October 6, 2017

Philips Medizin Systeme Boeblingen GmbH
Markus Stacha
Sr. Regulatory Affairs Engineer
Hewlett-Packard-Str.-2
Boeblingen, DE 71034 BW

Re: K171801
Trade/Device Name: IntelliVue Patient Monitor MX100, Multi-Measurement Module X3 and IntelliVue Hemodynamic Extension 867039
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, DSI, MLD, DQA, DXN, FLL, DRT, DSJ
Dated: September 4, 2017
Received: September 6, 2017

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 (DICE) 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 (DICE) 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,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number: K171801

Device Name: IntelliVue Patient Monitor MX100, Multi-Measurement Module X3, and IntelliVue Hemodynamic Extension 867039

Indications for Use *(Describe)*

Indications for Use statement for the MX100 and X3:

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.

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

The monitor is also intended for use during patient transport inside the hospital environment.

The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is 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 EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use (continued)

510(k) Number: K171801

The Masimo rainbow SET measurement is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRac). The Masimo rainbow SET measurement is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused.

Indications for Use statement for the Hemodynamic Extension 867039:

The measurement extension adds physiological measurements to a dedicated host device. It is intended for use by trained healthcare professionals for adult, pediatric, and neonatal patients in a hospital environment and for transport inside hospitals.

The measurement extension can only function when it is connected to a dedicated host device.

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 October 04, 2017.

2. The name and classification of the devices:

   Trade names: IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3.
   Common name: Multiparameter Patient Monitor.

   Trade name: IntelliVue Hemodynamic Extension 867039.
   Common name: Multifunction Patient Monitor Module.

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
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2900, II	DSA	Cable, Transducer and Electrode, incl. Patient Connector

Device Panel	Classification	ProCode	Description
	-	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
	§868.2375, II	BZQ	Monitor, Breathing Frequency
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical

3. The new IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3 are substantially equivalent to the legally marketed IntelliVue Patient Monitor MP2 and Multi-Measurement Module X2, marketed pursuant to K161531.
The new IntelliVue Hemodynamic Extension 867039 is substantially equivalent to the legally marketed IntelliVue Hemodynamic Extension M3012A, marketed pursuant to K033444.
The new Transpac IV Dual IBP Cable 453564588501 is substantially equivalent to the legally marketed Transpac® 4 Reusable Transducer Cable for Philips Monitors 989803177921 manufactured by ICU Medical, marketed pursuant to K061573.

4. Description of the new devices

The new IntelliVue Patient Monitor MX100, Multi-Measurement Module X3, and Hemodynamic Extension 867039 acquire multiple physiological patient signals, display measurement values, waves and trends, generate physiological and technical alarms, provide data recording and support patient data management.
The devices offer a monitoring solution optimized for the surgical, cardiac, medical and neonatal care environments. They can be located in the patient vicinity at the bedside or can be used mobile, during patient transport inside hospitals.
The measurement sensors are applied at diverse bodily locations, depending on the actual physiological parameters monitored.

The new devices have the same range of functions as the legally marketed predicate devices. They use the same measurement parameters as the predicates.
Whereas the predicate devices optionally provide one invasive pressure, the new devices optionally provide two invasive pressures (dual pressure) that can be measured with one pressure connector.
The MX100 and X3 provide multiple non-invasive and invasive measurements: ECG (including arrhythmia and ST), respiration, SpO2, NBP, dual invasive pressure, temperature, and CO2.
The Hemodynamic Extension 867039 adds optional measurements: dual invasive pressure, temperature, and cardiac output /continuous cardiac output to the host device. The measurement extension can only function when it is connected to a dedicated host device.

Specifications of all measurement characteristics, including measurement principles, methods, algorithms, and all detailed performance specifications and measurement alarm specifications, are the same as those in the predicate devices. The new devices reuse unchanged existing accessories of the predicates.

The new IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3 are compact, rugged, lightweight monitors with built-in measurements. The X3 can be used in two ways: as a multi-measurement module for the Philips IntelliVue family of patient monitors and as a stand-alone monitor.
The MX100 and X3 have a 6.1" TFT flat panel color display with a multi-finger touchscreen as input device.
The MX100 and X3 can interact with the Central Station via LAN or wireless link.

The new Transpac IV Dual IBP Cable 453564588501 is a reusable cable intended to connect two ICU Transpac pressure transducers with one of the new Philips measuring devices (Patient Monitor MX100, Multi-Measurement Module X3, or Hemodynamic Extension 867039). The cable transmits analog voltage signals from the pressure transducers to the Philips device and provides electrical power from the Philips device to the transducers.

5. Intended Use

The Intended Use of the new Philips IntelliVue Patient Monitor MX100, Multi-Measurement Module X3 and Hemodynamic Extension 867039 has not changed as a result of the device modification. The indications for use statement of the new devices is the same as that of the predicate devices, except for the environment of use. Whereas the predicate IntelliVue models MP2 and X2 can be used during patient transport inside and outside of the hospital environment, the use of the new IntelliVue MX100 and X3 is limited to the environment inside hospitals.

Indications for Use statement for the MX100 and X3:

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitor is intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.
The monitor is also intended for use during patient transport inside the hospital environment.
The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is 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 EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

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 Masimo rainbow SET measurement is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRac). The Masimo rainbow SET measurement is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused.

Indications for Use statement for the Hemodynamic Extension 867039:

The measurement extension adds physiological measurements to a dedicated host device. It is intended for use by trained healthcare professionals for adult, pediatric, and neonatal patients in a hospital environment and for transport inside hospitals.
The measurement extension can only function when it is connected to a dedicated host device.

6. Technological Characteristics

The new IntelliVue Patient Monitor MX100, Multi-Measurement Module X3 and Hemodynamic Extension 867039 have the same relevant-technological characteristics as their predicate devices (as stated in Item 3 above) with regard to operating principles, mechanism of action, energy sources, portability, user interface, robustness. They all have very similar dimensions, weight and environmental specifications.

The new MX100 and X3 and their predicates MP2 and X2 have the same hardware and software architecture. Both the new and the predicate devices are compact monitoring devices with a built-in central processing unit, measurement boards, and flat panel display with touch-screen.
The new measurement extension and the predicate measurement extension have the same hardware architecture. Both the new and the predicate extension are compact multi-parameter measuring devices without display and control elements, with built-in power board and measurement boards.

The new MX100 and X3 and their predicates MP2 and X2 can be powered from the same sources: dedicated external power supply, internal battery, or connected host monitor (new X3 and predicate X2 only).
The new measurement extension and the predicate extension are powered from the connected measuring host device via proprietary Philips MSL interface.

Whereas the housings of the predicate devices mainly consist of ABS + PC-FR plastics, the housing of all new devices mainly consist of PBT + PC plastics. The new housing materials enhance the ruggedness of the new devices, without compromising the electrical characteristics, by making them more resistant against mechanical and chemical stress (cleaning detergents).

The new MX100 and X3 have a 6.1 inch state-of-the-art TFT flat panel display with 1024x480 resolution and wide viewing angle. The display is covered by the very

resistant and easy to clean Corning® Gorilla® Glass, compared to the polyester film that covers the display of the predicates MP2 and X2. The new MX100 and X3 are supplied with a capacitive multi-touch screen as input device. The multi-touch screen allows use of operating controls such as swiping and multi-finger gestures.

The new devices use modern internal electronic components such as CPU and memory system. A state-of-the-art acceleration sensor is used to determine the monitor position for the adaption of the display orientation.

7. Summary of V&V activities

The new devices have been subject to a series of V&V activities:

- Testing according to the recognized consensus standards:
  - IEC 60601-1-2: 2007 (Ed. 3) (Electromagnetic Compatibility)
  - AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012 (Ed. 3.1) (Basic safety and essential performance)
  - IEC 60601-2-25: 2011 (Ed. 2) (Electrocardiographs)
  - IEC 60601-2-27: 2011 (Ed. 3) (ECG monitoring equipment)
  - IEC 80601-2-30: 2013 (Ed. 1.1) (Automated noninvasive sphygmomanometers)
  - IEC 60601-2-34: 2011 (Ed. 3) (Invasive blood pressure monitoring equipment)
  - ISO 80601-2-55: 2011 (Ed. 1) (Respiratory gas monitors)
  - ISO 80601-2-56: 2009 (Ed. 1) (Clinical thermometers)
  - ISO 80601-2-61: 2011 (Ed. 1) (Pulse Oximeters)
  - AAMI ANSI IEC 62304:2006 (Ed. 1) (Software life cycle processes)
  - IEC 60601-1-6: 2013 (Ed. 3.1) (Usability)
  - IEC 60601-1-8: 2012 (Ed. 2.1) (Alarms)

  All applicable requirements have been met.

- Additional relevant testing according to the device-specific FDA guidance documents:
  - "Non-Invasive Blood Pressure (NIBP) Monitor Guidance":
    - The intra-device variability between a minimum of three devices
    - Comparison to the intra-arterial reference standard for mean blood pressure.

  All applicable requirements have been met.

  - "Pulse Oximeters - Premarket Notification Submissions [510(k)s] - Guidance for Industry and Food and Drug Administration Staff":
    - Accuracy of Pulse Oximeters - testing that demonstrates that SpO2 and pulse rate values calculated by the OEM system are not corrupted during communication to the host device
    - Display values, outputs, and indicators.

  All applicable requirements have been met.

- Testing as required by the Hazard Analysis.

  All specified pass/fail criteria have been met. The test results have confirmed the effectiveness of the implemented design risk mitigation measures.

- Additional environmental testing (temperature, humidity) and mechanical testing (mechanical classes 7M1, 7M2, 7M3, and disinfectant resistance)
  All specified test requirements have been met. The tests have confirmed that the new devices work safely and according to their specifications and indicated claims during tests simulating general hospital conditions, handling and transport in hospital environments, disinfection, and storage.

- Unit level tests, integration tests, functional system level tests, and regression system level tests.
  The new devices perform according to the specified criteria:
  - Alarm, Measurement, Operating System, Display and Operation Unit Tests
  - Integration tests
  - Functional tests for Dual Pressure and Operating Controls
  - Alarm, Measurement, and Interface Regression Tests

  All specified test requirements have been met. The test results demonstrate that modified and previously available device functions work correctly according to the specifications and labeling claims.

- Usability and User Preference Testing on the new MX100 and X3.
  All specified test requirements have been met. The new devices have been found to be safe and effective for the intended users, uses, and use environments.

- Performance testing of Respiration rate and Cardiac Output (C.O.)
  All specified test requirements have been met. The new devices perform according to the specified criteria that are the same as those for the predicate devices:
  - Respiration rate accuracy and resolution, respiration wave bandwidth and respiration alarm delay
  - Accuracy and repeatability specifications for right heart and transpulmonary mode
  - Visibility of thermodilution curve in the cardiac output window on the host monitor where the new X3 is connected
  - Temperature drift limits and small signal warnings.

- Performance testing of the new Transpac IV Dual IBP Cable.
  All specified test requirements have been met. The new cable has passed all durability tests in simulated test scenarios:
  - Cleaning and Disinfection
  - Mechanical / tensile strength
  - Monitor connector insertion / removal force
  - Operating Temperature
  - Connector insertion cycle.

8. Conclusion

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new devices with respect to the predicates.
Testing comprised electrical and mechanical safety tests, EMC tests, environmental tests, performance tests, usability tests, functional 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 new devices meet all defined reliability requirements and performance claims.