APR 1 8 2013

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:

Mary Kruitwagen
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
United States

Tel: 978-659-4932
Fax: 978-659-7323
Email: mary.kruitwagen@philips.com

This summary was prepared on December 17, 2012.

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, and 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 VM4, VM6 and VM8 Patient Monitors marketed pursuant to K052707, K080495, K090483, and K101067. The predicate 510Ks for this submission are: K103652 and K094012 (May 12 2010) by Oridion Capnography Inc.

7. The modifications are as follows:
    1. Add arrhythmia analysis to the VM4, using the same arrhythmia software algorithm as in the VM6 and VM8\

    2. Add standby mode into CO_2 menu to preserve 'time to calibration' for situations where the monitor is in use, but not CO_2 monitoring.

    3. The LCD display backlight has changed to an LED backlight. The new backlight does not contain mercury.

    4. Replace the current Oridion CO_2 module with a RoHS compliant Oridion CO_2 module. This module, also referred to as the microMedi OEM board, is included in the Oridion Capnostream 20, and is cleared under K094012.

    5. Enhancement requests include:
        - Display the word 'Filter' in the ECG trace pane when the filter bandwidth setting is enabled. Filter will also be printed on strip recordings
        - Add a choice to enable a SpO_2 high/low and/or SpO_2 Desaturation alarm delay time. When enabled, the SpO_2 alarm delay will result in the SpO_2 alarm generation once the delay time has elapsed.
        - The temperature label, previously called temp, is now called T1.
        - Add a chime tone when a manually initiated NBP measurement is completed.
        - The patient demographic information may be edited through an additional access point of the title bar.
        - Separate Heart Rate (HR) and Pulse (Pulse) into distinct viewing panes with separate alarm limits. No other changes were made.
        - Increase the trend database to allow for 120 hours of data to be stored

    6. Add software hooks that will allow for connection to the Philips central station (trade name yet to be determined) once the central stations is developed, cleared and released. The following information is sent to the central:
        - Patient ID information
        - Patient type (adult, pediatric, neonatal)
        - Monitor name
        - Serial number of the connected monitor
        - Waveforms
        - Measurements
        - Alarm limits
        - Alarms
        - ECG lead setting
        - Pace detection setting
        - NBP interval mode setting
        - Demo mode notification
        - Working mode notification (whether monitor is in monitor mode, spot check mode and whether CO_2 is in standby, if applicable)
        - Audio off/audio paused
        - Waveform information including: Arrhythmia off, pacer pulse detection off, cannot analyze ECG, ECG (wave) freeze, IBP zero, Filter on.

8. The subject devices have the same Intended Use and Indications for Use as the legally marketed predicate device:

    "The SureSigns VM4, VM6 and VM8 Patient Monitors are for monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics, and neonates in

healthcare environments. Additionally, the monitor is intended for use in transport situations within a healthcare facility",

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

Standard and optional parameters include:

- *ECG*
- *Respiration*
- *NBP*
- *SpO_2*
- *IBP*
- *CO_2*
- *Temperature*

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.

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 Center – WO66-G609
Silver Spring, MD 20993-002

April 18, 2013

Philips Medical Systems North America, Co.
c/o: Mary Kruitwagen
Regulatory Engineer
3000 Minuteman Road
Andover, MA 01810

Re: K123900
Trade Name: SureSigns VM4, SureSignsVM6, and SureSigns VM8
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
(including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX, DSJ, DSK, DXN, DRT, DQA, DSA, FLL, CCK
Dated: March 12, 2013
Received: March 19, 2013

Dear Ms. Mary Kruitwagen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Owen P. Faris -S

for

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

Enclosure

Indications for Use

510 (k) Number (if known): _____

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.

Standard and optional parameters include:

- ECG
- Respiration
- NBP
- SpO_2
- IBP
- CO_2
- Temperature

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)

Owen P. Faris -S
2013.04.18
15:59:41 -04'00'