K052049
p1/2

AUG 26 2005

PHILIPS

9. 510(k) Summary

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
3000 Minuteman Road
Andover, MA 01810

Contact Person:
Mr. Songhua Zhang
Regulatory Engineer
Tel: 978-659-7319
Fax: 978-659-3712
Email: songhua.zhang@philips.com

This summary was prepared on July 18, 2005.

2. The name of this device is the Philips 12-Lead Algorithm. Classification names are as follows:

Classification	ProCode	Description
Unclassified, Class II	74 LOS	ECG Analysis System
870.2340, II	74 DPS	Electrocardiograph

3. Based on ECG signals acquired from ten electrodes (12 leads), the 12-lead analysis algorithm monitors signal quality, measures waveform components and recognizes patterns, and performs basic rhythm analysis. Using the extended measurements and patient-specific information, the algorithm generates those interpretive statements from the criteria program that summarize the findings for the ECG and highlight key areas of concern for physician review.

K052049
p 2/3

PHILIPS

4. The new device is substantially equivalent to the previously cleared M5000A Series Cardiograph with Philips 12-Lead Algorithm cleared under K020708.

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 and functionality characteristics of the new device. Testing involved system level tests, integration tests and regression tests from hazard analysis. Pass/Fail criteria were based on the specifications and test results showed substantial equivalence. The results demonstrate that the functionality of the modified Philips 12-Lead Algorithm meets all performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2005

Philips Medical Systems
c/o Ms. Songhua Zhang
Regulatory Engineer
3000 Minuteman Road, Mail Stop 220
Andover, MA 01810-1099

Re: K052049
Trade Name: Philips 12-Lead Algorithm
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: July 26, 2005
Received: July 29, 2005

Dear Ms. 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) 276-0295. 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 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,

B Zuckerman for

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

Enclosure

8. Indications for Use Statement

510(k) Number (if known): K052049

Device Name: Philips 12-Lead Algorithm

Indications for Use:

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.

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

Songhua Zhang
Regulatory Specialist
Philips Medical Systems

Date: July 25, 2005

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052049