September 4, 2018

Philips Medizin Systeme Boeblingen GmbH
Stefan Breuer
Senior Regulatory Affairs Engineer
Hewlett-Packard-Str. 2
Boeblingen, 71034 De

Re: K181314
Trade/Device Name: IntelliVue Patient Monitor MX100, IntelliVue Multi-Measurement Module X3, IntelliVue Microstream Extension 867041
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, DSJ, DSK, DXN, DXG, KRB, DRT, DRQ, DPS, MLC, DRJ, DQA, DSB, DSA, MSX, DRG, CCK, BZQ, FLL
Dated: August 1, 2018
Received: August 6, 2018

Dear Stefan Breuer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Arielle Drummond -S

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181314

Device Name
IntelliVue Patient Monitor MX100, Multi-Measurement Module X3, Microstream Extension 867041

Indications for Use *(Describe)*
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.

The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and which are mainly free from cardiac arrhythmia.
The PPV measurement is validated for use with adult patients only.

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

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Indications for Use (continued)

Indications for Use Statement for the Microstream Extension 867041

The measurement extension adds physiological measurements (Microstream CO_2 and optionally temperature, invasive blood pressure and cardiac output) 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.

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.

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.

5.1 Submitter

The submitter of this Premarket Notification is:

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This summary was prepared on May 15, 2018.

5.2 Name and Classification of the Devices

Trade names: IntelliVue Patient Monitor MX100, Multi-Measurement Module X3, Microstream Extension 867041
Common name: Multiparameter Patient Monitor

Trade name: IntelliVue Microstream Extension 867041
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, I	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

5.3 Substantial Equivalence

The modified IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3 with Software Rev. M.03 with the derived measurement PPV are substantially equivalent to the legally marketed IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3, marketed pursuant to K171801, and to IntelliVue Patient Monitor MP5, marketed pursuant to K161531.

The modified IntelliVue Microstream Extension 867041 with Cardiac Output is substantially equivalent to the legally marketed IntelliVue Microstream Extension 867041 and the legally marketed IntelliVue Capnography Extension 867040, both marketed pursuant to K172904.

5.4 Description of the Device

IntelliVue Patient Monitor MX100 and
IntelliVue Multi-Measurement Module X3

The IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3 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 body locations, depending on the actual physiological parameters monitored.

The MX100 and X3 provide multiple non-invasive and invasive measurements: ECG (including arrhythmia and ST), respiration, SpO_2, NBP, dual invasive pressure, temperature, and CO_2.

The modification that is subject of this Premarket Notification adds the derived measurement PPV (pulse pressure variation), which is calculated from beat-to-beat arterial pressure values. This is the same measurement as in the predicate device IntelliVue Patient Monitor MP5.

IntelliVue Microstream Extension 867041

The Microstream Extension 867041 adds to the dedicated host device (IntelliVue Patient Monitor or Multi-Measurement Module) physiological measurements: Microstream CO_2, and optionally dual invasive pressure and temperature.

The measurement extension is not a stand-alone device; it can only function when it is connected to a dedicated host device.

The modified Microstream Extension now provides the additional optional measurement cardiac output to the host devices. The cardiac output measurement is the same as in the predicate device IntelliVue Capnography Extension 867040.

5.5 Intended Use

IntelliVue Patient Monitor MX100 and
IntelliVue Multi-Measurement Module X3

This is the same Intended Use as that for the legally marketed predicate devices IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3.

The Indications for Use Statement has been modified to add the PPV Indication from the legally marketed predicate device IntelliVue Patient Monitor MP5.

Indications for Use statement for the IntelliVue Patient Monitor MX100 and Multi-Measurement Module 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.

The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and which are mainly free from cardiac arrhythmia.

The PPV measurement is validated for use with adult patients only.

IntelliVue Microstream Extension 867041

This is the same Intended Use as that for the legally marketed predicate device IntelliVue Microstream Extension 867041.

The Indications for Use Statement has been modified to add the cardiac output measurement from the legally marketed predicate device IntelliVue Capnography Extension 867040.

Indications for Use statement for the Microstream Extension 867041:

The measurement extension adds physiological measurements (Microstream CO2 and optionally temperature, invasive blood pressure and cardiac output) 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.

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.

5.6 Technological Characteristics

IntelliVue Patient Monitor MX100 and
IntelliVue Multi-Measurement Module X3

The modifications to the IntelliVue Patient Monitor MX100 and the Multi-Measurement Module X3 are limited to minor software changes that do not affect technological characteristics of the devices. The common software of the devices has slightly been modified in order to provide the derived measurement Pulse Pressure Variation (PPV).

The hardware of the subject devices remains unchanged; all accessories are re-used unchanged from the predicate devices.

IntelliVue Microstream Extension 867041

The modifications to the IntelliVue Microstream Extension 867041 are limited to the addition of the Cardiac Output measurement board. This board is re-used, without any hardware or software change, from the legally marketed predicate device IntelliVue Capnography Extension 867040. All accessories are re-used from the predicate device, without any change.

All Subject Devices

Design, materials, energy source, portability, user interface, radio technology, measurement principle, and all physical, environmental, and performance specifications of the devices remain all unchanged. The modified IntelliVue Patient Monitor MX100, Multi-Measurement Module X3 and Microstream Extension 867041 have the same relevant technological characteristics as their predicate devices with regard to operating principles, mechanism of action, energy sources, portability, user interface, robustness, dimensions, weight and environmental specifications.

5.7 Summary of V&V Activities

IntelliVue Patient Monitor MX100 and
IntelliVue Multi-Measurement Module X3

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

- Testing according to the recognized consensus standards:
  - AAMI ANSI IEC 62304:2006 (Ed. 1) (Software life cycle processes)
  - IEC 60601-2-34: 2011 (Ed. 3) (Invasive blood pressure monitoring equipment)

  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.
- Unit level tests, functional system level tests, and regression system level tests.
  The modified devices perform according to the specified criteria:
  - Functional unit level tests for Derived Measurement PPV
  - Functional system level tests for Derived Measurement PPV
  - Regression Tests for unchanged host monitors

  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.
- Performance testing of derived measurement PPV
  - Verification of PPV calculation by comparison to predicate device
  - Verification of PPV artifact detection mechanism
  - Verification of calculation of the average PPV

  All applicable requirements have been met. The modified devices perform according to the specified criteria that are the same as those for the predicate devices.

IntelliVue Microstream Extension 867041

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

- Testing according to the recognized consensus standards:
  - AAMI ANSI IEC 62304:2006 (Ed. 1) (Software life cycle processes)
  - AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012 (Ed. 3.1) (Basic safety and essential performance)

- IEC 60601-1-2: 2007 (Ed. 3) (Electromagnetic Compatibility)

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 modified 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.
- Functional system level tests, and regression system level tests.
  The modified devices perform according to the specified criteria:
  - Functional system level tests for Cardiac Output (C.O.) measurement
  - Regression Tests for unchanged host monitors and unchanged other measurements in Microstream Extension 867041

  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.
- Performance testing of Cardiac Output (C.O.)
  - Verification of accuracy and repeatability for right heart measurement
  - Verification of accuracy and repeatability for transpulmonary measurement
  - Verification of the visibility of Thermodilution Curve in Cardiac Output Application Window
  - Verification of temperature drift limits and small signal warnings.

  All specified test requirements have been met. The modified devices perform according to the specified criteria that are the same as those for the predicate devices:

5.8 Conclusion

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicates.

Testing comprised electrical and mechanical safety tests, EMC tests, environmental tests, performance 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 modified devices meet all defined reliability requirements and performance claims.