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

April 19, 2017

Philips Medical Systems
Mr. Greg Li
Regulatory Affairs Specialist
3000 Minuteman Rd.
Andover, Massachusetts 01810

Re: K163649
Trade/Device Name: SureSigns VS3 Vital Signs Monitor
(reference numbers: 863071, 863072, 863073, 863074)
SureSigns VS4 Vital Signs Monitor
(reference number: 863283)
Regulation Number: 21 CFR 870.1100
Regulation Name: Blood Pressure Alarm
Regulatory Class: Class II
Product Codes: DSJ, DSK, DXN, DQA, DSA, FLL and CCK (for VS4 only)
Dated: December 16, 2016
Received: December 23, 2016

Dear Mr. Greg Li:

This letter corrects our substantially equivalent letter of March 31, 2017.

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 Industry and Consumer Education 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K163649

Device Name
SureSigns VS3 Vital Signs Monitor (reference numbers: 863071, 863072, 863073, 863074)
SureSigns VS4 Vital Signs Monitor (reference number: 863283)

Indications for Use *(Describe)*

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.

Parameter (patient types): NBP (Adult, Pediatric, Neonatal); SpO2 (Adult, Pediatric, Neonatal); Temperature (Adult, Pediatric, Neonatal)

Contraindications: Not for transport outside the healthcare facility

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.

Parameter (patient types): NBP (Adult, Pediatric, Neonatal); SpO2 (Adult, Pediatric, Neonatal); Temperature (Adult, Pediatric, Neonatal); CO2 (Adult, Pediatric, Neonatal); RRa (Adult, Pediatric); SpHb (Adult, Pediatric)

Contraindications: Not for transport outside the healthcare facility

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:

Greg Li
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
United States

Tel: 978-659-4227
Fax: 978-659-7323
Email: Greg.li@philips.com

2. Date this summary is prepared:
   This summary is prepared on 16 December, 2016.

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

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:

   SureSigns VS3 Vital Signs Monitor cleared under k151761
   SureSigns VS4 Vital Signs Monitor cleared under k151761

8. The modifications are as following:

   The subject VS3 and VS4 will be modified with the current QuickAlert to include On-device multi-parameter configurable Modified Early Warning Scores (MEWS).

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

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	√	√	√

Contraindications: Not for transport outside the healthcare facility

The subject device VS4 has identical Intended Use and Indications for Use as the legally marketed predicate device, currently marketed VS4:

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	√	√	

Contraindications: Not for transport outside the healthcare facility

10. The subject devices VS3 and VS4 have the same fundamental technological characteristics as the legally marketed predicate devices VS3 and VS4. There is no addition, deletion or change to the current measurements or alarming, no specification change to current SureSigns VS3 or SureSigns VS4 monitor.

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 tests according risk assessment. Pass/Fail criteria were based on the specifications cleared for the subject device and test results showed substantial equivalence. The modified VS3 and VS4 monitors passed all specified verification tests. The results demonstrate that the Philips SureSigns VS3 Vital Signs monitor and the Philips SureSigns VS4 Vital Signs monitor meet all performance claims and support a determination of substantial equivalence.