JAN 17 2002

16. 510(k) Summary

K014157

510(k) Summary for the Heartstream FR2 AED with the M3848A and M3849A

1. Date Summary Prepared

December 11, 2001

2. Submitter's Name and Address

Philips Medical Systems
Heartstream
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3. Contact Person

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Heartstream
Telephone: (206) 664-5000
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4. Device Name

Proprietary Name: Heartstream FR2 AED with M3848A and M3849A
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 modified Heartstream FR2 AED with the M3848A and M3849A is the Heartstream FR2 AED. The modified device is also substantially equivalent to the Medtronic/Physio-Control LifePak 500.

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 model 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 factors design 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. An optional rechargeable lithium-ion battery with a typical capacity of 100 shocks and 4 hours of operating time, and its companion charger, will also be available.

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.

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, 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

8. Comparison of Technology Characteristics

The modified Heartstream FR2 AED with the M3848A employs the same fundamental scientific technologies as the commercially available Heartstream FR2 AED. The modified device is also similar to the Medtronic/Physio-Control LifePak 500.

9. Data Used in Determination of Substantial Equivalence

The modified Heartstream FR2 with the M3848A and M3849A employs the similar technologies to provide similar performance characteristics as the predicate devices.

Bench testing demonstrated that the performance of the M3848A and M3849A meets specifications. In addition, it was demonstrated by simulated use testing that the M3848A and M3849A are appropriate for the intended users.

10. Conclusion

The modifications proposed to include the M3848A and M3849A to the FR2 accessory product offerings do not present new issues of safety or effectiveness.

LAST PAGE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

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

Re: K014157
Heartstream FR2 AED with M3848A and M3849A
Regulation Number: 21 CFR 870.1025
Regulation Name: Automatic External Defibrillator
Regulatory Class: III (three)
Product Code: MKJ
Dated: December 17, 2001
Received: December 19, 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. In addition, if you wish to change or expand the current indications for use to include non-military environments, you will need to submit a new 510(k) premarket notification, and receive FDA clearance prior to marketing the device.

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

12.Indications for Use

Indications for Use

510(k) Number (if known): K014157

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

Indications for Use: The Heartstream FR2 is indicated for use on persons experiencing the symptoms of sudden cardiac arrest:

- Lack of responsiveness
- Lack 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. DO NOT DELAY TREATMENT TO DETERMINE THE CHILD'S EXACT AGE/WEIGHT.

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, advanced life support, or other physician-authorized emergency medical response.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(K) Number K014157

Prescription Use ✓ or Over-The-Counter Use _____