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8. 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 2, 2003.

2. The name of this device is the M5100A/M5101A TraceMaster ECG Management System. Classification names are as follows:

Classification	ProCode	Description
870.2800, II	74 DSH	Recorder, Magnetic Tape, Medical

3. The TraceMaster ECG System is a computer system which allows viewing, manual editing, printing, and archiving of digitized ECG records. TraceMaster communicates with Web-based clients, faxes, printers etc through a client/server industry-standard network with other hospital information systems.

4. The new device is substantially equivalent to the previously cleared M1730B/M3700A TraceMaster ECG Management System cleared under K974420.

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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 devices.

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 ECG Management System meets all performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Philips Medical Systems
c/o Mr. Songhua Zhang
Regulatory Engineer
3000 Minuteman Road
Andover, MA 01810

Re: K032103
Trade Name: TraceMaster ECG Management System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II (two)
Product Code: DSH
Dated: July 2, 2003
Received: July 8, 2003

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 (301) 594-4646. 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 (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

K032103

7. Indications for Use Statement

510(k) Number (if known): K032103

Device Name: TraceMaster ECG Management System

Indications for Use: The TraceMaster ECG System is a computer system which allows viewing, manual editing, printing, and archiving of digitized ECG records.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032103