road, Suite 102
Guilford, CT 06437

Re: K033144
Trade Name: Defibtech Electrode Adapter
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: September 26, 2003
Received: September 30, 2003

Dear Mr. Rogers:

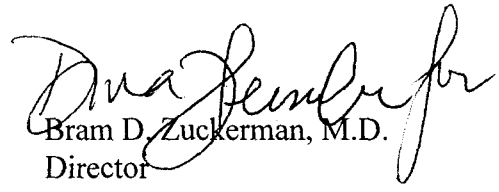
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

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Applicant: Defibtech, LLC

510(k) Number (if known): Not Applicable

Device Name: *Defibtech Electrode Adapter*

Indications For Use:

FOR USE WITH DEFIBTECH ELECTRODES FOR AUTOMATIC AND MANUAL EXTERNAL DEFIBRILLATORS FOR MONITORING, PACING AND DEFIBRILLATION UP TO 360 JOULES.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off)
vision of Cardiovascular Devices
510(k) Number K033144