

APR 11 2008

8.0 510(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 pre-market notification is Philips Medical Systems

This summary was prepared on 27 November 2007

2. The name of this device is the Philips ECG algorithm Software Release PH100B. Classification names are as follows:

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

3. The new device is substantially equivalent to the previously cleared Philips 12-Lead ECG Algorithm software cleared under K020708 and K052049.
4. The modification is a change that provides interpretive analysis capability for additional posterior and right sided heart lead placement locations beyond the standard lead placements used with a 12 lead ECG.
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. The modification also incorporates a subset of the diagnostic statement changes recommended in the Journal of the American College of Cardiology Volume 49, No.10, 2007, pages 1128-1135. "Recommendations for the Standardization and Interpretation of the Electrocardiogram"
8. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new algorithm with respect to the predicate. Testing involved use of standard ECG databases, system level tests, integration tests, and verification of risk mitigation identified in the hazard analysis. Results from interpretive ECG analysis programs are used as in an advisory nature. Physicians are required to over read each ECG report and also consider the ECG waveforms, the patient's clinical history before agreeing with the ECG analysis program statement.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2008

Philips Medical Systems
c/o Mr. Paul Schrader
Senior Manager, Regulatory Affairs
3000 Minuteman Rd.
Andover, MA 01810

Re: K073376
Trade/Device Name: Philips ECG Algorithm
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: LOS, DPS
Dated: March 10, 2008
Received: March 12, 2008

Dear Mr. Schrader:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at ((240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



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

Enclosure

2.0 Indications for Use

510(k) Number (if known): K073376

Device Name: Philips ECG 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 over read 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 X
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use N/A
(21 CFR 801 Subpart C)

(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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(Division Sign-Off)
Division of Cardiovascular Devices
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