K 101067

510K 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(c).

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

Peng Cui
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
United States

Tel: 978-659-7966
Fax: 978-659-3819
Email: peng.cui@philips.com

MAY - 7 2010

This summary was prepared on April 9, 2010.

2. The names of the subject devices are the Philips SureSigns Series Patient Monitors, SureSigns VM4, VM6, and VM8 Patient Monitors

3. The trade names of the devices are the SureSigns VM4, SureSigns VM6, SureSigns VM8 Patient Monitors.

4. The common usual name is multi-parameter patient monitor

5. The Classification names are as follows:

Device Panel	Classification	ProCode	Description	Applicable Subject Devices
Circulatory System Devices	870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)	VM4, VM6, VM8
	870.1110, II	DSJ	Alarm, Blood Pressure	VM4, VM6, VM8
	870.1110, II	DSK	Computer, Blood Pressure	VM4, VM6, VM8
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive	VM4, VM6, VM8
	870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm	VM4, VM6, VM8
	870.2700, II	DQA	Oximeter	VM4, VM6, VM8
	870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient connector	VM4, VM6, VM8
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical	VM4
Anesthesiology & Respiratory Therapy	868.1400, II	CCK	Analyzer, Gas,	VM8

6. The modified devices are substantially equivalent to previously cleared Philips device, SureSigns VM Series Patient Monitors marketed pursuant to K052707, K080495 and K090483.

7. The modifications are as follows:

- The OEM CO_2 module, from Oridion Medical Ltd. is being changed to a new version of the Oridion miniMedi module. This module was cleared under FDA K060065. The subject device will include the SARA respiratory algorithm cleared in the predicate device SureSigns VM1 (K082280).
- An apnea alarm is being added to the existing impedance respiration and CO_2 measurements; however, the device is not an apnea monitor.
- A new main board will be used that is host to the previously cleared Philips NBP module (previously cleared under K090483) and includes the addition of speaker malfunction detection capability.
- The Front end board has been modified to comply with China SFDA dielectric production test requirements.
- An alternate internal component speaker will be used.
- An additional optional bar code reader has been made available.
- Optional RS232 serial port adaptor has been made available.
- Several new accessories are being listed for use with the device.
- Software enhancements include:
  - the addition of two SpO_2 technical alarms
  - a speaker malfunction technical alarm
  - a new CO_2 technical alarm
  - additional Patient ID fields have been added
  - roll-over tool tips for quick software icon identification
  - an additional 7 second recording option has been added
  - battery reconditioning has been improved
  - when connected to an external device the monitors can synchronize its trend database clock to a master device time, such as an EMR system
- Impedance respiration is added to SureSigns VM4 patient monitor, which is already in the predicate device of SureSigns VM6 and SureSigns VM8 cleared under K052707.
- The Instructions for Use will include some additional warnings and cleaning instruction clarifications for the pTemp measurement.
- The Instructions for Use will include some additional information and warnings for the CO_2 measurement.
- The device label will include the IPX1 symbol.

8. The subject devices have the same intended use as the legally marketed predicate device. The SureSigns VM Series Patient Monitors are for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. For monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Additionally, the monitors may be used in transport situations within a healthcare facility.

9. The subject devices have the same fundamental technological characteristics as the legally marketed predicate devices. The subject devices use the same design as the predicate devices. The addition of the apnea alarms, the three new technical alarms and the use of the CO_2 miniMedi board does not significantly change the fundamental characteristics over the predicate devices

10. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject devices with respect to the predicates. 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, the specifications of the subject device and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VM4, VM6 and VM8 Patient Monitors meet all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY - 7 2010

Philips Medical Systems
c/o Mr. Peng Cui
Senior Manager, Regulatory Affairs
3000 Minuteman Road
Andover, MA 01810

Re: K101067
Trade/Device Name: SureSigns VM4, SureSigns VM6, SureSigns VM8 (reference numbers 863063, 863064, 863065, 863066, and 863068)
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: April 9, 2010
Received: April 16, 2010

Dear Mr. Cui:

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.

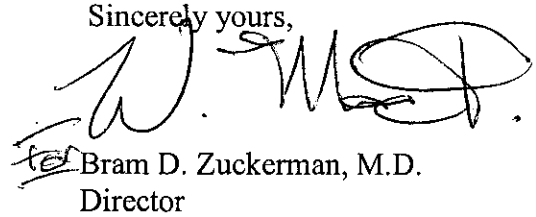
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

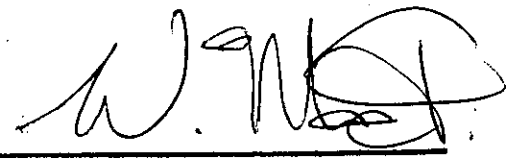
510 (k) Number (if known): K101067

Device Name: SureSigns VM4 (reference number: 863063)
SureSigns VM6 (reference numbers: 863064, 863065)
SureSigns VM8 (reference numbers: 863066, 863068)

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

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 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

510(k) Number_____