K023749

Confidential

Special 510(k) Modification

NOV 1 9 2002

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 C.F.R. §807.92.

The submitter of this premarket notification is:

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Quality Program Manager
Cardiac and Monitoring Solutions
New Clinical Ventures Division/eCare MS 0024
Philips Medical Systems
3000 Minuteman Road
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Date of summary: October 25, 2002

Device name: The M3810A Philips TeleMonitoring System with M3812B TeleStation

Common name: Physiological Transmitter and Receiver

Classification names

Regulation Number	ProCode	Classification Name
870.2910	DRG	Physiological Signal Transmitters And Receivers
870.1130	DXN	Non-invasive Blood Pressure Measurement System
870.2340	DPS	Electrograph
870.2720	FRW	Patient Scale

Predicate Devices: The modified device is substantially equivalent to the previously cleared Modification of Physiological Signal Transmitter & Receiver pursuant to K993169 (September 22, 1999).

Modifications: The primary modification is a change to add the functionality of glucose meter downloads and subjective questions (automated interactions).

Intended Use: The modified device has the same intended use as the legally marketed predicate devices. The M3810A Philips TeleMonitoring System with M312B TeleStation is intended to be used upon prescription by a licensed physcian or authorized healthcare provider by patients as a means to automatically collect and transmit medical information, such as weight, blood pressure, and non-diagnostic ECG, over normal residential telephone lines, between a patient, typically at home, and a healthcare professional at

	the authorized provider. Apart from the convenience features added for enhanced interaction, and blood glucose meter data transmission, that is the same intended use as previously cleared for the M3810A Interactive Health System
Technological characteristics	The modified device has the same technological characteristics as the legally marketed predicate devices.
Testing	Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the modified device. Testing involved safety testing from the risk analysis, including laboratory studies for biocompatibility electrical safety testing, EMC testing and radio telemetry testing and user evaluations for consumer accuracy. Acceptance criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2002

Philips Medical Systems
c/o Mr. J.P. Ouellette, M.S.
Quality Program Manager
3000 Minuteman Road
Andover, MA 01810

Re: K023749
Trade Name: The M3810A Philips TeleMonitoring System with M3812B TeleStation
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: November 6, 2002
Received: November 8, 2002

Dear Mr. Ouellette:

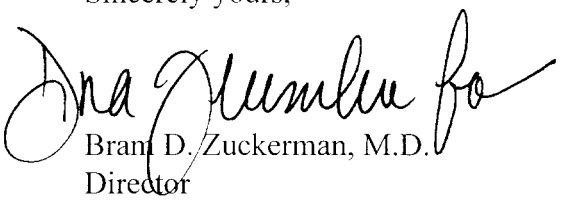
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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



Brant 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: The M3810A Philips TeleMonitoring System with M3812B TeleStation

Indications for Use:

The M3810A Philips TeleMonitoring System with M3812B TeleStation is indicated for patients at home, who are capable and willing to self administrate this device, upon the prescription of their healthcare provider, to collect and transmit medical information such as weight, blood pressure (including pulse rate) and non-diagnostic ECG rhythm strip to the healthcare provider at another location. The patient takes these measurements, typically once per day, and the information is transmitted automatically via normal telephone lines to the healthcare provider. The device may be used for the management of congestive heart failure, hypertension, ischemic heart disease, weight management, cardiovascular risk management, post cardiovascular surgery, post myocardial infarction, and other post cardiac events. The device does not send any real time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

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)

Division of Cardiovascular & Respiratory Devices
510(k) Number K023749
DOF 11/18