



K972418
SEP 25

**510(k) Summary
Heartstream Electrode Adapters**

General Information

Trade Name	Heartstream Defibrillation Pads with Preattached Electrode Adapter
	Heartstream Electrode Adapter
FDA Panel and Classification	Cardiovascular, 74 DRO, Class III MKJ
Contact Person	Cindy Pestka Regulatory Affairs Manager
Address	Heartstream, Inc. 2401 4th Ave. Suite 300 Seattle, WA 98121

Substantially Equivalent Devices

<u>Manufacturer</u>	<u>Product</u>
Heartstream, Inc.	Heartstream External Defibrillation Pads
Katecho, Inc.	K-Defib/Pace Multifunction Electrodes
Darox	R2 series of adapters and cables

Description of Device & Intended Use

Heartstream electrode adapters serve as an interface to allow Heartstream electrodes to be connected to various manual defibrillators for external cardiovascular pacing as well as monitoring and delivery of defibrillation shocks up to 360J.

Heartstream electrode adapters are made of rigid thermoplastic material (or equivalent), with varying configurations depending upon the manual defibrillator for which they are designed. The adapters will be provided as reusable stand-alone accessories (to be used in conjunction with standard Heartstream electrodes) or preattached to a Heartstream electrode set, for single use.

510(k) Summary: Heartstream Electrode Adapters (Cont.)

Technological Characteristics

All Heartstream electrode adapters are designed to comply with applicable portions of relevant standards, including:

- *IEC 601-1, Medical electrical equipment, Part 1: General requirements for safety, 1993*
- *IEC 601-2-4, Medical electrical equipment, Part 2: Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator/Monitors, 1993*
- *IEC 601-2-25, Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographs*
- *ANSI/AAMI DF39-1993, Automatic external defibrillators and remote-control defibrillators. September 16, 1993*

Testing per these standards demonstrated that the Heartstream electrodes effectively deliver defibrillation energy up to 360J, allow for external transcutaneous cardiac pacing, demonstrate mechanical and electrical compatibility with manual defibrillators, and minimize safety risks to the user and patient.

Summary of Substantial Equivalence

Heartstream electrode adapters were evaluated in terms of indications for use, technological characteristics and materials, and compared to equivalent devices currently on the market.

The Heartstream electrode adapter is very similar in form, fit and function to other comparable devices. Marketed adapters and adapter cables typically consist of two connectors (or a double-sided connector) joined by an insulated conductor or cable of varying length. One connector (or one side of the connector) fits into the connector socket of the defibrillator, while the other attaches to the proximal end of the electrode set. The connectors are typically made of a rigid thermoplastic material. Adapters and adapter cables are designed so that both connectors are firmly seated when in use, and so they do not expose a user to a risk of accidental electrical contact. They are also designed to ensure that all pacing, monitoring and/or defibrillation functions are not adversely affected by their placement. These characteristics apply to both the stand-alone Heartstream electrode adapter and the Heartstream electrodes with a preattached adapter.

Heartstream electrodes with a preattached electrode adapter are substantially equivalent to the standard Heartstream electrodes regarding device design and usage for defibrillation, and Katecho K-Defib/Pace multifunction electrodes regarding device design and usage for defibrillation, monitoring and pacing.

Heartstream stand-alone electrode adapters are substantially equivalent to the Darox R2 series of adapter cables regarding device design and use as an interface between electrodes and defibrillators for defibrillation, monitoring and pacing, for use with numerous defibrillators.

Therefore, due to the similarity of design features, materials, and the similarity of the indicated use to other predicate devices, Heartstream, Inc. believes this product does not raise any new safety or effectiveness issues.



SEP 25 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lori Glastetter
Heartstream, Inc.
2401 4th Avenue, Suite 300
Seattle, Washington 98121

Re: K972418
Heartstream Electrode Adapters
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: June 26, 1997
Received: June 27, 1997

Dear Ms. Pestka:

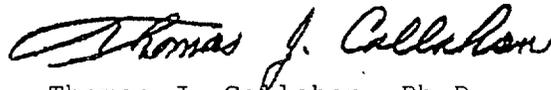
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number: K972418

Device Names: Heartstream Electrode Adapter, and
Heartstream External Defibrillation Pads with Preattached
Electrode Adapter

Indications for Use: **Heartstream Electrode Adapter:** For use with Heartstream
Defibrillators or Manual Defibrillators with a Quick-Combo®
Connection System. For Defibrillation, Monitoring and Pacing.

**Heartstream External Defibrillation Pads with Preattached
Electrode Adapter:** For use with Heartstream Defibrillators or
Manual Defibrillators with a Quick-Combo® Connection System.
For Defibrillation, Monitoring and Pacing.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)