November 15, 2018

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

Re: K181831
Trade/Device Name: IntelliVue Multi-Measurement Module MMX
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, DRQ, DRT, DPS, MLC, DRJ, DQA, DSB, DSA, MSX, CCK, BZQ, FLL
Dated: October 11, 2018
Received: October 15, 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)*
K181831

Device Name
IntelliVue Multi-Measurement Module MMX

Indications for Use *(Describe)*

The Philips Multi-Measurement Module (MMX) is for use with Philips IntelliVue Patient Monitors.

The Multi-Measurement Module, with its host patient monitor, is intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in healthcare facilities.
It sends processed measurement data (for example, measurement waves and numerics) to the monitor screen, generates alerts, and supports the transfer of patient data between monitors.

The Multi-Measurement Module is intended for use by trained healthcare professionals in a hospital environment. The Multi-Measurement Module is additionally intended for use in transport situations within hospital environments together with its host patient monitor.

The Multi-Measurement Module is only for use on one patient at a time. It is not intended for home use. It is not a therapeutic device. The Multi-Measurement Module is for prescription use only.

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 with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

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

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 July 04, 2018.

5.2 Name and Classification of the Devices

Trade names: IntelliVue Multi-Measurement Module MMX
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
	§870.2060, 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
	§870.2600, 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
	-	MSX	System, Network and Communication, Physiological Monitors

Device Panel	Classification	ProCode	Description
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 newly introduced IntelliVue Multi-Measurement Module MMX is substantially equivalent to

- the legally marketed IntelliVue Multi-Measurement Module X1 with Capnography Extension M3014A, marketed pursuant to K161531 and K050762
- the legally marketed IntelliVue Multi-Measurement Module X3, marketed pursuant to K171801.

5.4 Description of the Device

The newly introduced IntelliVue Multi-Measurement Module MMX acquires multiple physiological patient signals, sends processed measurement data (for example, measurement waves and numerics) to the host monitor screen, generates alerts, and supports the transfer of patient data between monitors.

The device, together with its compatible host monitor, offers a monitoring solution optimized for the surgical, cardiac, medical and neonatal care environments. It 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 physiological parameters monitored.

The new device has the same range of functions as the legally marketed predicate devices; it provides the same measurement parameters as the predicates.

The Multi-Measurement Module MMX provides multiple non-invasive and invasive measurements: ECG (including arrhythmia and ST), respiration, SpO_2, NBP, dual invasive pressure, temperature, and CO_2.

5.5 Intended Use

The Philips Multi-Measurement Module MMX is for use with Philips IntelliVue Patient Monitors.

The Multi-Measurement Module, with its host patient monitor, is intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in health care facilities.

It sends processed measurement data (for example, measurement waves and numerics) to the monitor screen, generates alerts, and supports the transfer of patient data between monitors.

The Multi-Measurement Module is intended for use by trained healthcare professionals in a hospital environment. The Multi-Measurement Module is additionally intended for use in transport situations within hospital environments together with its host patient monitor.

The Multi-Measurement Module is only for use on one patient at a time. It is not intended for home use. It is not a therapeutic device. The Multi-Measurement Module is for prescription use only.

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 with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

5.6 Technological Characteristics

The new IntelliVue Multi-Measurement Module MMX has the same technological characteristics as its predicate device IntelliVue Multi-Measurement Module X1 with Capnography Extension M3014A. It has the same operating principles, mechanism of action, energy sources, portability, user interface, and comparable robustness. Dimensions, weight and environmental specifications are very similar.

The new IntelliVue Multi-Measurement Module MMX also has the same technological characteristics as its predicate device IntelliVue Multi-Measurement Module X3. It has the same operating principles, mechanism of action, portability and robustness. The implementation of the physiological measurements are identical in hardware and software. Dimensions, weight and environmental specifications are very similar.

5.7 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:
  - AAMI/ANSI/IEC 62304:2006 (Software life cycle processes)
  - AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012 (Ed. 3.1) (Basic safety and essential performance)
  - IEC 60601-1-2:2014 (Ed. 4.0) (Electromagnetic Compatibility)
  - IEC 60601-1-8: 2012 (Ed. 2.1) (Alarms)
  - IEC 60601-2-25: 2011 (Ed. 2.0) (Electrocardiographs)
  - IEC 60601-2-27: 2011 (Ed. 3.0) (ECG monitoring equipment)
  - IEC 80601-2-30: 2013 (Ed. 1.1) (Automated noninvasive sphygmomanometers)
  - IEC 60601-2-34: 2011 (Ed. 3.0) (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)

All applicable requirements have been met.

- Additional relevant testing according to the device-specific FDA guidance documents:
  - "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 SpO_2 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.
  - "Non-Invasive Blood Pressure (NBP) 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.
- 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)
  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 and storage.
- Integration tests, functional system level tests, and regression system level tests
  The new devices perform according to the specified criteria:
  - Integration tests
  - Functional tests for physiological parameters
  - Regression tests for patient monitor compatibility and operating system

  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.

5.8 Conclusion

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device 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 new devices meet all defined reliability requirements and performance claims.