

K063375

## 8.0 510(k) Summary

JAN 11 2007

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is Philips Medical Systems

This summary was prepared on 24 October 2006

2. The name of this device is the HeartStart MRx Monitor/Defibrillator Software Release 7.01. Classification names are as follows:

Classification	ProCode	Description
870.2340, II	74 DPS	Electrocardiograph device
870.1130, II	74 DXN	Non-invasive blood pressure
870.2700, II	74 DQA	Pulse oximeter
870.2300, II	74 MWI	Monitor, Physiological, Patient
870.2300, II	74 MSX	System, Network and Communication, Physiological Monitors
868.1400, II	74 CCK	End-tidal Carbon Dioxide
870.5550, II	74 DRO	External Transcutaneous Pacemaker (Non-invasive)
870.5300, II	74 LDD	Low-energy defibrillator
870.1025, III	74 MKJ	Defibrillators, Automatic, External
870.5200, III	74 LIX	Cardiopulmonary Resuscitation Aid
870.1110, II	74 DSK	Blood Pressure Computer
880.2910, II	80 FLL	Clinical Electronic Thermometer

3. The new device is substantially equivalent to the previously cleared HeartStart MRx Monitor/Defibrillator software cleared under K031187 and K051134, as well as K061707).
4. The modification is a change that provides an optional Bluetooth™ wireless technology option to transfer data from the MRx to a Bluetooth enabled device. This wireless connection is an alternative to the current RS232 cable connection capability.
5. The new device has the same Indications for Use as the legally marketed predicate device.
6. The new device has the same technological characteristics as the legally marketed predicate device.
7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, integration tests, environmental tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the device meets all performance claims.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 11 2007

Philips Medical Systems  
Ms. Denise Haley  
Sr. Quality and Regulatory Engineer  
3000 Minuteman Road  
Andover, MA 01810

Re: K063375

Trade Name: HeartStart MRx Models M3535A/M3536A

Regulation Number: 21 CFR 870.5310

Regulation Name: Automatic External Defibrillator

Regulatory Class: Class III

Product Code: MKJ

Dated: December 12, 2006

Received: December 12, 2006

Dear Ms. Haley:

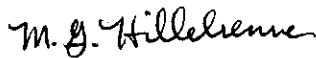
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for

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

Enclosure

## 2.0 Indications for Use

510(k) Number (if known): K063375

Device Name: HeartStart MRx Monitor/Defibrillator

### **Indications for Use:**

The HeartStart MRx is for use for the termination of ventricular tachycardia and ventricular fibrillation. The device is for use by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician.

### **AED Therapy**

To be used in the presence of a suspected cardiac arrest on patients of at least 8 years of age that are unresponsive, not breathing and pulseless.

### **Manual Defibrillation**

Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronous defibrillation is indicated for termination of atrial fibrillation.

### **Non-invasive External Pacing Therapy**

The pacing option is intended for treating patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

### **Pulse Oximetry**

The SpO2 option is intended for use when it is beneficial to assess a patient's oxygen saturation level.

### **Non-invasive Blood Pressure Monitoring**

The NBP option is intended for non-invasive measurement of a patient's arterial blood pressure.

### **End-tidal CO2**

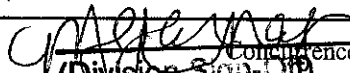
The EtCO2 option is intended for non-invasive monitoring of a patient's exhaled carbon dioxide and to provide a respiration rate.

### **12-Lead ECG**

The 12-Lead ECG function is to provide a conventional diagnostic 12-Lead ECG report, which may include measurements and interpretative statements.

[continued....]

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Division of Cardiovascular Devices

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Device Name: HeartStart MRx Monitor/Defibrillator

**Indications for Use:** [continued....]

**Q-CPR**

The Q-CPR™ option provides feedback designed to encourage rescuers to perform resuscitation in accordance with AHA/ERC guidelines for chest compression rate, depth, and duty cycle and ventilation rate, volume and flow rate (inflation time).

The Q-CPR option is contraindicated as follows:

- The Q-CPR option is contraindicated for use on neonatal and pediatric patients (under 8 years of age or weighing less than 25 kg).
- The Q-CPR option is not for use when CPR is contraindicated.

**Invasive Pressure**

The Invasive Pressure option is indicated for measuring arterial, venous, intracranial and other physiological pressures on patients.

**Temperature**

The Temperature option is indicated for measuring temperature in patients.

Prescription Use Yes  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use No  
(21 CFR 807 Subpart C)

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