JAN 1 4 2002

K013425

14.PreMarket Notification Summary

510(k) Summary for the Heartstream FR2 AED

1. Date Summary Prepared

October 15, 2001

2. Submitter's Name and Address

Philips Medical System
Heartstream
2401 Fourth Avenue, Suite 500
Seattle, WA 98121

3. Contact Person

Tamara Yount
Philips Medical System
Heartstream
Telephone: (206) 664-5141
Facsimile: (206) 664-5001

4. Device Name

Proprietary Name: Heartstream FR2 AED with ECG Cable
Common Name: Automated external defibrillator
Classification Names: Low-Energy Defibrillator

5. Predicate Devices

The legally marketed device to which Philips Medical Systems, Heartstream claims equivalence for the Heartstream FR2 AED with ECG Cable is the Heartstream FR2 AED, Laerdal Heartstart 3000, Heartstream XLT Defibrillator/Monitor and the Active Corporation ActiveECG device.

The design and intended use of the modified Heartstream FR2 AED is substantially equivalent in safety and performance to the devices named above.

6. Device Description

The Heartstream FR2 is an automated external defibrillator available in two models, including one with ECG display and manual shock capability. Features include self-testing, impedance-compensating biphasic truncated exponential waveform, multi-parameter Patient Analysis System (PAS), and human factor designs to facilitate use by lay responders.

A non-rechargeable lithium manganese dioxide battery powers the FR2 with a typical capacity of 300 shocks or 12 hours of operating time.

Except for specific programmed periods when a responder needs to deliver uninterrupted CPR, the FR2 continuously and automatically analyzes the ECG and alerts the responder when the ECG changes to a possible shockable rhythm. Analysis continues even after the FR2 advises a shock and arms - if the ECG spontaneously converts to a non-shockable rhythm prior to a responder pressing the shock button, the FR2 disarms.

If significant artifact is detected in the ECG, Heartstream's PAS suspends further analysis until reliable data is available. When a shockable rhythm is detected, the FR2 directs the responder to press the shock button to deliver a biphasic shock to the patient.

Event and incident data can be recorded during FR2 use with an optional data card having a recording capacity of four hours of event and ECG data (or thirty minutes with voice recording).

The FR2 has an optional Training and Administration Pack that is used for device training and for customizing FR2 set-up options. Use of the Training and Administration Pack converts the FR2 to a training device with ten training "scripts" that simulate different SCA scenarios.

The FR2 also has an infrared communication port to facilitate communication of set-up parameters.

An optional reusable ECG Cable can be inserted into the AED's connector port to permit the viewing of lead II ECG and heart rate on the FR2's main crystal display screen. Three lead wires, connected to standard disposable ECG electrodes, are labeled according to AAMI or IEC conventions. If a potentially shockable rhythm is detected (using the existing FR2 PAS algorithm) or if the heart rate drops below 30 beats per minute, voice and text prompts are generated.

7. Intended Use

The Heartstream FR2 is intended for use by personnel who have been trained in its operation. The user should be qualified by training in basic life support, or advanced life support, or other physician-authorized emergency medical response.

The Heartstream FR2 is indicated for use on victims of sudden cardiac arrest exhibiting the following signs:

- Unresponsiveness
- Absence of breathing

At the discretion of emergency care personnel, the M3860A FR2 with ECG display enabled can also be used with the FR2 ECG Cable to display the rhythm of a responsive

or breathing patient, regardless of age. The FR2 and ECG Cable system provides a non-diagnostic display for attended patient monitoring. While connected to the FR2 ECG Cable, the FR2 evaluates the patient's ECG and disables its shock capability.

8. Comparison of Technology Characteristics

The modified Heartstream FR2 AED with the ECG Cable employs the same fundamental scientific technologies as the Laerdal Heartstart 3000, the Heartstream XLT Defibrillator/Monitor and the Active Corporation ActiveECG device.

9. Data Used in Determination of Substantial Equivalence

The Heartstream FR2 employs the same technologies as the predicate devices used for comparison. The FR2 acquires and analyzes ECG signals, and utilizes the same shock advisory criteria like the predicates and the FR2 without the ECG Cable.

Bench testing demonstrates that the performance of the ECG Cable meets specifications is appropriate for its intended application.

10. Conclusion

The modifications proposed to include an optional ECG Cable to the FR2 accessory offerings do not present new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 4 2002

Ms. Tamara Yount
Philips Medical Systems
2401 Fourth Avenue, Suite 500
Seattle, WA 98121-1436

Re: K013425
Trade Name: Heartstream FR2 AED with an ECG Cable
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrythmia Detector and Alarm
Regulatory Class: III (three)
Product Code: MKJ and DPS
Dated: October 15, 2001
Received: October 16, 2001

Dear Ms. Yount:

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) 594-4646. 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,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

11.Indications for Use

510(k) Number (if known): To be assigned K013425

Device Name: Philips Medical Systems, Heartstream FR2 Automated External Defibrillator (AED) with ECG Cable

Indications For Use:

The FR2 is intended to be used with disposable Heartstream defibrillation pads applied to a person who is experiencing the symptoms of sudden cardiac arrest (SCA): unresponsiveness and absence of breathing.

When the patient is under 8 years or weighs less than 55 pounds (25 kg), the FR2 should be used with attenuated pediatric defibrillation pads.

The FR2 is intended for use by personnel who have been trained in its operation. The user should be qualified by training in basic life support (BLS), advanced life support (ALS) or other physician-authorized emergency medical response.

At the discretion of emergency care personnel, the M3860A FR2 with ECG display enabled can also be used with the FR2 ECG Cable to display the rhythm of a responsive or breathing patient, regardless of age. The FR2 and ECG Cable system provides a non-diagnostic display for attended patient monitoring. While connected to the FR2 ECG Cable, the FR2 evaluates the patient's ECG and disables it's shock capability.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013425

Prescription Use ✓ or Over-The-Counter Use _____

(Per 21 CFR 801.109)