OCT 5 - 2005

510(k) Summary for the Philips HeartStart FR2+ AED with Modifications

1. 510(k) Submission Number

#K051632

2. Date Summary Prepared

October 3, 2005

3. Submitter's Name and Address

Philips Medical Systems
Heartstream
2301 Fifth Avenue, Suite 200
Seattle, WA 98121

4. Contact Person

Tamara Yount
Philips Medical Systems
Heartstream
Telephone: (206) 664-5000
Facsimile: (206) 664-5001

5. Device Name

Proprietary Name:	Philips HeartStart FR2+ AED
Common Name:	Automated external defibrillator
Classification Name:	Low-Energy Defibrillator

6. Predicate Device

The legally marketed device to which Philips Medical Systems, Heartstream claims equivalence for the Philips HeartStart FR2+ AED with modifications is the Philips/Heartstream HeartStart FR2+ AED.

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

7. Device Description Summary

The HeartStart 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, FR2+ 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 at least 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. The FR2+ is highly configurable, with over 10 possible parameters. 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 liquid 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+ algorithm) or if the heart rate drops below 30 beats per minute, voice and text prompts are issued.

8. Intended Use

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

If in doubt, apply the pads.

When the patient is under 8 years or weighs less than 55 pounds (25 kg), apply FR2 infant/child reduced-energy defibrillator pads, if available.

WARNING: Performance of the SMART CPR AUTO1 and AUTO2 settings has not been established in patients under 8 years or 55 lb (25 kg). See Appendix E for more information.

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

9. Comparison of Technology Characteristics

The modified Philips HeartStart FR2+ employs the same fundamental scientific technologies as the currently available Philips HeartStart FR2+.

10. Data Used in Determination of Substantial Equivalence

The FR2+ employs most the same technologies as the predicate device used for comparison.

Testing demonstrated the performance of the modified FR2+ is acceptable and meets predefined criteria.

11. Conclusion

The modifications proposed 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

OCT 5 - 2005

Philips Medical Systems
Heartstream
c/o Ms. Tamara Yount
Senior Regulatory Specialist
2301 Fifth Avenue, Suite 200
Seattle, WA 98121

Re: K051632
Trade Name: Philips HeartStart FR2+ AED
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: September 22, 205
Received: September 23, 205

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

Indications for Use

510(k) Number (if known): #K051632

Device Name: Philips FR2+ Automated External Defibrillator (AED)

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) or Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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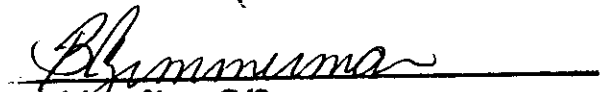
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051632