DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Philips Medical System
c/o Ms. Teresa Skarr
Manager, Regulatory and Medical Affairs
2301 Fifth Avenue, Suite 200
Seattle, WA 98121-1825

Re: K040904
Trade Name: Philips HeartStart Home Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: III (three)
Product Code: NSA
Dated: September 14, 2004
Received: September 15, 2004

Dear Ms. Skarr:

This letter corrects our substantially equivalent letter of September 16, 2004, sent by fax, regarding the Philips HeartStart Home Defibrillator, addressed to Ms. Teresa Skarr, 2301 Fifth Avenue, Suite 200, Seattle WA 38121-1825. The name in the salutation of the letter, Mr. Smirles, was incorrect. Instead it should be Ms. Skarr.

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 of our September 16, 2004, letter) 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 (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 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 continue 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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

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

SEP 1 6 2004

510(k) Summary

510(k) Number: #K040904

510(k) Summary for the Philips HeartStart Home OTC Defibrillator

1. Date Summary Prepared:

September 13, 2004

2. Submitter's Name and Address

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

3. Contact Person

Teresa Skarr
Manager, Regulatory and Medical Affairs
Philips Medical Systems
Heartstream
2301 Fifth Avenue, Suite 200
Seattle, WA 98121
Telephone: (206) 664-5290
Facsimile: (206) 664-2070
E-mail: teresa.skarr@philips.com

4. Device Name

Proprietary Name: Philips HeartStart Home Defibrillator
Common Name: Defibrillator
Classification Name: Automated External Defibrillator

5. Predicate Devices

The legally marketed device to which Philips Medical Systems, Heartstream claims equivalence for the HeartStart Home OTC Defibrillator is the HeartStart Home Rx Defibrillator (cleared under K020715) and the FR2 Defibrillator (cleared under K003565).

The design, performance, and intended use of the HeartStart Home Defibrillator are substantially equivalent in safety and performance to the predicates.

6. Device Description

The HeartStart Home Defibrillator was designed to be safe, easy and ready to use. Features of the HeartStart Home Defibrillator include self-testing and self-calibration, an impedance-compensating biphasic truncated exponential therapy waveform, a multi-parameter ECG analysis system for determining if a shock is required, and an integrated human factors design to facilitate use by lay responders.

A non-rechargeable lithium manganese dioxide battery powers the HeartStart Home Defibrillator with a minimum capacity of 90 shocks and 3 hours of operating time.

The HeartStart Home Defibrillator monitors the progress of the rescue and issues voice instructions as appropriate, keeping pace with the user. The defibrillator incorporates a shock-delivery protocol that pauses at predefined intervals to allow users to deliver CPR, with CPR coaching available. Except during these pause intervals for CPR, the defibrillator continuously and automatically analyzes the patient's ECG to determine if a shock is needed. The defibrillator incorporates technologies that assess the ECG validity using both common mode and differential mode signals; these technologies were designed to ensure that a shock is not advised unless the defibrillator is applied to a patient in a shockable heart rhythm.

The HeartStart Home Defibrillator utilizes the same biphasic, impedance-compensating exponential waveform used in previous-generation Philips AEDs. With the standard pads cartridge installed, the HeartStart Home Defibrillators delivers 150J shocks (nominal) after a shockable rhythm has been detected, and the user presses the shock button as instructed by the defibrillator. The HeartStart Home Defibrillator offers no manual-shock capability.

7. Intended Use

The HeartStart Home Defibrillator should be used to treat someone who you think may be a victim of sudden cardiac arrest. A person in sudden cardiac arrest:

- does not respond when shaken, and
- is not breathing normally.

If in doubt, apply the pads.

8. Comparison of Technology Characteristics

The HeartStart Home OTC Defibrillator is identical to the commercially available HeartStart Home Defibrillator and incorporates many of the same technologies and features as the commercially available FR2 defibrillator.

9. Data Used in Determination of Substantial Equivalence

The HeartStart Home OTC Defibrillator employs the same or similar technologies as the predicate devices. The safety and effectiveness of the 150J biphasic waveform used in the HeartStart Home Defibrillator was demonstrated in clinical trials and field studies included in previous 510(k) submissions. Similarly, the sensitivity and specificity of the ECG analysis system used in the HeartStart Home Defibrillator was demonstrated in bench and field studies in previous 510(k) submissions.

For the current 510(k), several reports were included for review by the Cardiovascular System Devices Panel and presented for panel discussion and public comment. Relevant reviews of the available literature and the Philips AED technology platform were conducted, including:

- **Literature Review:** Relevant publications in medical literature and safety databases were summarized, demonstrating the features that are important to defibrillator safety, effectiveness and usability.

- **Field Performance Summary:** The field performance of the HeartStart Home Defibrillator and its technology platform was reviewed, demonstrating the safety history of over 150,000 Philips AEDs that have accumulated over 160,000 service years.

- **Lay User Survey:** A telephone survey was conducted of all ForeRunner and FR2 home and business customers. This survey confirmed that there were no previously unreported safety or effectiveness issues in uses of these devices by laypersons.

Additional studies supporting the safety and usability of the HeartStart Home Defibrillator were conducted, including:

- **Safety and Usability Study:** A total of 124 volunteers with no prior exposure to a defibrillator were randomized to attempt a mock-rescue on a manikin relying only upon the voice instructions and graphics of the defibrillator, or alternatively to view a brief training videotape prior to using the defibrillator. Safety and usability endpoints were assessed. The HeartStart Home Defibrillator was used safely by all participants and successfully used by both naïve and video trained volunteers at 87% (n = 61) and 89% (n = 63). There was no difference detected between participants who had no prior exposure or training in defibrillator use and the video-trained participants.

- **Labeling Evaluation:** A total of 353 participants with no prior exposure to a defibrillator were randomly assigned to review and take a multiple-choice written comprehension test on one of the four major labeling pieces for the HeartStart

Home Defibrillator. This evaluation found that all four of the major HeartStart Home labeling materials were well understood. The users who had reviewed materials that would be available with the device during a use were asked to participate in a mock-rescue scenario with the HeartStart Home Defibrillator. Safety and usability endpoints were assessed. All participants in the mock-rescue portion of the evaluation used the HeartStart Home Defibrillator safely (n = 178), and the majority were able to use the defibrillator successfully (97% for the Quick Reference Guide, and 83% for the Owner's Manual).

- **Design Validations:** The design validation studies conducted by Philips prior to the initial HeartStart Home Rx Defibrillator release were included in the current 510(k) for the over-the-counter version of the device. These studies assessed safety and usability endpoints in mock-rescue scenarios for adult (n = 20) and infant/child (n = 10) use. All participants used the defibrillator safely, and all participants in the adult use scenario used the defibrillator successfully.

- **Post-Market Study:** Philips' commitment to continue and expand its ongoing post-market study of home use, and the plan with proposed revisions, were included in the 510(k).

The safety and effectiveness of the HeartStart Home Defibrillator has been established through extensive clinical and animal data presented in previous 510(k) submissions, as supplemented by the safety and usability data presented in the current 510(k) and summarized herein.

10. Conclusion

The safety and effectiveness data supports the substantial equivalence of the HeartStart Home Defibrillator without prescription labeling to its predicates.

Indications for Use

510(k) Number (if known): #K040904

Device Name:

Philips HeartStart Home Defibrillator

Indications for Use:

The HeartStart Home Defibrillator should be used to treat someone who you think may be a victim of sudden cardiac arrest. A person in sudden cardiac arrest:

- does not respond when shaken, and
- is not breathing normally.

If in doubt, apply the pads.

Prescription Use _____ or Over-The-Counter Use ____X____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040904