 PHILIPS

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

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OCT 17 2013

This summary was prepared on June 21, 2013.

2. The name and classification of the device

Trade name: IntelliVue Patient Monitor MX500 and MX550
Common name: Multiparameter Patient Monitor

Classification:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§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
	§870.2340, 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
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart

Device Panel	Classification	ProCode	Description
	§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 subject devices Philips IntelliVue Patient Monitors MX500 and MX550, software Rev. K.10, are substantially equivalent to the previously cleared Philips IntelliVue Patient Monitor MP50 marketed pursuant to K122439, K120366, K113441, K113657, K110474, K110622, K102562, K093268, K083517, K082633, K082583, K071426, K063315, K062283, K061610, K061052, K060541, K060221, K053522, K052961, K052801, K050762, K050141, K042845, K041235, K040304, and K032858.

4. Description of the device

   The IntelliVue Patient Monitors MX500 and MX550 are modification of the legally marketed IntelliVue Patient Monitor MP50.

The MX500 and MX550 are display units with a TFT LCD flat panel display and built-in CPU. The models MX500 and MX550 differ only in the size of their flat panel displays: MX500 has a 12" and MX550 has a 15" display.
The MX500 and MX550 do not have any built-in measurements. They can be connected to one Philips M3001A Multi-Measurement Server, M3002A (X2) Multi-Measurement Module, any one of the M3012A, M3014A, M3015A/B or M3016A Measurement Server Extensions, plug-in measurement modules M1006B Invasive Blood Pressure, M1011A Intravascular SO2, M1012A C.O. /CCO, M1014A Spirometry, M1020B SpO2, M1027A EEG, M1029A Temperature, 865383 NMT, 865115 IntelliBridge EC10, to the 865298 (TcG10) Transcutaneous Gas Module and to the M1013A (G1) or M1019A (G5) Gas Modules. These external devices provide non-invasive and invasive measurements such as ECG with arrhythmia and ST, respiration, SpO2, NBP, invasive blood pressure, temperature, CO2, C.O., CCO, Intravascular SO2, Spirometry, EEG and NMT.

The MX500 and MX550 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 MX500 and MX550 offer a monitoring solution optimized for the surgical, cardiac, medical and neonatal care environments. They are located in the patient vicinity either at the bedside or used mobile, during patient transport in the hospital.
The MX500 and MX550 have a color display with touch-screen as primary input device. They also support a specialized remote control, keyboard and pointing devices such as a mouse.
The MX500 and MX550 interact with the connected external measurement devices locally at the bedside or in transport situations and with the Central Station via LAN or WLAN.

5. Intended Use

The subject devices IntelliVue Patient Monitor MX500 and MX550 have the same intended use as the legally marketed predicate IntelliVue Patient Monitor MP50.

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.

BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.
Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

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 subject devices IntelliVue Patient Monitors MX500 and MX550 have the same range of functions as the legally marketed predicate IntelliVue Patient Monitor MP50. MX500 and MX550 reuse unchanged external measurement modules and measurement accessories as already used by the predicate MP50.

MX500 and MX550 have the same relevant-technological characteristics as the predicate MP50 with regard to energy sources, portability, user interface, and robustness.

Compared to the predicate MP50, the MX500 and MX550 have modified technological characteristics with regard to the usage of state of the art hardware components such as wide-screen display, CPU, memories and interfaces, regarding a more compact form factor, resulting in slightly different dimensions and weight, regarding environmental conditions and operating time with internal battery.
The housing of the MX500 and MX550 is made of plastic whereas the housing of the predicate IntelliVue Patient Monitor MP50 is made of plastic and partly of magnesium alloy. The MX500 and MX550 reuse plastic materials of the predicate MP50. Biocompatibility aspects are not affected because the devices do not have contact with patients.

The fundamental scientific technology of the new IntelliVue Patient Monitors MX500 and MX550 is the same as that of the predicate IntelliVue Patient Monitor MP50.
The differences in technological characteristics between the subject devices MX500 and MX550 and the predicate device MP50 do not diminish safety or effectiveness.

7. Summary of V&V activities

- Testing according to the recognized consensus standards:
  - IEC 60601-1-2:2001 +A1:2004 (EMC)
  - IEC 60601-1:1988 +A1:1991+A2:1995 (General Safety)
  - IEC 60601-1-8:2003 (Alarms)
  - IEC 62304:2006 (Software life cycle processes)

  All applicable requirements have been met.

- Environmental testing (temperature, humidity), mechanical testing (shock, vibration, and free fall).
  All specified test requirements have been met. The tests confirmed that the IntelliVue Patient Monitor MX500 and MX550 worked safely and according to their specifications and indicated claims during tests simulating general hospital conditions, handling and transport in hospital environments, and storage.

- Regression testing on the IntelliVue Patient Monitor MX500 and MX550. The performed regression testing comprised function tests of all physiological measurement parameters (which remain unchanged in this submission), recorder module, display, battery functionality, battery operating and charging time, human interface, external interfaces, alarming system, and tests as identified by the hazard analysis.
  All specified criteria have been met. The tests demonstrated that the IntelliVue Patient Monitor MX500 and MX550 worked safely, effectively, and correctly in accordance with specifications and labeling claims in the intended environment of use.

8. Conclusion

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate.
Testing comprised regression tests, electrical and mechanical safety tests, EMC tests, and environmental tests.
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 IntelliVue Patient Monitor 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

October 17, 2013

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

Re: K131872
Trade/Device Name: IntelliVue Patient Monitors MX500 and MX550
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX, DRT, DSI, MLD, DSJ, DSK, DXN, DXG, KRB, DRQ, DPS, MLC, DRW, KRC, DRJ, DQA, DSP, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWR, GWS, FLL
Dated: September 20, 2013
Received: September 23, 2013

Dear Mr. 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 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,

Owen P. Faris -S

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):_____

Device Name: **IntelliVue Patient Monitor MX500 and MX550**

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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)

Digitally signed by Owen P. Faris -S
Date: 2013.10.17 15:44:16 -04'00'

Indications for Use (continued)

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