K111905

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OCT - 4 2011

510(k) 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 C.F.R. §807.92.

1. The submitter of this Premarket Notification is:

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This summary was prepared on June 30, 2011.

2. The name of the device:

New device:
Trade name: IntelliVue Guardian Software, Revision A.00
Common name: Clinical Information Management System

Modified devices (labeling modification only):
Trade name: IntelliVue CL SpO2 Pod
Common name: Telemetry Transceiver

Trade name: IntelliVue CL NBP Pod
Common name: Telemetry Transceiver

Classification names of the new IntelliVue Guardian Software are as follows:

Device Panel	Classification	ProCode	Description
General Hospital	not classified	NSX	Software, transmission and storage, patient data
Cardiovascular Devices	§870.2450, II	DXJ	Display, cathode-ray tube, medical

Classification names of the modified (labeling modification only) IntelliVue CL SpO2 Pod and CL NBP Pod are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.1025, II	DSI	Detector and Alarm, Arrhythmia
	§870.1100, II	DSJ	Alarm, Blood-Pressure
	§870.1110, II	DSK	Computer, Blood-Pressure
	§870.1120, II	DXQ	Cuff, Blood-Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.2030, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal

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Device Panel	Classification	ProCode	Description
	§870.2700, II	DQA	Oximeter
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
	-	MSX	System, Network and Communication, Physiological Monitors

3. The new Philips IntelliVue Guardian Software, Rev. A.00, is substantially equivalent to the previously cleared Philips IntelliVue Clinical Information Portfolio marketed pursuant to K992636 and K100272, Philips IntelliVue XDS application software K082633, K083517, K091927, K093268, K100939, K101449, K102562, K110622, and Philips IntelliVue Early Warning Scoring application K093268, K102562, K110622.

The modified Philips IntelliVue CL SpO2 Pod and CL NBP Pod are substantially equivalent to the previously cleared IntelliVue CL SpO2 Pod and CL NBP Pod marketed pursuant to K101600.

4. Description of the device

New IntelliVue Guardian Software:
The new IntelliVue Guardian Software is a Clinical Information Management System. It collects and manages vital signs data acquired from the IntelliVue Cableless Measurements and IntelliVue patient monitors. The Guardian Software provides trending, review, reporting, notification, clinical documentation, calculations, clinical advisories including EWS deterioration status, remote viewing and operating, interfacing, storage, and printing.
The IntelliVue Guardian Software is software only product intended to be installed on a customer supplied PC or Server.
The IntelliVue Guardian Software is compatible with the following measuring devices:

- Philips IntelliVue Cableless Measurements CL SpO2 Pod and CL NBP Pod,
- Philips IntelliVue MP5 and MP5SC patient monitors.

Modified IntelliVue CL SpO2 Pod:
The IntelliVue CL SpO2 Pod is a small, battery powered, wrist worn pulse oximeter device. It contains Philips FAST-SpO2 (Fourier Artifact Suppression Technology) to provide reliable saturation values under various artifact conditions including motion and low perfusion. It provides continuous operating mode and intermittent operating mode with configurable measurement intervals. Integrated monochrome LCD display shows measured values, measurement signal quality, battery state, and RF signal strength. It has three hardkeys for basic operation and

navigation. It supports specialized Philips reusable and disposable SpO2 sensors.
The IntelliVue CL SpO2 Pod remains unchanged as it is. The modification, which is subject of this Premarket Notification, is solely limited to the labeling change in order to indicate the usage of this device together with the new Philips IntelliVue Guardian Software.

Modified IntelliVue CL NBP Pod:
The IntelliVue CL NBP Pod is a small, battery powered, non-invasive blood pressure and pulse rate measurement device. It uses oscillometric method for measuring NBP. It produces numerics for systolic, diastolic and mean blood pressure values and pulse rate. Integrated monochrome LCD Display shows measured values, battery state, and RF signal strength. It has three hardkeys for basic operation and navigation. It supports specialized Philips reusable and disposable NBP cuffs.
The IntelliVue CL NBP Pod remains unchanged as it is. The modification, which is subject of this Premarket Notification, is limited to the labeling change in order to indicate the usage of this device together with the new Philips IntelliVue Guardian Software.

The IntelliVue CL SpO2 Pod and CL NBP Pod are compatible with the following medical devices:

- Philips IntelliVue Patient Monitors MP5, MP5T, MP5SC, MP2, X2
- Philips IntelliVue Telemetry System Transceiver TRx4841A and TRx4851A
- Philips IntelliVue Guardian Software

5. Intended Use/ Indications for Use

New IntelliVue Guardian Software:
The new IntelliVue Guardian Software is indicated for use by healthcare providers whenever there is a need for generation of a patient record.

The IntelliVue Guardian Software is intended for use in the collection, storage and management of data from IntelliVue Cableless Measurements and IntelliVue Patient Monitors that are connected through networks.

The indication statements of the subject device IntelliVue Guardian Software are the same as those of the predicate Philips IntelliVue Clinical Information Portfolio Software, except that the subject device provides a subset of the indications of the predicate device. Whereas the predicate is indicated for generation of a patient record and for computation of drug dosage, the subject device is only indicated for generation of a patient record. Whereas the predicate is intended for use with any Philips or third-party vendor medical measuring devices, the subject device is only intended for use with a limited number of Philips IntelliVue medical measuring devices. For this reason the different indication statements do not impact the safety and effectiveness of the subject device.

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Modified IntelliVue CL SpO2 Pod:
The IntelliVue CL SpO2 Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters SpO2 and pulse rate wirelessly.

The intended use of the IntelliVue CL SpO2 Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring, recording, and alarming of arterial oxygen saturation and pulse rate of adult and pediatric patients.

The IntelliVue CL SpO2 Pod is also intended for acquisition of arterial oxygen saturation and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL SpO2 Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

Modified IntelliVue CL NBP Pod:
The IntelliVue CL NBP Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters non-invasive blood pressure and pulse rate wirelessly.

The intended use of the IntelliVue CL NBP Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring, recording, and alarming of systolic, diastolic, and mean pressure and pulse rate of adult and pediatric patients.

The IntelliVue CL NBP Pod is also intended for acquisition of systolic, diastolic, and mean pressure and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL NBP Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

The above indication statements of the IntelliVue CL SpO2 Pod/ CL NBP Pod have been modified in order to emphasize that the acquired physiological data can not only be used for monitoring purposes but also for a clinical information management system.

The indication statements have also been modified to reduce the level of specificity with regard to the compatible medical devices. Whereas the previous indication statements have contained detailed references to the particular models of the compatible medical devices, the modified indication statements reference the type of compatible devices. The detailed information on compatible medical devices is still contained in the device labeling, such as Instructions for Use. Therefore, this indication statement modification does not affect the safety and effectiveness of the IntelliVue CL SpO2 Pod/ CL NBP Pod.

The intended use of the IntelliVue CL SpO2 Pod/ CL NBP Pod has not changed. The same clinical users can measure the same physiological parameters of the same target patient population in the same environment of use.
The use of acquired physiological data for an information management system does not affect the safety and effectiveness of the IntelliVue CL SpO2 Pod/ CL NBP Pod. This use is considerably less critical, compared to the previously cleared use of measurement data acquired from these devices for monitoring and alarming purposes.

6. Technological Characteristics

New IntelliVue Guardian Software:
The new Philips IntelliVue Guardian Software, Rev. A.00, has the same technological characteristics as the legally marketed predicate Philips IntelliVue Clinical Information Portfolio software.
The Guardian Software is software only product intended to be installed on a standard PC or Server. It has client server architecture and it is compliant with the up to date Microsoft® Operating System and databases.
The Guardian Software supports a standard hospital LAN interface and Philips device interfaces for connection to the compatible measuring devices.

Modified IntelliVue CL SpO2 Pod and CL NBP Pod:
The modification to the IntelliVue CL SpO2 Pod/ CL NBP Pod is solely limited to the labeling change in order to indicate the usage of these devices together with the new Philips IntelliVue Guardian Software. This labeling modification does not affect the technological characteristics of the IntelliVue CL SpO2 Pod/ CL NBP Pod.

7. Summary of performed testing

Non-Clinical Performance Tests (bench testing):
The purpose of the performance testing was to ensure the performance of the new IntelliVue Guardian Software by verifying and stressing the PC server and client specifications and simulating various scenarios of real customer deployments in the hospital.

The conducted performance tests have confirmed static and dynamic performance of the complete system comprising the new IntelliVue Guardian Software installed on server and clients, the compatible measuring devices, and the hospital IT infrastructure according to the specifications, under conditions simulating real environment of use.

Clinical Evaluation:
The objective of the Clinical Evaluation was to ensure that the new IntelliVue Guardian Software, used together with the compatible IntelliVue Patient Monitors MP5/MP5SC and IntelliVue

Cableless Measurements CL SpO2 Pod/NBP Pod was clinically useful and would be accepted by the clinical users.
The performed Clinical Evaluation has shown that the new IntelliVue Guardian Software, with its Early Warning Scoring capability, in combination with the compatible measuring devices was clinical useful and was accepted by the clinical users.

Further Testing:

- Testing as identified in the Hazard Analysis,
- Functionality testing on the new IntelliVue Guardian Software,
- Functionality Testing on the IntelliVue CL SpO2 Pod together with the new IntelliVue Guardian Software
- Functionality Testing on the IntelliVue CL NBP Pod together with the new IntelliVue Guardian Software
- Functionality Testing on the IntelliVue CL SpO2/CL NBP Pod and Philips proprietary access point CL Hotspot with the new IntelliVue Guardian Software
- Remote Operating Functionality Testing on the IntelliVue CL SpO2/CL NBP Pod and the new IntelliVue Guardian
- Remote Viewing Functionality Testing on the IntelliVue CL SpO2/CL NBP Pod and the new IntelliVue Guardian Software
- Functionality testing on the IntelliVue Patient Monitor MP5/ MP5SC together with the new IntelliVue Guardian Software.

The results of this testing have confirmed safe, effective, and reliable function within specifications of the new IntelliVue Guardian Software used together with compatible IntelliVue patient monitors MP5/MP5SC and IntelliVue Cableless Measurements CL SpO2 Pod/CL NBP Pod, in the specified IT infrastructure.

8. Conclusion

Verification and validation testing activities were conducted to establish the performance, safety, effectiveness, functionality, usability, and reliability characteristics of the new and modified devices.
V&V testing included bench performance tests, functionality tests, system tests, and clinical evaluation. All tests were successfully completed.
The results demonstrate that the new IntelliVue Guardian Software and the modified IntelliVue CL SpO2 Pod, CL NBP Pod are as safe, as effective and perform as well as the predicate devices.
The new and modified devices are substantially equivalent in intended use and fundamental technological characteristics to the appropriate predicate devices. The devices introduce no new questions concerning the safety or efficacy and are, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Germany

OCT - 4 2011

Re: K111905
Trade/Device Name: IntelliVue Guardian Software, Revision A.00.01 and IntelliVue CL SpO2 Pod and CL NBP Pod
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II (two)
Product Codes: DXJ, MSX, DSI, DSK, DSJ, DXQ, DXN, DXG, DRT, DRQ, DQA, DRG, DSA
Dated: September 22, 2011
Received: September 26, 2011

Dear Mr. Stacha:

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): K111905 p 1/2

Device Name:

- Philips IntelliVue Guardian Software, Revision A.00
- Philips IntelliVue CL SpO2 Pod and CL NBP Pod

Indications for Use:

IntelliVue Guardian Software:

The IntelliVue Guardian Software is indicated for use by healthcare providers whenever there is a need for generation of a patient record.

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Prescription Use (Part 21 CFR 801 Subpart D) Yes AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) No

(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 K111905

Indications for Use (continued): K111905 p 2/2

IntelliVue CL SpO2 Pod:

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The IntelliVue CL SpO2 Pod is also intended for acquisition of arterial oxygen saturation and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL SpO2 Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.

IntelliVue CL NBP Pod:

The IntelliVue CL NBP Pod is indicated for use by health care professionals whenever there is a need for acquisition or monitoring of physiological patient parameters non-invasive blood pressure and pulse rate wirelessly.

The intended use of the IntelliVue CL NBP Pod when used together with a patient monitor or with a telemetry system transceiver is for monitoring, recording, and alarming of systolic, diastolic, and mean pressure and pulse rate of adult and pediatric patients.

The IntelliVue CL NBP Pod is also intended for acquisition of systolic, diastolic, and mean pressure and pulse rate data of adult and pediatric patients for a clinical information management system.

The IntelliVue CL NBP Pod is intended for use by health care professionals inside hospitals. It is not intended for home use. It is not a therapeutic device.