K020715

NOV 8 2002

510(k) Summary

510(k) Number (if known): K020715

510(k) Summary for the Philips M5066A/M5068A

1. Date Summary Prepared

November 6, 2002

2. Submitter's Name and Address

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

3. Contact Person

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

4. Device Name

Proprietary Name: M5066A/M5068A
Common Name: Automated external defibrillator
Classification Names: Low-Energy Defibrillator

5. Predicate Devices

The legally marketed device to which Philips Medical Systems, Heartstream claims equivalence for the M5066A/M5068A is the Heartstream FR2 AED. The modified device is also substantially equivalent to the Cardiac Science/SurVivaLink FirstSave AED and the Katecho Adult/Defibrillator/Pacing Electrodes.

The design and intended use of the M5066A/M5068A is substantially equivalent in safety and performance to the devices named above.

6. Device Description

The M5066A/M5068A is an automated external defibrillator indicated to treat victims of sudden cardiac arrest (SCA). Features of the M5066A/M5068A

includes self-testing and self-calibration, an impedance-compensating biphasic truncated exponential therapy waveform, a multi-parameter Patient Analysis System (PAS) for determining if a shock is required and integrated human factors designs to facilitate use by lay responders.

A non-rechargeable lithium manganese dioxide battery powers the M5066A/M5068A with a minimum capacity of 40 shocks and 30 minutes of operating time.

Except for specific programmed periods when a responder needs to deliver uninterrupted CPR, the M5066A/M5068A continuously and automatically analyzes the patient's ECG and alerts the responder when the ECG changes to a possible shockable rhythm. Analysis continues even after the M5066A/M5068A advises a shock and arms - if the ECG spontaneously converts to a non-shockable rhythm prior to a responder pressing the shock button, the M5066A/M5068A disarms.

If significant artifact is detected in the ECG, the PAS suspends further analysis until reliable data is available. When a shockable rhythm is detected, the M5066A/M5068A directs the responder to press the shock button to deliver a biphasic shock to the patient.

The M5066A/M5068A has an infrared communication port to facilitate data management. Event and incident data is recorded during use that can be retrieved later for viewing, printing, annotating and forwarding. Factory settings of the M5066A/M5068A can be customized. In addition, the M5066A/M5068A converts into a training device with selectable training "scripts" that simulate different SCA scenarios.

7. Intended Use

The M5066A is designed to be used on a person in sudden cardiac arrest, who is:

- unresponsive when shaken, and
- not breathing normally.

If in doubt, apply the pads.

If the victim is an infant or child younger than eight years old or weighs less than 55 lbs (25 kg), you should use the special infant/child pads. If the child appears older/larger, use the adult pads. Do not delay treatment to determine the child's exact age or weight.

The M5066A is intended for use by people who have been specifically trained in its operation. A M5066A user should also have training in cardiopulmonary

resuscitation (CPR) or another physician-authorized emergency medical response program in accordance with local and state requirements.

The M5068A is designed to be used on a person who is in sudden cardiac arrest and who is:

- unresponsive when shaken, and
- not breathing normally.

The defibrillator should not be used on a person who is:

- responsive when shaken, or
- breathing normally.

If you are not certain if the person is in sudden cardiac arrest, apply the defibrillator and follow its instructions.

For children 8 years or older, or who weigh 55 pounds or more, use the M5068A with the adult pads that come with it. For younger children to those who weigh less than 55 pounds, the special infant/child pads should be used. When used with these pads, the M5068A delivers a lower energy appropriate for infants and small children.

The M5068A is intended for use by people who have been specifically trained in its operation. The user should also have training in cardiopulmonary resuscitation (CPR) or another physician-authorized emergency response program in accordance with local and state requirements.

8. Comparison of Technology Characteristics

The M5066A/M5068A employs the same fundamental scientific technologies as the commercially available FR2 AED. The device is also similar to the Cardiac Science/SurVivaLink FirstSave AED and Katecho Adult Electrodes.

9. Data Used in Determination of Substantial Equivalence

The M5066A/M5068A employs the similar technologies to provide similar performance characteristics as the predicate devices.

Testing demonstrated that the performance of the M5066A/M5068A meets its specifications. Furthermore, additional bench testing will demonstrate that the M5066A/M5068A will meet its predefined criteria.

10. Conclusion

The introduction of the M5066A/M5068A does 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

Philips Medical Systems
c/o Ms. Tamara Yount
2401 Fourth Avenue, Suite 500
Seattle, WA 98121-1436

NOV 8 2002

Re: K020715
Philips M5066A/M5068A
Regulation Number: 870.1025
Regulation Name: Arrythmia Detector and Alarm
Regulatory Class: III (three)
Product Code: MKJ
Dated: September 3, 2002
Received: September 5, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

Enclosure

12.Indications for Use

November 1, 2002

510(k) Number (if known): #K020715

Device Name: Philips M5066A/M5068A

Indications for Use: The M5066A is designed to be used on a person in sudden cardiac arrest, who is:

- unresponsive when shaken, and
- not breathing normally.

If in doubt, apply the pads.

If the victim is an infant or child younger than eight years old or weighs less than 55 lbs (25 kg), you should use the special infant/child pads. If the child appears older/larger, use the adult pads. Do not delay treatment to determine the child's exact age or weight.

The M5066A is intended for use by people who have been specifically trained in its operation. A M5066A user should also have training in cardiopulmonary resuscitation (CPR) or another physician-authorized emergency medical response program in accordance with local and state requirements.

Caution: Federal Law (USA) restricts this device to the sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020715

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Prescription Use _____ or Over-The-Counter Use _____

Indications for Use (continued)

November 1, 2002

510(k) Number (if known): #K020715

Device Name: Philips M5066A/M5068A

Indications for Use:. The M5068A is designed to be used on a person who is in sudden cardiac arrest and who is:

- unresponsive when shaken, and
- not breathing normally.

The defibrillator should not be used on a person who is:

- responsive when shaken, or
- breathing normally.

If you are not certain if the person is in sudden cardiac arrest, apply the defibrillator and follow its instructions.

For children 8 years or older, or who weigh 55 pounds or more, use the M5068A with the adult pads that come with it. For younger children to those who weigh less than 55 pounds, the special infant/child pads should be used. When used with these pads, the M5068A delivers a lower energy appropriate for infants and small children.

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