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PHILIPS

APR 2 5 2002

510(k) Summary of Safety and Effectiveness
for
Philips Medical Systems
M5000A Series Cardiograph

1. **DATE SUMMARY PREPARED** January 23rd, 2002

2. **SUBMITTER'S NAME AND ADDRESS**

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

3. **CONTACT PERSON**

Mr. Songhua Zhang
Regulatory Affairs Engineer
Telephone: (978) 659-7319
Facsimile: (978) 659-7360

4. **DEVICE NAME**

Proprietary (trade) Name: M5000A Series Cardiograph
Common Name: Electrocardiograph
Classification Name: Electrocardiograph, CFR 870.2340
Product Code: 74DPS
Class: II
Panel: Cardiovascular / Circulatory System Devices Panel (74)

5. **PREDICATE DEVICE** The legally marketed devices to which equivalence is being claimed is the M1700A Cardiograph manufactured by Philips Medical Systems (formerly Healthcare Solutions Group of Hewlett-Packard Co.) – K895520

6. **DEVICE DESCRIPTION**

The M5000A Series Cardiograph is Philips Medical Systems' cardiograph offering a full complement of features, for both adult and pediatric patients.
The Cardiograph offers increased speed and ease-of-use for patient data entry. The device also consists of a digital patient acquisition module, LCD display and rechargeable battery, thermal printer, optional barcode scanner or magnetic card strip reader.
The Cardiograph provides crisp, easy-to-read ECGs on a standard page. Records are clearly labeled with ECG data and patient information.

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7. INTENDED USE

M5000 Series Cardiograph:

Intended Use

To acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze and store these ECG signals for review by the user. To be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to overread and validate (or change) the computer generated ECG interpretation.

Indications for Use

Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

12-LDx Interpretive Algorithm:

Intended Use

To analyze multi-channel ECG signals from adult and pediatric patients with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to overread and validate (or change) the computer generated ECG interpretation.

Indications for Use

Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The M5000A Series Cardiograph has the similar cardiograph characteristics as the

predicate M1700A PageWriter Xli Cardiograph. For example, they both contain the same ECG measurements, adult and pediatric analysis programs, software filtering algorithm, ECG basic controls and both have the similar standardization, DC offset sensitivity, time base and accuracy stability, bandwidth, input dynamic range, storage of recorded signals. The M5000A Series Cardiograph has similar hardware design as the predicate M1700A Cardiograph, they both have thermal ECG printer, digital patient acquisition module, rechargeable battery, and LCD display.

The technological differences do not affect the safety or effectiveness of the device. Any safety issues that may be raised by the new device are addressed in the device's risk analysis and the device verification and validation activities.

9. Non-clinical Tests Used in Determination of Substantial Equivalence

The substantial equivalence of the M5000A Series Cardiograph is demonstrated by the following non-clinical testing:

- Testing to applicable standards: AAMI EC11, IEC 60601-1, UL 2601.1, IEC 60601-2-25, IEC 60601-1-2
- The performance, functionality, and reliability characteristics of the device and algorithm software testing follow established test procedures and quality system.

10. Conclusions from Non-clinical Testing

Prior to marketing in the US, M5000A will have completed the testing listed above with acceptable results, demonstrating substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2002

Philips Medical Systems, Inc.
c/o Mr. Ned E. Devine
Program Manager III
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49548

Re: K020708
Trade Name: M5000A Series Cardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: April 8, 2002
Received: April 10, 2002

Dear Mr. Devine:

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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):
Device Name: M5000A Series Cardiograph

M5000A Series Cardiograph

Intended Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K060705