K052707
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7.0 510(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 CFR 807-92.

1. The submitter of this pre-market notification is:

Michael J. Doyle
Philips Medical Systems - Cardiac & Monitoring Systems
3000 Minuteman Road
Andover, MA 01810
United States
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Email: mike.doyle@philips.com

This summary was prepared on September 26, 2005.

2. The names of the devices are the Philips M3046B Compact Portable Patient Monitors. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Circulatory System Devices	870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	870.1110, II	DSJ	Alarm, Blood Pressure
	870.1110, II	DSK	Computer, Blood Pressure
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive
	870.1435, II	DXG	Computer, Diagnostic, Pre-programmed, Single-function
	870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm
	870.2340, II	DPS	Electrocardiograph
	870.2700, II	DQA	Oximeter
	870.2850, II	DRS	Extravascular Blood Pressure Transducer
	870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient connector
Anesthesiology & Respiratory Therapy	868.1400, II	CCK	Analyzer, Gas,
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical

3. The modified devices are substantially equivalent to previously cleared Philips devices marketed pursuant to K971910,

K981576, K990972, K991773, K992273, K993383, K000822, K001057, K001333, and K003621.

4. The modification is the introduction of Release B.00 software for the Philips M3046B Compact Portable Patient Monitors and Accessories.

5. The modified devices have the same intended use as the legally marketed predicate devices. They are intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatric, and neonates in healthcare environments and during transport within healthcare environments.

6. The modified devices have the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the Philips M3046B Compact Portable Patient Monitors meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Philips Medical Systems
c/o Mr. Michael J. Doyle
Regulatory Specialist
3000 Minuteman Road
Andover, MA 01810

Re: K052707
Trade Name: M3046B Compact Portable Patient Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: September 27, 2005
Received: September 29, 2005

Dear Mr. Doyle:

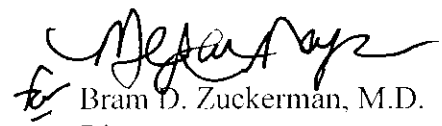
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0120. 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K052707

Device Name: Philips M3046B Compact Portable Patient Monitor

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Intended use: For monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Additionally, the monitor may be used in transport situations within a healthcare facility.

Prescription Use: Yes AND/OR Over-the Counter Use: No
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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

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