K090483
p1/2

MAR 20 2009

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:

Larry Milana
Philips Medical Systems
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   This summary was prepared on January 27, 2009.

2. The names of the subject devices are the Philips SureSigns VM Series Patient Monitors, the SureSigns VS2 Vital Signs Monitor, and the SureSigns VS3 Vital Signs Monitor.

3. The trade names of the devices are the SureSigns VM Series Patient Monitors, the SureSigns VS2 Vital Signs Monitor, and the SureSigns VS3 Vital Signs Monitor.

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

5. The classification of the SureSigns VS2 Vital Signs Monitor, the SureSigns VS3 Vital Signs Monitor, and the SureSigns VM Series Patient Monitors are not changed by the addition of the picoNIBP (non - invasive blood pressure) OEM Module.

6. The modified devices are substantially equivalent to previously cleared Philips device, M3046B Compact Configurable Portable Patient Monitor marketed pursuant to K052707.

7. The modification is to replace the currently cleared CAS NBP module with the picoNIBP(non - invasive blood pressure) OEM Module (which was cleared in K051366) to the VS2 Vital Signs Monitor, the VS3 Vital Signs Monitor, and the VM Series (VM 4/6/8) Patient Monitors.

   In addition, this submission includes a change in plastics to Valox and the addition of new $SP0_2$ sensors and the disclosure of IPX1 rating for ingress protection to vertical water drops for all subject devices.

8. The modified devices have the same intended use as the legally marketed predicate device. The Philips SureSigns VM Series Patient Monitors, SureSigns VS2 Vital Signs Monitors and SureSigns VS3 Vital Signs 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 modified devices have the same fundamental technological characteristics as the legally marketed predicate devices. The subject devices use the same design as the predicate device.

10. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicate. 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 and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VM Series Patient Monitors, SureSigns VS2 Vital Signs Monitors and SureSigns VS3 Vital Signs Monitors meet all claims and support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2009

Philips Medical System
c/o Mr. Larry Milana
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810

Re: K090483
Suresigns VS2 monitor, Suresigns VS3 vital signs monitor, Suresigns VM series patient monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (Two)
Product Code: MXH, (DPS, DXN, DQA, CCK and FFL)
Dated: February 24, 2009
Received: February 25, 2009

Dear Mr. Milana:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K090483

Indications for Use

510 (k) Number (if known): _____

Device Name: SureSigns VS2 (reference numbers: 863079, 863080, 863081, 863082)
SureSigns VS3 (reference numbers: 863069, 863070, 863071, 863072, 863073, 863074)
SureSigns VM Series Patient Monitors (VM1/3/4/6/8) (reference numbers: 863063, 863064, 863065, 863066, 863068, 863077,863078)

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

Intended Use: 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.

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)

for B Zuckerman 3/20/09

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090483