DEC 17 1998

510(k) Summary K984286
Heartstream Electrode Adapters

General Information

Trade Name	Heartstream Electrode Adapter
FDA Panel and Classification	Cardiovascular, 74 MKJ, Class III
Contact Person	William D. Jordan Regulatory Affairs Specialist
Address	Heartstream, Inc. A wholly-owned subsidiary of Hewlett Packard Company 2401 4th Ave. Suite 500 Seattle, WA 98121

Substantially Equivalent Devices

Manufacturer	Product
Heartstream, Inc. A wholly-owned subsidiary of Hewlett Packard Company	Heartstream Electrode Adapter

Description of Device & Intended Use

Heartstream electrode adapters serve as an interface to allow Heartstream electrodes to be connected to various manual and automatic 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 and conductive material (or equivalent), with varying configurations depending upon the 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.

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 and automatic defibrillators, and minimize safety risks to the user and patient.

Summary of Substantial Equivalence

The Heartstream Electrode Adapter is very similar in form, fit and function to the predicate device. All adapter applications are tested using the actual model defibrillators specified on the packaging label. The adapter engineering specifications for the predicate and new device are the same – full compatibility with the specified defibrillator. The technology is the same – thermoplastic (or equivalent) adapter body with gold plated conductors. The applicable voluntary standards and guidances for both the predicate and new device are the same.

As with the predicate, the adapters 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. The adapters are also designed to ensure that all pacing, monitoring and/or defibrillation functions are not adversely affected by their placement.

Heartstream, Inc. concludes that the new adapter does not raise any new safety or effectiveness concerns and that the predicate and new devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1998

Mr. William D. Jordan
Hewlett-Packard Company
Heartstream Operation
2401 Fourth Avenue, Suite 300
Seattle, WA 98121-1436

Re: K984286
Heartstream Electrode Adapter
Regulatory Class: III (three)
Product Code: MLN
Dated: November 30, 1998
Received: December 1, 1998

Dear Mr. Jordan:

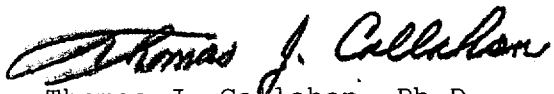
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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/dsma/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

Submitted: November 18, 1998

510(k) Number:

Device Names: Heartstream Electrode Adapter

Indications for Use: **Heartstream Electrode Adapter**: For use with Automatic and Manual External Defibrillators and Heartstream Electrodes. For Defibrillation, Monitoring and Pacing.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984286

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)