MAY 19 2014

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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. Submitter of this premarket notification

Markus Stacha
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany
Tel: +49 7031 463-2840 Fax: +49 7031 463-2442
e-mail: markus.stacha@philips.com

This summary was prepared on April 16, 2014.

2. The name and classification of the devices:

Trade name: IntelliVue Patient Monitors MX400, MX450, MX500, and MX550
Common name: Multiparameter Patient Monitor

Classification:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance

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Device Panel	Classification	ProCode	Description
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
Anesthesiology Devices	§868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	§868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	§868.1880, II	BZC	Data calculator Pulmonary-function
	§868.2375, II	BZQ	Monitor, Breathing Frequency
	§868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	§868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
	§868.2775 II	KOI	Electrical peripheral nerve stimulator
Neurological Devices	§882.1400, II	GWR	Electroencephalograph
	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalograph Sigmal
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical

3. The modified devices Philips IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 software Rev. K.20 are substantially equivalent to the previously cleared IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 software Rev. K.10 marketed pursuant to K130849 and K131872 and the IntelliVue Patient Monitor MX800 marketed pursuant to K122439, K120366, K113441, K113657, K110474, K110622, K102562, K101449, and K100939.

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4. Description of the device

The subject devices IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 are display units with a TFT LCD flat panel display and built-in CPU. The specific models differ in the size of their flat panel displays and in the number of supported external measurement modules.
MX400 has a 9" display, MX450 and MX500 have a 12" display and MX550 has a 15" display. In addition to the MX400 and MX450, the MX500 and MX550 models have three integrated slots for use with the dedicated external plug-in modules.
The monitors do not have any built-in measurements. They are intended to be connected to any one of the external IntelliVue family physiological multi-measurement modules and/or (MX500/MX550 only) to the IntelliVue plug-in measurement modules.
The monitors support multiple non-invasive and invasive measurements such as ECG, arrhythmia, ST, QT, SpO2, respiration rate, pulse rate, heart rate, invasive and non-invasive blood pressure, temperature, CO2, C.O., CCO, intravascular SO2, spirometry, EEG, gas measurements, and NMT. The interaction with the patient depends on the monitored physiological parameter(s).
The monitors acquire multiple physiological patient signals (via connected external measurement modules), display measurement values, waves and trends, generate physiological and technical alarms, provide data recording and support patient data management.
The monitors offer a monitoring solution optimized for the surgical, cardiac, medical and neonatal care environments. They are located in the patient vicinity at the bedside. The monitors can also be used mobile, during patient transport in a hospital setting.
The measurement sensors of the connected external measurement modules are applied at diverse bodily locations, depending on the actual physiological parameters monitored, e.g. on a patient's finger for the pulse oximetry or on a patient's upper arm for the non-invasive blood pressure.
The monitors have a color display with touch-screen as a primary input device. They also support a specialized remote control, keyboard and pointing devices such as a mouse. One external display, which provides an adaptive duplicate image of the primary display, can be connected to a built-in video port.
The monitors interact with the connected external measurement devices locally at the bedside or in transport situations and with the Central Station via LAN or wireless link.

The modification, which is subject of this Premarket Notification, enables the IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 via software update to support two additional features: Remote Display application and Remote Applications.
The Remote Display application feature provides the possibility to view an independent monitor screen on an external display and to operate patient monitor from the external display.
The Remote Applications feature allows the user of the patient monitor to access remotely hosted, pre-configured applications made available by the hospital.
The added functionalities are the same as those already provided by other legally marketed Philips IntelliVue Patient Monitors, such as predicate model MX800. For access to the Remote Applications, the predicate IntelliVue Patient Monitor MX800 supports commercial application server technology, whereas the modified IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 support commercial application server

technology as well as the HTML5 protocol for compatibility with standard web application servers

5. Intended Use

The modified IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 have the same intended use as the legally marketed predicate devices.

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment. The monitors are additionally intended for use in transport situations within hospital environments.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.
The IntelliVue NMT Module is intended to be used as an objective neuromuscular transmission monitor, using accelerometry for measuring the muscle contraction following an electrical stimulation of a peripheral nerve. The NMT Module is intended to be used with adult and pediatric patients.

6. Technological Characteristics

The modification to the IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 is limited to some minor software changes and does not affect technological characteristics of the devices. The devices software has slightly been modified in order to support the new features Remote Display application and Remote Applications.
Design, materials, energy source, portability, user interface, radio technology, measurement principle, and all performance specifications of the devices remain all unchanged.

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7. Summary of V&V activities

The modified IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 have been subject to the following V&V activities:

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

- Functional tests of the modified patient monitors with the Remote Display application feature in order to verify support of the IntelliVue XDS Remote Display. The conducted tests demonstrate that parameter data, alarm and/ or INOP information and operating windows provided by the modified patient monitors are correctly presented on the Remote Display and that the patient monitors can be operated from the Remote Display.

- Functional tests of the modified patient monitors with the Remote Applications feature in order to verify support of applications hosted on network servers. The conducted tests demonstrate that the remote applications are correctly shown on the display of the modified patient monitors and can be operated with user input devices.

- Regression Tests of the modified patient monitors to confirm that the unchanged and not affected functions of the previous software Rev. K.10 also work correctly with the new software Rev. K.20. The regression tests demonstrate that the modified patient monitors work safely, effectively, and correctly in accordance with all specifications and labeling claims.

8. Conclusion

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicates.
Testing comprised functionality and regression tests. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence.
The results demonstrate that the Philips IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 meet all defined reliability requirements and performance claims.

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

May 19, 2014

Philips Medizinsysteme Boeblingen Gmbh, Cardiac An
Markus Stacha
Sr. Regulatory Affairs Engineer
Hewlett-Packard Str.2
Boeblingen, D 71034 GM

Re: K141015
Trade/Device Name: Intellivue Patient Monitor Mx400, Intellivue Patient Monitor Mx450, Intellivue Patient Monitor Mx500, Intellivue Patient
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient (with arrhythmia detection or alarms)
Regulatory Class: II
Product Code: MHX, DSI, MLD, DSJ, DSK, DXN, DXG, KRB, DRQ, DRT, DPS, MLC, DRW, KRC, DRJ, DQA, DSB, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWR, GWS, FLL
Dated: April 16, 2014
Received: April 21, 2014

Dear Markus 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.

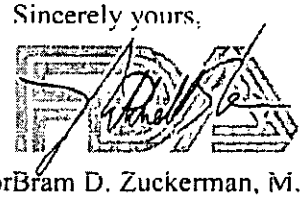
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 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,



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): K141015

Device Name: **IntelliVue Patient Monitors MX400, MX450, MX500, and MX550**

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.05.19 14:56:17 -04'00'