K033444

NOV 2 1 2003

9.0 510(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 premarket notification is:
   Tapan D. Shah
   Regulatory Affairs Engineer
   Cardiac and Monitoring Systems
   3000, Minuteman Road
   Andover, MA - 01810
   USA
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   Email: tapan.shah@philips.com

   This summary was prepared on October 27, 2003

2. The name of this device is Hemodynamic Extension to the Multi-measurement Server - M3012A.

   Classification names are as follows:

Regulation Number	Classification Name
870.2850	Extravascular Blood Pressure Transducer
870.1435	Computer, Diagnostic, Pre-Programmed, Single-Function
870.2900	Cable, Transducer and Electrode, Patient (including connector)
870.1110	Computer, Blood Pressure
870.1915	Probe, Thermodilution
870.1100	Alarm, Blood Pressure
870.2060	Amplifier and Signal Conditioner, Transducer Signal
870.2600	System, Signal Isolation
880.2910	Thermometer, electronic, clinical

3. The new device is substantially equivalent to previously cleared devices marketed pursuant to K882609, K002758, K020531, K032858, and K992273.

4. The modification is the creation of a new measurement extension for the Philips patient monitor family (supported by the M3001A multi-measurement server).

5. The new device has the same intended use as the legally marketed predicate devices. When used in the hospital environment or mobile environment for patient transport monitoring, the device is intended for measuring and alarming multiple physiological parameters and waves in adult, pediatric, and neonatal patients.

6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities were conducted to establish the performance and reliability characteristics of the new module using simulated systems. Testing included system level tests, integration tests, environmental tests, safety testing from hazard analysis, interference testing, and hardware testing. Pass/Fail criteria were based on standards, where applicable, and on the specifications cleared for the predicate devices. The test results showed substantial equivalence. The results demonstrate that the Measurement Server Extension meets all the reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2003

Philips Medical Systems
c/o Mr. Tapan D. Shah
Regulatory Affairs Engineer
Cardiac and Monitoring Sytems
3000 Minuteman Road
Andover, MA 01810

Re: K033444
Trade Name: Philips Medical Systems M3012A – Hemodynamic Extension to the Multi-Measurement Server
Regulation Number: 21 CFR §870.1025
Regulation Name: Patient Physiological Monitor (arrhythmia detection and alarm)
Regulatory Class: Class III (three)
Product Code: MHX
Dated: October 27, 2003
Received: October 29, 2003

Dear Mr. Shah:

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. 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) 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,

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

Enclosure

3.1 ODE Indications Statement

Indications for Use Statement

510(k) Number (if known)	
Device Name	Philips M3012A - Hemodynamic Extension to the Multi-Measurement server
Indications for Use	Indications for Use (M3046A): For monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in hospital and/or medical transport environments. Indications for Use (MP40/50/60/70/90): Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters patients. Intended for monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in hospital environments.

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 K033444

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