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4 510(k) Summary

AUG 11 2006

Date Summary Prepared
June 12, 2006

Submitter's Name and Address
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Device Name

Proprietary Name:	HeartStart MRx Invasive Pressure Option and Temperature Option
Common Name:	Invasive Blood-Pressure Measurement System Electronic Thermometer

Classification names:

Classification	ProCode	Description
870.5300, Class II	74 LDD	Low-Energy Defibrillator
870.1025, Class III	74 MKJ	Defibrillators, Automatic, External
870.5200, Class III	74 LIX	Cardiopulmonary Resuscitation Aid
870.5550, Class II	74 DRO	External Transcutaneous Pacemaker (noninvasive)
870.2340, Class II	74 DPS	Electrocardiograph Device
870.1130, Class II	74 DXN	Non-Invasive Blood Pressure
868.1400, Class II	74 CCK	End Tidal Carbon Dioxide
870.2700, Class II	74 DQA	Pulse Oximeter
870.2300, Class II	74 MWI	Monitor, Physiological, Patient
870.1110, Class II	74 DSK	Blood Pressure Computer
880.2910, Class II	80 FLL	Clinical Electronic Thermometer

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Predicate Devices

The legally marketed devices to which Philips Medical Systems claims equivalence for the HeartStart MRx Invasive Pressure Option and Temperature Option are as follows:

- Philips Medical Systems HeartStart MRx Monitor/Defibrillator K031187, K051134, and
- ZOLL Medical Corp. M Series IBP Option and Temperature Option K011865

The design of the HeartStart MRx is substantially equivalent in safety and performance to the devices listed above.

Device Description

The HeartStart MRx is a lightweight, portable external defibrillator, offering two modes of operation for defibrillation: manual mode and semi-automatic mode (AED). The HeartStart MRx can also be used for ECG monitoring of a patient, non-invasive external pacing, 12-Lead ECG, non-invasive blood pressure, end-tidal CO_2 ($EtCO_2$), pulse oximetry (SpO_2), Q-CPR™, invasive pressure and temperature measurements.

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
- Trending - Store the vital sign trends for physiologic data that are being monitored by the user
- Cerebral Perfusion Pressure
- Pulse rate from SpO_2 or Invasive Pressure

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Intended Use

The Intended use/Indications for Use information is provided in the "Indications for Use Statement" section.

Comparison of Technology Characteristics

The HeartStart MRx with Invasive Pressure and Temperature Options employs the same fundamental scientific technologies as the commercially available predicate devices used for comparison. The HeartStart MRx 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 previous HeartStart MRx. Heart rate alarms, noninvasive pacing, pulse oximetry, 12-Lead ECG, NIBP, $EtCO_2$, Q-CPR™ functions are provided, as in the HeartStart MRx. The HeartStart MRx's Invasive Pressure and Temperature functionalities are substantially equivalent to the ZOLL M Series defibrillator.

Tests Used in Determination of Substantial Equivalence

The tests used in the determination of substantial equivalence included only bench testing. Bench testing includes hardware and software testing demonstrating that the performance of the device meets its specifications.

Conclusion from Testing

Based on the results of the testing described above, it is concluded that the HeartStart MRx with Invasive Pressure and Temperature Options 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

AUG 11 2006

Philips Medical Systems
c/o Mr. Songhua Zhang
Regulatory Specialist
Ultrasound and Monitoring Business Group Cardiac Systems
3000 Minuteman Road
Andover, MA 01810-1099

Re: K061707
Trade/Device Name: HeartStart MRx Invasive Pressure Option and Temperature Option
Regulation Number: 21 CFR 870.5310
Regulation Name: Automatic External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: June 12, 2006
Received: June 16, 2006

Dear Mr. Zhang:

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,

B Zuckerman for

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

Enclosure

3 Indications for Use Statement

510(k) Number (if known): To be assigned

Device Name: Philips Medical Systems, HeartStart MRx Defibrillator/Monitor

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.

Noninvasive 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.

Noninvasive Blood Pressure Monitoring

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

Prescription Use Yes (Part 21 CFR 801 Subpart D)	AND/ OR	Over-The-Counter Use No (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 K061707

Indications for Use - Continued

510(k) Number (if known): To be assigned
Device Name: Philips Medical Systems, HeartStart MRx Defibrillator/Monitor

End-tidal CO2

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 function is 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 that 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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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