AUG 31 2010

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 02, 2010.

2. The names of the devices are:

New devices:

Trade name: Philips IntelliVue CL SpO2 Pod
Common name: Telemetry Transceiver

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

Modified devices:

Trade names: Philips IntelliVue Patient Monitors MP5, MP5T, MP2, X2
Common names: Multiparameter Patient Monitors

Trade name: Philips IntelliVue Telemetry System Transceiver TRx4841A
Common name: Telemetry Transceiver

Classification names 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
	§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

Device Panel	Classification	ProCode	Description
	-	MSX	System, Network and Communication, Physiological Monitors

3. The new Philips IntelliVue CL SpO2 Pod and IntelliVue CL NBP Pod are substantially equivalent to the previously cleared Nihon Kohden Transmitter ZS-940PA series marketed pursuant to K043517, Philips IntelliVue Telemetry System Transceiver TRx4841A marketed pursuant to K081793, K041741, K040357, and Philips Multi-Measurement Server M3000A/M3001A marketed pursuant to K001333, K013427, K020531, K030973, K033715, K062268, K090360.

   The new reusable NBP cuffs 989803163171, 989803163191, 989803163211 and Extension Air Hose 989803163131 for the CL NBP Pod are substantially equivalent to the Philips reusable cuffs M1573A, M1574A, M1575A marketed pursuant to K001333, Philips Extension Air Hose M1598B marketed pursuant to K031187.

   The new disposable NBP cuffs 989803163181, 989803163201, 989803163221 for the CL NBP Pod are substantially equivalent to the Philips disposable cuffs M4574B, M4575B, M4577B marketed pursuant to K071885, Hewlett-Packard/Philips disposable cuffs M1876A, M1877A, M1878A marketed pursuant to K941811, K925910, K923682, K923343, K922058, K910490, K903771, K903523, K900032, K896030, K882609.

   The modified reusable SpO2 sensor Mobile CL RSpO2-1A Reusable SpO2 Sensor for IntelliVue CL SpO2 Pod is substantially equivalent to the Philips reusable SpO2 sensor M1192AN marketed pursuant to K033715 and Nellcor disposable SpO2 sensor MAX-A marketed pursuant K081937.

   The modified disposable SpO2 sensor Mobile CL DSpO2-1A Single Patient SpO2 Sensor for IntelliVue CL SpO2 Pod is substantially equivalent to the Philips disposable SpO2 sensor M1134A marketed pursuant to K091572 Philips reusable SpO2 sensor M1192AN marketed pursuant to K033715, and Nellcor disposable SpO2 sensor MAX-A marketed pursuant to K081937.

   The modified Philips IntelliVue Patient Monitors MP5, MP5T, MP2, X2 are substantially equivalent to previously cleared IntelliVue Patient Monitors MP5, MP5T, MP2, X2 marketed pursuant to K062392, K063725, K071426, K072070, K081793, K082633, K083228, K083517, K091395, K100939.

   The modified Philips IntelliVue Telemetry System Transceiver TRx4841A is substantially equivalent to previously cleared IntelliVue Telemetry System Transceiver TRx4841A marketed pursuant to K081793, K041741, K040357.

4. Description of the devices

   The new Philips IntelliVue CL SpO2 Pod is a small, battery powered, wrist worn pulse oximeter device for cableless monitoring of patients. 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 new Philips IntelliVue CL NBP Pod is a small, battery powered, non-invasive blood pressure and pulse rate measurement device for cableless monitoring of patients. 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 Philips IntelliVue MP5, MP5T, MP2, X2 are robust, portable, lightweight, compact in size and modular in design patient monitors with integrated displays and multiple physiological measurements and interfaces to dedicated external measurement devices. With the built-in battery the monitors can also function during transport situations.
With the built-in physiological measurements the monitors MP5, MP2, and X2 provide the following measurement capability: Invasive Blood Pressure, Temperature, CO2, ECG/Respiration, SpO2, and NIBP. The MP5T model provides internal SpO2 and NIBP measurements.
The monitors MP5, MP5T, MP2, X2 can be interfaced to several dedicated external devices to extend the measurement capabilities. The monitors MP5, MP2 and X2 can also be connected to another IntelliVue patient monitor (MP20 to MP90), where they act as multi-measurement modules acquiring measurements for the host monitor. The network interfaces provide the monitors MP5, MP2 and X2 with networking capability via wired or wireless network connections. The monitors MP5, MP5T, MP2, and X2 can also interface via cable or wirelessly via short range radio to the IntelliVue Telemetry Transceiver TRx4841A.

As a result of the current modification, the MP5, MP5T, MP2, X2 patient monitors can be interfaced wirelessly via short range radio to the new CL NBP and SpO2 Pods.

The Philips IntelliVue Telemetry System Transceiver TRx4841A is a small, lightweight, battery powered patient-worn device for monitoring ECG and SpO2. The TRx4841A Transceiver uses transmission through a body (finger tip) method and Philips FAST-SpO2 algorithm to measure SpO2. The TRx4841A Transceiver provides ECG using standard ECG and EASI derived 12-lead monitoring, 6-lead monitoring with 2 V-leads and EASI derived 12-lead ECG technology with only 5 leads.

The TRx4841A Transceiver sends patient digitized ECG/SpO2 signals via cable or wirelessly (via SRR) to the IntelliVue Patient Monitors MP5, MP5T, MP2, X2 or wirelessly (via WMTS 1.4 GHz) to the Philips IntelliVue Information Center, which displays ECG waveforms, heart rate, and SpO2 values, detects and analyzes the ECG for cardiac arrhythmias and displays alarm conditions and INOP's. Displays, settings, recordings, and alarms are controlled from the IntelliVue Information Center or the Patient Monitors.

As a result of the current modification, the transceiver TRx4841A can be interfaced wirelessly via short range radio to the new CL NBP and SpO2 Pods. The transceiver TRx4841A sends patient digitalized SpO2/NBP signals from the connected CL NBP and SpO2 Pods wirelessly (via WMTS 1.4 GHz) to the Philips IntelliVue Information Center, which displays the physiological measurement values and indicates alarms.

5. Intended Use/ Indications for Use

The IntelliVue CL SpO2 Pod is indicated for use by health care professionals whenever there is a need for monitoring the physiological patient parameters SpO2 and pulse rate wirelessly. The intended use of the IntelliVue CL SpO2 Pod when used together with IntelliVue Patient Monitors MP5, MP5T, MP2, X2, or with the IntelliVue Telemetry System Transceiver TRx4841A, is for monitoring, recording, and alarming arterial oxygen saturation and pulse rate of adult and pediatric patients inside hospitals. The device is intended for use by health care professionals. It is not intended for home use. The device is not a therapeutic device.
This is the same intended use as that of the predicate Nihon Kohden Transmitter ZS-940PA series, except for the compatible monitoring devices and number of physiological parameters: whereas the Transmitter ZS-940PA provides SpO2, pulse rate, non-invasive blood pressure, ECG, and respiration, the CL SpO2 Pod only provides SpO2 and pulse rate. The new CL SpO2 Pod is compatible with Philips monitoring devices whereas the Nihon Kohden Transmitter ZS-940PA is compatible with Nihon Kohden monitoring devices.

The IntelliVue CL NBP Pod is indicated for use by health care professionals whenever there is a need for monitoring the physiological patient parameters non-invasive blood pressure and pulse rate wirelessly.
The intended use of the IntelliVue CL NBP Pod when used together with IntelliVue Patient Monitors MP5, MP5T, MP2, X2, or with the IntelliVue Telemetry System Transceiver TRx4841A is for monitoring, recording, and alarming of systolic, diastolic, and mean pressure and pulse rate of adult and pediatric patients inside hospitals. The device is intended for use by health care professionals. It is not intended for home use. The device is not a therapeutic device.
This is the same intended use as that of the predicate Nihon Kohden Transmitter ZS-940PA series, except for the compatible monitoring devices and number of physiological parameters:

whereas the Transmitter ZS-940PA provides non-invasive blood pressure, pulse rate, SpO2, ECG, and respiration, the CL NBP Pod only provides non-invasive blood pressure and pulse rate. The new CL SpO2 Pod is compatible with Philips monitoring devices whereas the Nihon Kohden Transmitter ZS-940PA is compatible with Nihon Kohden monitoring devices.

The modified Philips IntelliVue Patient Monitors MP5, MP5T, MP2, X2 have the same intended use as the legally marketed monitors MP5, MP5T, MP2, X2.
The IntelliVue Patient Monitors MP5, MP5T, MP2, X2 are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
Intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in a hospital environment and during patient transport inside of the hospital environment. The MP2, X2, and MP5 monitors are also intended for use during patient transport outside of the hospital environment. They are not intended for home use. The monitors are only for use on one patient at a time. They are not therapeutic devices.

The modified IntelliVue Telemetry System Transceiver TRx4841A has the same intended use as the legally marketed Transceiver TRx4841A.
The IntelliVue Telemetry System Transceiver TRx4841A is indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
Intended to provide ambulatory and bedside monitoring, recording and alarming of ECG and SpO2 parameters of adult and pediatric patients in transport and hospital environments.
It is intended to be used by trained healthcare personnel. It is not intended for home use. The device is only for use on one patient at a time. It is not for use with infant or neonatal patients.

6. Technological Characteristics

The new IntelliVue CL SpO2 Pod and CL NBP Pod and their medical accessories have the same or substantial equivalent technological characteristics, such as design, material, energy source, portability, user interface, radio technology, measurement principle, as the legally marketed predicate devices
The new IntelliVue CL SpO2 Pod and CL NBP Pod and their medical accessories use partly different patient skin contacting materials, than the predicates. The only relevant characteristic for the intended applications is the biocompatibility of these materials. The biocompatibility of the different materials, hence the equivalence to the predicate devices, has been proved by successful testing to the applicable biocompatibility standards of the IEC 10993-x standard family.

The modification of the IntelliVue Patient Monitors MP5, MP5T, MP2, X2 and the IntelliVue Telemetry System Transceiver TRx4841A is solely limited to the software changes necessary due to the

wireless communication with the introduced IntelliVue CL SpO2 Pod and CL NBP Pod. This software modification does not affect the technological characteristics of the modified patient monitors MP5, MP5T, MP2, X2 and the transceiver TRx4841A.

7. Brief discussion of non-clinical performance tests

The determination of the substantial equivalence of the performance of the new IntelliVue CL SpO2 Pod and CL NBP Pod and their measurement accessories was based, in addition to the clinical performance validation, on bench performance testing. For the CL SpO2 Pod the accuracy of the pulse rate in the specified measurement range has been validated. In addition, the verification of averaging of the calculated numerics (SpO2, pulse rate, perfusion index) has been verified. The bench performance testing has demonstrated that the new CL SpO2 Pod has performed within specifications, which have been substantial equivalent to those of the predicate device.

For the CL NBP Pod the accuracy of systolic/ diastolic and mean pressure, such as accuracy of pulse rate in the specified measurement range has been validated. The comparative testing has demonstrated that the new CL NBP Pod and its cuffs have produced the same results as the appropriate predicate devices.

8. Brief discussion of clinical performance tests

The determination of substantial equivalence of the performance of the new IntelliVue CL SpO2 Pod and CL NBP Pod and their measurement accessories was based, in addition to the bench performance testing, on clinical performance validation. For the CL SpO2 Pod and its sensors the clinical desaturation study to determine the SpO2 accuracy in the specified measurement range, according to the recognized consensus standard ISO 9919, has been performed. The clinical desaturation study has demonstrated that the new CL SpO2 Pod and its sensors have worked within the specified accuracy and have met the performance requirements of the ISO 9919 standard and the recommendations of the draft guidance document 'Pulse Oximeters - Premarket Notification Submissions [510(k)s]'.

For the CL NBP Pod and its cuffs the clinical study to determine the systolic and diastolic accuracy of blood pressure in the specified measurement range, using the auscultatory reference method according to the recognized consensus standard ANSI/AAMI SP10, has been performed. The clinical study has demonstrated that the new CL NBP Pod and its cuffs have worked within the specified accuracy and have met the performance requirements of the ANSI/AAMI SP10 standard.

9. Conclusion

Verification and validation testing activities were conducted to establish the performance, safety, functionality, and reliability characteristics of the new and modified devices.

Declarations of Conformity to the above listed recognized consensus standards are provided in the Annexes A.01 to A.06.

9.2 Summary Reports

The new IntelliVue CL SpO2 Pod and CL NBP Pod, the modified IntelliVue Patient Monitors MP5, MP5T, MP2, X2 and the modified IntelliVue Telemetry System Transceiver TRx4841A have been subject to a series of verification and validation (V&V) testing, as required by the applicable standards, relevant SpO2 and NIBP guidance documents, hazard analysis, and additional R&D V&V requirements, in order to demonstrate their safe and effective use in accordance with specifications under simulated and clinical use conditions.

The V&V activities have confirmed safe, reliable, secure, and effective function within specifications of the new IntelliVue CL SpO2 Pod and CL NBP Pod, the modified Monitors MP5, MP5T, MP2, X2 and Transceiver TRx4841A, in the intended environment of use.

In addition to the testing required in the applicable recognized consensus standards and particular guidance documents, the following testing has been performed:

- Environmental testing
  - Mechanical testing on the new IntelliVue CL SpO2 Pod and CL NBP Pod.
  - Temperature and humidity testing on the new IntelliVue CL SpO2 Pod and CL NBP Pod.

  All specified test requirements have been met. Please refer to Sub-Sec 9.2.1 'Environmental Testing' for details.

- Radio Frequency (RF) wireless communication testing on the new CL SpO2 Pod and CL NBP Pod with the modified monitors MP5/MP5T, MP2/X2 and the modified transceiver TRx4841A, based on the FDA guidance document 'Radio-Frequency Wireless Technology in Medical Devices'.

  All specified test requirements have been met.

  The following specific items have been subject to the RF wireless communication tests:

  - Performance of wireless functions
    For details please refer to Sub-Sec. 9.2.2 'Radio Frequency (RF) Testing' and Table 16.9.1 'Summary of Tests on the IntelliVue CL SpO2 Pod/ NBP Pod, as required

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 31 2010

Philips Medizin Systeme Boeblingen GmbH
c/o Mr. Markus Stacha
Sr. Regulatory Affairs Engineer
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany

Re: K101600
Device Name: Philips IntelliVue CL SpO2 Pod and IntelliVue CL NBP Pod
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (Two)
Product Codes: DQA, DSI, DSJ, DSK, DXQ, DXN, DXG, DRT, DRQ, DSA, DRG, MSX, MHX
Dated: June 2, 2010
Received: June 8, 2010

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. 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,

M. J. Hillebrenner

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): K101600

Device Names:

- Philips IntelliVue CL SpO2 Pod and IntelliVue CL NBP Pod
- Philips IntelliVue Patient Monitors MP5, MP5T, MP2, X2
- Philips IntelliVue Telemetry System Transceiver TRx4841A

Indications for Use:

IntelliVue CL SpO2 Pod:

The IntelliVue CL SpO2 Pod is indicated for use by health care professionals whenever there is a need for monitoring the physiological patient parameters SpO2 and pulse rate wirelessly. The intended use of the IntelliVue CL SpO2 Pod when used together with IntelliVue Patient Monitors MP5, MP5T, MP2, X2, or with the IntelliVue Telemetry System Transceiver TRx4841A, is for monitoring, recording, and alarming arterial oxygen saturation and pulse rate of adult and pediatric patients inside hospitals. The device is intended for use by health care professionals. It is not intended for home use. The device 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 monitoring the physiological patient parameters non-invasive blood pressure and pulse rate wirelessly.
The intended use of the IntelliVue CL NBP Pod when used together with IntelliVue Patient Monitors MP5, MP5T, MP2, X2, or with the IntelliVue Telemetry System Transceiver TRx4841A is for monitoring, recording, and alarming of systolic, diastolic, and mean pressure and pulse rate of adult and pediatric patients inside hospitals. The device is intended for use by health care professionals. It is not intended for home use. The device is not a therapeutic device.

continued on next page

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)

M.A. Villalobos

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101600

Indications for Use (continued):

Philips IntelliVue Patient Monitors MP5, MP5T, MP2, X2:

The IntelliVue Patient Monitors MP5, MP5T, MP2, X2 are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
Intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in a hospital environment and during patient transport inside of the hospital environment. The MP2, X2, and MP5 monitors are also intended for use during patient transport outside of the hospital environment.
They are not intended for home use. The monitors are only for use on one patient at a time. They are not therapeutic devices.

Philips IntelliVue Telemetry System Transceiver TRx4841A:

The IntelliVue Telemetry System Transceiver TRx4841A is indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
Intended to provide ambulatory and bedside monitoring, recording and alarming of ECG and SpO2 parameters of adult and pediatric patients in transport and hospital environments.
It is intended to be used by trained healthcare personnel. It is not intended for home use. The device is only for use on one patient at a time. It is not for use with infant or neonatal patients.