K051134

SEP - 8 2005

17. 510(k) Summary

Date Summary Prepared

April 25, 2005

Submitter's Name and Address

Philips Medical Systems
Cardiac and Monitoring Systems
Cardiac Resuscitation
3000 Minuteman Road
Andover, MA 01810-1099

Contact Person

Peter Ohanian
Philips Medical Systems
Cardiac and Monitoring Systems
Cardiac Resuscitation
Telephone: (978) 659-3397
Facsimile: (978) 659-7360

Device Name

Proprietary Name:	HeartStart MRx monitor/defibrillator with Q-CPR™ option
Common Name:	Monitor/defibrillator
Classification Names:	Low-Energy Defibrillator, Arrhythmia Detection & Alarms (Automatic External Defibrillator), External Transcutaneous Pacemaker (noninvasive), ECG, Non-Invasive Blood Pressure, End Tidal Carbon Dioxide, Pulse Oximeter, and Cardiac Monitor; Cardiopulmonary Resuscitation (CPR) Aid

Predicate Devices

The legally marketed devices to which Philips Medical Systems claims equivalence for the HeartStart MRx monitor/defibrillator with Q-CPR™ option are as follows:

- Philips Medical Systems HeartStart MRx monitor/defibrillator, and
- ZOLL Medical Corp. Zoll AED Plus with CPR-D Padz external defibrillator

The design of the HeartStart MRx monitor/defibrillator with Q-CPR™ option is substantially equivalent in safety and performance to the devices listed above.

Device Description

The HeartStart MRx monitor/defibrillator with Q-CPR™ option is a lightweight, portable external defibrillator, offering two modes of operation for defibrillation (manual mode and semi-automatic mode (AED)) and having an option to provide visual and audible feedback to the rescuer on the quality of CPR.

In manual mode, the HeartStart MRx monitor/defibrillator with Q-CPR™ option is a full-featured manual defibrillator, designed for use by clinicians trained in Advanced Cardiac Life Support (ACLS). Manual operation allows users to select energy levels for external and internal defibrillation, perform synchronized cardioversion and provide non-invasive external pacing.

In AED mode, the HeartStart MRx monitor/defibrillator with Q-CPR™ option, allows the provider who is trained in Basic Life Support (BLS) to provide defibrillation therapy. The device analyzes a patient's rhythm and advises the user to provide a shock. Voice prompts guide the user through the defibrillation process by providing instructions and patient information. The voice prompts are reinforced by messages that appear on the display.

In both modes of operation, the HeartStart MRx monitor/defibrillator with Q-CPR™ option utilizes impedance compensating biphasic truncated exponential therapy waveform.

The HeartStart MRx monitor/defibrillator with Q-CPR™ option can also be used for ECG monitoring of a patient using either 3 or 5 lead cables.

Additionally, the HeartStart MRx monitor/defibrillator with Q-CPR™ option is offered with the following optional functionality:

Non-Invasive External Pacing:

The pacing option is intended for treating patients with symptomatic bradycardia. This parameter is used by ACLS trained clinicians typically performed in a hospital environment.

12-Lead ECG:

The 12-Lead ECG option is intended to provide a conventional diagnostic 12-Lead ECG report, which may include measurements and interpretative statements. This parameter is used in both the hospital and pre-hospital environment by ACLS and BLS trained clinicians.

Non-Invasive Blood Pressure:

The NIBP option is intended for noninvasive measurement of a patient's arterial blood pressure. This parameter is used in both the hospital and pre-hospital environment by ACLS and BLS trained clinicians.

Endtidal CO2:

The EtCO2 option is intended for noninvasive monitoring of a patient's exhaled carbon dioxide and also provides a respiration rate. This parameter is used by ACLS trained clinicians and performed in both the pre-hospital and hospital environments.

Pulse Oximetry:

The SpO2 option is intended for use when it is beneficial to assess a patient's arterial oxygen saturation level. This parameter is used by trained clinicians and performed in both the pre-hospital and hospital environments.

Features

- ECG monitoring through pads or separate monitoring electrodes
- Alarms on Heart Rate Limits and shockable rhythms
- Built-in strip chart printer
- Display for viewing waveforms and messages
- Automated self test with indicator
- Internally stored event summary which may be printed
- Voice prompts in AED mode
- Adjustable ECG size
- Adjustable volume control
- Setup mode, automatic self tests and error handling
- Lithium Ion battery
- Internal Defibrillation
- External Paddles with patient contact indicator
- 3, 5, and 12 Lead ECG cables
- Battery Charging Kit
- PCMCIA Data card for data and event capture
- Data recording, management, and transfer
- Event Review
- AC Power Module
- DC Power Module

Indications for Use

The HeartStart MRx monitor/defibrillator with Q-CPR™ option 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 Therapy

Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronized 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 NIBP option is intended for noninvasive measurement of a patient's arterial blood pressure.

Endtidal CO2 Monitoring

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

12-Lead ECG:

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

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.

Comparison of Technology Characteristics

The HeartStart MRx monitor/defibrillator with Q-CPR™ option is the same as the HeartStart MRx monitor/defibrillator, except for the added Q-CPR™ functions. The HeartStart MRx monitor/defibrillator with Q-CPR™ option employs the same fundamental scientific technologies as the commercially available predicate devices used for comparison. The HeartStart MRx monitor/defibrillator with Q-CPR™ option acquires and analyzes ECG signals, utilizes the same shock advisory criteria, and advises the user to deliver a shock when required utilizing voice prompts as in the HeartStart MRx monitor/defibrillator without the Q-CPR™ option. Heart rate alarms, noninvasive pacing, pulse oximetry, 12-Lead ECG, NIBP, and EtCO2 technologies and functions are identical to those in the HeartStart MRx monitor/defibrillator. The HeartStart MRx monitor/defibrillator with Q-CPR™ option's AED and CPR assist technologies and functions are substantially equivalent to those of the Zoll AED Plus with CPR-D Padz external defibrillator.

Tests Used in Determination of Substantial Equivalence

The tests used in the determination of substantial equivalence included bench testing and biocompatibility testing. Bench testing includes hardware and software testing demonstrating that the performance of the device meets its specification. Biocompatibility testing was conducted on the patient-contact materials of the Q-CPR™ sensor.

Conclusion from Testing

Based on the results of the testing described above, it is concluded that the HeartStart MRx monitor/defibrillator with Q-CPR™ option does not raise any different questions regarding the safety or effectiveness as compared with the predicate devices. It is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2005

Philips Medical System
c/o Mr. Peter Ohanian
Director, Quality and Regulatory Affairs
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, Massachusetts 01810-1099

Re: K051134
Trade Name: Heartstart MRx with Q-CPR Option Models M3535A or M3536A
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ, LDD, DRO, DPS, DXN, CCK, DQA, MWI LIX
Dated: August 29, 2005
Received: August 30, 2005

Dear Mr Ohanian:

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) 276-0295. 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,

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

Enclosure

2. Indications for Use

510(k) Number (if known): K051134

Device Name: Philips Medical Systems, HeartStart MRx monitor/defibrillator with Q-CPR™ option

The HeartStart MRx monitor/defibrillator with Q-CPR™ option 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 Therapy

Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronized 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 NIBP option is intended for noninvasive measurement of a patient's arterial blood pressure.

[continued...]

Prescription Use ___X___ and/or Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K051134

510(k) Number (if known): K051134

Device Name: Philips Medical Systems, HeartStart MRx monitor/defibrillator with Q-CPR™ option

Indications for Use: [continued...]

Endtidal CO2 Monitoring

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

12-Lead ECG

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

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.

Prescription Use ___X___ and/or Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K051134