K992543

MAY 1 8 2000

510(k) Summary for Heartstream XLT Defibrillator/Monitor

Date Summary Prepared

May 17, 2000

Submitter's Name and Address

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Contact Person

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Device Name

Proprietary Name:	Heartstream XLT Defibrillator/Monitor
Common Name:	Defibrillator/Monitor
Classification Names:	Low-Energy Defibrillator, Electrocardiograph, External Transcutaneous Pacemaker (noninvasive), and Oximeter

Predicate Devices

The legally marketed devices to which Hewlett-Packard claims equivalence for the Heartstream XLT Defibrillator/Monitor are as follows:

- The HP CodeMaster 100 Defibrillator/Monitor,
- The HP Heartstream ForeRunner AED for the defibrillation waveform and voice prompts,
- The HP CodeMaster XL for the battery, and
- The HP Viridia Telemetry System for SpO_2 functionality.

The design of the Heartstream XLT Defibrillator/Monitor is substantially equivalent in safety and performance to the devices listed above.

Device Description

The Heartstream XLT Defibrillator/Monitor has two modes of operation: AED and manual. Non-invasive external pacing, as well as SpO_2 and 3/5-wire ECG monitoring are also available.

The Heartstream XLT defibrillator uses the Heartstream SMART biphasic waveform for defibrillation, the same waveform utilized in the Heartstream ForeRunner AED.

ECG data and events can be stored on a Data Card by the Heartstream XLT for later downloading and reporting with the Heartstream CodeRunner data management system.

Intended Use

The Heartstream XLT Defibrillator/Monitor is for use by emergency personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac life support, defibrillation, or other physician-authorized emergency medical response.

Comparison of Technology Characteristics

The Heartstream XLT Defibrillator/Monitor employs the same technologies as the predicate devices used for comparison. The XLT acquires and analyzes ECG signals like the predicates, utilizes the same shock advisory criteria utilized in the CodeMaster 100, and advises the user to deliver a shock when required utilizing voice prompts as in the Heartstream ForeRunner AED. The Heartstream SMART Biphasic waveform is utilized for defibrillation shocks, as in the Heartstream ForeRunner AED. Heart rate alarms, noninvasive pacing and pulse oximetry functions are provided, as in the HP CodeMaster. The XLT's SpO_2 technology is identical to the HP Viridia Telemetry System. The battery type and chemistry are the same as the HP CodeMaster XL battery.

Nonclinical Tests Used in Determination of Substantial Equivalence

The objective of the testing performed on the Heartstream XLT Defibrillator/Monitor was to determine whether any of the device's new or revised functions raise any questions regarding the safety or effectiveness of the device. The philosophy of this approach is that if the Heartstream XLT passes equivalent tests done with the previous devices, then it can be concluded that there are no questions with respect to safety or effectiveness of the new Heartstream XLT.

For each function on the Heartstream XLT that is leveraged from previous HP products, such as the CodeMaster 100 or the Heartstream ForeRunner, the testing done for the previous product was repeated in order to demonstrate equivalence, although in some cases, more stringent procedures and/or acceptance criteria were required for the XLT. In other cases, the features of the predicate devices are identical to those on the Heartstream XLT and did not require repetition.

The nonclinical tests used in determination of substantial equivalence include both bench and animal testing. Bench testing includes hardware, algorithm and software

testing. Animal testing was also performed in order to evaluate the safety and effectiveness of the Heartstream SMART biphasic waveform up to 200J.

Conclusion from Testing

Based on the results of the testing described above, it is concluded that the Heartstream XLT does not raise any different questions regarding the safety or effectiveness as compared with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2000

Ms. Teresa Skarr
Regulatory and Medical Affairs Manager
Agilent Technologies
Heartstream Operation
2401 Fourth Ave., Suite 500
Seattle, WA 98121-1436

Re: K992543
Heartstream XLT Defibrillator/Monitor Model M3500B
Regulatory Class: III
Product Code: 74 MKJ, DRO, LDD, MWI
Dated: April 5, 2000
Received: April 6, 2000

Dear Ms. Skarr:

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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K992543

Device Name: Heartstream XLT Defibrillator/Monitor

Indications For Use: The Heartstream XLT Defibrillator/Monitor is to be used for the termination of ventricular tachycardia and ventricular fibrillation.

This device is for use by emergency personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac life support, defibrillation, or other physician-authorized emergency medical response. It must be used by or on the order of a physician.

The SMART Biphasic waveform utilized in the Heartstream XLT Defibrillator/Monitor has undergone clinical testing in adults. These trials support the waveform's effectiveness for defibrillation of ventricular tachyarrhythmias at 150J.

In the manual mode operation, the Heartstream XLT Defibrillator/Monitor incorporates some user selectable lower energy levels that were not used in the clinical trials.

AED Therapy:
To be used in the presence of a suspected cardiac arrest on patients that are unresponsive, not breathing and pulseless.

The AED mode is not intended for use on children less than 8 years of age. For children older than 8 years, the American Heart Association recommends that standard operating procedures for AEDs be followed. American Heart Association. *Textbook of Advanced Cardiac Life Support*. Dallas, Tex: AHA;1997.

Pacing:
Noninvasive pacing is one method of treating patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

SpO_2 Monitoring:
SpO_2 monitoring is indicated for use when it is beneficial to assess a patient's oxygen saturation level.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)