K133961

JUN 2 6 2014

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 and contact person of this pre-market notification is:

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Philips Medical Systems
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Andover, MA 01810
United States

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2. Date this summary is prepared:
This summary is prepared on December 19, 2013.

3. The names of the subject devices are as following:
SureSigns VS3
SureSigns VS4

4. The trade names of the devices are SureSigns VS3 and SureSigns VS4.

5. The common usual name for both the VS3 and the VS4 is multi-parameter patient monitor

6. The Classification names are as follows:

Device Panel	Classification	ProCode	Description	Applicable subject devices
Cardiovascular	870.1100, II	DSJ	Alarm, Blood Pressure	VS3, VS4
	870.1110, II	DSK	Computer, Blood Pressure	VS3, VS4
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive	VS3, VS4
	870.2700, II	DQA	Oximeter	VS3, VS4
	870.2900, II	DSA	Cable, transducer and electrode, patient connector	VS3, VS4
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical	VS3, VS4
Anesthesiology & Respiratory Therapy	868.1400, II	CCK	Analyzer, Gas	VS4

7. The modified devices are substantially equivalent to previously cleared devices from Philips and suppliers:

SureSigns VS3 Vital Signs Monitor cleared under K120132
SureSigns VS4 Vital Signs Monitor cleared under K120132
SureSigns VM8 Patient Monitor cleared under K123900

Masimo Rainbow SET Radical 7R CO-Oximeter cleared under K100428
Exergen TemporalScanner Thermometer cleared under K011291
Oridion Capnography Inc for Capnostream 20 with microMediCO2 module cleared under K094012

8. The modifications are as follows:

   a) Add CO2 measurement to VS4. This is achieved by using the Oridion MicroMedi OEM module. This same module is used in Philips SureSigns VM8 patient monitor for the same measurement. The SureSigns VM8 was FDA cleared under K123900. Oridion microMediCO2 OEM module includes IPI feature for its CO2 measurement. VM8 doesn't include the IPI feature. The predicate device for VS4 IPI feature is the Oridion microMediCO2 OEM module with. The Oridion microMedi CO2 OEM module was cleared under K094012.

   b) Add SpHb measurement to VS4. This measurement and the following new added Respiratory (c) and Masimo SpO2 (d) are achieved using the OEM Masimo Rainbow SET module (MX board). The same module is used in the Masimo Rainbow SET Radical 7R CO-Oximeter for the same measurements. And the Masimo Rainbow SET Radical 7R CO-Oximeter is FDA cleared under K100428.

   c) Add Respiratory Rate RRa measurement to VS4. Details refer to above item (b). In addition, FDA 510(k) K120984 cleared the RRa sensor, RAS-125c, for use on pediatric patients with body weight>10Kg. So RRa will be supported on both adult and pediatric patients.

   d) Add Masimo SpO2 measurement with Pulse rate to VS4. Details refer to above item (b).

   e) Add Temporal Temperature measurement to VS4. This is achieved by using the OEM Exergen TemporalScanner Thermometer. This Exergen TemporalScanner Thermometer is FDA cleared under K011291. The OEM thermometer has a RS232 cable added to connect the thermometer to the VS4 monitor.

   f) Add QuickNBP mode to both VS3 and VS4. QuickNBP measurement mode utilizes a single oscillometric pulse for the determination of the pressure level at a particular pressure step. This compares to the regular NBP measurement mode that utilizes multiple oscillometric pulses to determine the pressure level at a particular pressure step. QuickNBP is based on the same algorithm that provides the regular NBP measurements in SureSigns VS3, VS4 monitors. Same as measure method in STAT mode. The NBP specifications of VS3 and VS4 are not changed due to the addition of the QuickNBP mode.

9. The subject device VS3 has the same Intended Use and Indications for Use as the legally marketed predicate device, currently marketed VS3:

   Indications for Use:
   The SureSigns VS3 vital signs monitor is for use by health care professionals whenever there is a need for monitoring the physiological parameters of

patients. The SureSignsVS3 is for monitoring, recording and alarming of multiple physiological parameters in healthcare environments for patient types listed below. Additionally, the monitor may be used in transport situations within a healthcare facility.

	Patient Types		
Parameter	**Adult**	**Pediatric**	**Neonatal**
NBP	√	√	√
SpO2	√	√	√
Temperature	√	√	√

The indications for Use of subject VS4 has following parameters added to the legally marketed SureSigns VS4: CO2, RRa and SpHb

Indications for Use:
The SureSigns VS4 vital signs monitor is for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The SureSigns VS4 is for monitoring, recording and alarming of multiple physiological parameters in healthcare environments for patient types listed below. Additionally, the monitor may be used in transport situations within a healthcare facility.

	Patient Types		
Parameter	**Adult**	**Pediatric**	**Neonatal**
NBP	√	√	√
SpO2	√	√	√
Temperature	√	√	√
CO2	√	√	√
RRa	√	√	
SpHb	√	√	

10. The subject devices have the same fundamental technological characteristics as the legally marketed predicate devices. The subject devices use the same algorithms for the measurements as the predicate devices.

11. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject device. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the subject device and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VS3 Vital Signs monitor and the Philips SureSigns VS4 Vital Signs monitor meet all safety and reliability requirements and performance claims and support 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 20993-0002

June 26, 2014

Philips Medical Systems
Greg Li
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Andover, MA 01810 US

Re: K133961
Trade/Device Name: SureSigns VS3, SureSigns VS4
Regulation Number: 21 CFR 870.1100
Regulation Name: Multi-Parameter Patient Monitor
Regulatory Class: Class II
Product Code: DSJ, DSK, DXN, DQA, DSA, FLL, CCK
Dated: May 28, 2014
Received: May 29, 2014

Dear Greg Li,

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

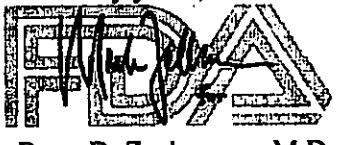
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



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): K133961

Device Name:

SureSigns VS3 (reference numbers: 863071, 863072, 863073, 863074)
SureSigns VS4 (reference number: 863283)

Indications for Use for SureSigns VS3 Vital Signs Monitor

The SureSigns VS3 vital signs monitor is for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The SureSignsVS3 is for monitoring, recording and alarming of multiple physiological parameters in healthcare environments for patient types listed below. Additionally, the monitor may be used in transport situations within a healthcare facility.

	Patient Types		
Parameter	**Adult**	**Pediatric**	**Neonatal**
NBP	√	√	√
SpO2	√	√	√
Temperature	√	√	√

Indications for Use for SureSigns VS4 Vital Signs Monitor

The SureSigns VS4 vital signs monitor is for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The SureSigns VS4 is for monitoring, recording and alarming of multiple physiological parameters in healthcare environments for patient types listed below. Additionally, the monitor may be used in transport situations within a healthcare facility.

	Patient Types		
Parameter	**Adult**	**Pediatric**	**Neonatal**
NBP	√	√	√
SpO2	√	√	√
Temperature	√	√	√
CO2	√	√	√
RRa	√	√	
SpHb	√	√	

K133961

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)