K132320

PHILIPS

MAR 2 6 2014

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 March 25, 2014.

2. Trade name: Philips IntelliVue CL Respiration Pod.
Common name: Telemetry Transceiver

Classification of the modified IntelliVue CL Respiration Pod:

Device Panel	Classification	ProCode	Description
Anesthesiology Devices	§868.2375, II	BZQ	Monitor, Breathing Frequency
Cardiovascular Devices	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
	-	MSX	System, Network and Communication, Physiological Monitors

3. The modified Philips IntelliVue CL Respiration Pod is substantially equivalent to the previously cleared IntelliVue CL Respiration Pod marketed pursuant to K122223.

4. Description of the modified device

The IntelliVue CL Respiration Pod is a small body-worn, cableless, battery powered, respiration rate and pulse rate measuring and monitoring device. It uses specifically designed adhesive attachment (Mobile CL Resp Attachment, cleared with K122223), which holds the CL Respiration Pod at the patient chest.

The CL Respiration Pod provides and communicates measurements values and other information (e.g. battery state) wirelessly via Short Range Radio (SRR) to an assigned compatible IntelliVue Patient Monitor or IntelliVue GuardianSoftware. It can also provide information on basic posture (like supine, prone, upright etc.) and activity of the patient. The CL Respiration Pod can be controlled from the assigned IntelliVue Patient Monitor or IntelliVue GuardianSoftware.

5. Intended Use / Indications for Use

The Intended Use and Indications for Use of the modified Philips IntelliVue CL Respiration Pod has not changed as a result of the device modification.
The device has the following detailed Indications for Use Statement in its Instructions for Use:

Intended Use / Indications for Use of the modified Philips IntelliVue CL Respiration Pod:

The IntelliVue CL Respiration Pod is indicated for use by health care professionals whenever there is a need for intermittent or spot-check acquisition and monitoring of physiological patient parameters respiration rate and pulse rate wirelessly in specific hospital areas. The IntelliVue CL Respiration Pod is mainly indicated for use in general medical and surgery wards and in waiting areas of emergency rooms.
It is not indicated for use in hospital areas in which continuous patient monitoring is needed, such as intensive care units or operating rooms.

The intended use of the IntelliVue CL Respiration Pod when used together with a patient monitor is for intermittent or spot-check monitoring and recording of, and to generate alarms for, respiration rate and pulse rate of adult patients.

The IntelliVue CL Respiration Pod is also intended for acquisition of respiration rate and pulse rate data of adult patients for a clinical information management system.

The Intellivue CL Respiration Pod is intended for use by health care professionals. It is not intended for home use. It is not a therapeutic device.

The IntelliVue CL Respiration Pod is not intended for use on patients with extremely high values for respiration rate (above 60 rpm).

The IntelliVue CL Respiration Pod is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias, e.g. very fast atrial fibrillation or ventricular tachycardia (rapid irregular pulse rate). For monitoring of these patients, a device for continuous ECG monitoring is necessary. The IntelliVue CL Respiration Pod is not a substitute for an ECG monitor.

Warning:
Do not use the CL Respiration Pod on patients with rapid, irregular heart rates greater than 110 bpm. Use under these conditions has not been clinically validated.

Rx only: US Federal Law restricts these devices to sale by or on the order of a physician.

6. Technological Characteristics

The modified IntelliVue CL Respiration Pod has substantially equivalent technological characteristics, such as design, materials, energy source, portability, user interface, radio technology, measurement principle, as the legally marketed predicate device IntelliVue CL Respiration Pod.

The CL Respiration Pod is a small, battery powered, wireless, and body worn respiration and pulse rate measuring and monitoring device. It is attached to the patient's left costal arch using a specialized accessory, the adhesive Mobile CL Resp Attachment. The CL Respiration Pod has a multicolor LED and a single key to display states and allow basic operation locally. The CL Respiration Pod is connected during its use wirelessly via SRR to a compatible IntelliVue Patient Monitor or IntelliVue GuardianSoftware.

The CL Respiration Pod uses a measurement principle that is based on the thoracic movements. Inclination changes of the incorporated accelerometer sensor, caused by chest and abdomen movements during breathing and heart contraction, produce a voltage signal, from which respiration and pulse rate signals are derived.
The modified Philips IntelliVue CL Respiration Pod uses the same measurement principle (respiratory effort and heart contraction/beating) to derive the respiration and pulse signal as the predicate Philips IntelliVue CL Respiration Pod.

With the means of the built-in accelerometer sensor, the modified CL Respiration Pod also detects activity and basic posture of the patient. This is the same technology as used by the legally marketed Philips IntelliVue CL Respiration Pod (K122223).

7. Summary of V&V activities

- Clinical Performance Tests
  A Bland-Altman statistical comparison between respiration rate and pulse rate performance measured by the modified IntelliVue CL Respiration Pod and the predicate IntelliVue CL Respiration Pod (K122223) has been performed based on clinical data.
  Two separate clinical data sets have been used. The identical data set of K122223 has been reused for the development of the modifications. An additional not yet used clinical data set with patient signals was used to validate the algorithm changes. The additional clinical data set consists of 21 male and 5 female patients between 17 and 86 years of age. A total duration of 621h 10min has been recorded. 2276855 ECG beats and 255307 breathes were used for the comparison.
  The results of the statistical comparison demonstrate the substantial equivalency of the modified IntelliVue CL Respiration Pod with the predicate IntelliVue CL Respiration Pod (K122223).

- Non-Clinical Performance Tests (bench testing):
  Verification of respiration rate and pulse rate range, accuracy, resolution and signal quality, by comparison of the reported respiration and pulse rate with the simulated values. The test results have shown that the respiration rate and pulse rate accuracy, resolution, and signal quality met in the whole measurement range the defined specifications. The modified CL Respiration Pod is substantially equivalent to the predicate IntelliVue CL Respiration Pod with respect to these measurement parameters.

- Testing as identified in the Hazard Analysis. All specified pass/fail criteria have been met. The test results have confirmed the effectiveness of implemented design risk mitigation measures.

- Software Functional testing of the modifications of the IntelliVue CL Respiration Pod in combination with its compatible, legally marketed devices, the IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC and the IntelliVue GuardianSoftware. All specified criteria have been met. The test results have confirmed that the modified device has functioned substantially equivalent to the predicate device and according to the specifications and Instructions for Use in the intended environment of use.

- Regression testing of the IntelliVue CL Respiration Pod in combination with the related, unchanged parts of the IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC and the IntelliVue GuardianSoftware. All specified criteria have been met. The test results have confirmed that the modified device has functioned substantially equivalent to the predicate device and according to the specifications and Instructions for Use in the intended environment of use.

- Mechanical testing (shock, vibration, and free fall).
  All specified test requirements have been met. The test has confirmed that the modified CL Respiration Pod has functioned substantially equivalent to the predicate device and according to the specifications and the modified CL Respiration Pod can operate after shock and vibration tests for class 7M3.

8. Conclusion

Verification and validation testing activities were conducted to establish the equivalence of the performance, functionality, effectiveness, and reliability characteristics of the modified device with respect to the subject device.

V&V testing included clinical and bench performance tests, system level, functionality and regression and mechanical tests. All clinical and non-clinical tests were successfully completed. The results demonstrate that the modified Philips IntelliVue CL Respiration Pod has functioned substantially equivalent to the predicate device Philips IntelliVue CL Respiration Pod (K122223).

The modified device is substantially equivalent in intended use and fundamental technological characteristics to the predicate device. The device introduces no new questions concerning the safety or effectiveness and is, therefore, substantially equivalent to the predicate device.

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

March 26, 2014

Philips Medizin Systeme Boeblingen GmbH
Johannes Schmid
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany

Re: K132320

Trade/Device Name: Philips IntelliVue CL Respiration Pod
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Class: II
Product Code: BZQ
Dated: February 20, 2014
Received: February 24, 2014

Dear Mr. Schmid:

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" (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,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statements

1.A.1 **Indications for Use CL Respiration Pod**

510(k) Number (if known): K132320

Device Name: Philips IntelliVue CL Respiration Pod

IntelliVue CL Respiration Pod:

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Warning:
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Rx only: US Federal Law restricts these devices to sale by or on the order of a physician.

Prescription Use (Part 21 CFR 801 Subpart D)		AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)
	___Yes__		__No___

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
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