



November 22, 2023

Philips Medizin Systeme Boeblingen GmbH
Monica Da Silva
Principal Regulatory Affairs Specialist
Hewlett-Packard-Strasse 2
Boeblingen, BW 71034
Germany

Re: K230604

Trade/Device Name: IntelliVue Patient Monitor MX100 (867033), IntelliVue Multi-Measurement Module X3 (867030)

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, DQA, DRT, DSI, DSJ, DXN, FLL, MLD

Dated: October 27, 2023

Received: October 27, 2023

Dear Monica Da Silva:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K230604

Device Name

IntelliVue Patient Monitor MX100 (867033)
IntelliVue Multi-Measurement Module X3 (867030)

Indications for Use (Describe)

Intended Use:

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.

Indication for Use:

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

The monitor is only for use on one patient at a time.

The monitor is not a therapeutic device.

Caution: 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 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 Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only.

Warning: 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 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 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.

It is not intended for home use.

Warning: The monitor is not intended for use in an MRI environment or in an oxygen-enriched environment (for example, hyperbaric chambers).

Contraindications: There are no known contraindications for the IntelliVue MX100/X3 Patient Monitor/Multi-Measurement Module.

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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510(k) Summary				
510(k) Summary				
1.1 Submitter				
Date Prepared	March 3, 2023			
Submitter/Owner	Philips Medizin Systeme Böblingen GmbH FDA Establishment Number 9610816 Hewlett-Packard-Str. 2 71034 Böblingen Germany			
Key Contact	Monica da Silva Principal Regulatory Affairs Specialist moncia.dasilva@philips.com Phone: +49 151 40903561			
510(k) Submission No.	K230604			
1.2 Device				
Trade Name	IntelliVue Multi-Measurement Module X3 IntelliVue Patient Monitor MX100			
Common Name	Multiparameter Patient Monitor			
Classification Name	Panel & Name: Cardiovascular Devices Subpart & Division: 21 CFR §870.1025 Regulatory Class: II Product Code: MHX			
1.3 Predicate Device				
Predicate Device	510(k) No.	Company	Device Name	Product Code
	K182979	Philips	IntelliVue Multi-Measurement Module X3 IntelliVue Patient Monitor MX100	MHX
The subject devices are substantially equivalent to the legally marketed predicate devices.				
1.4 Device Description				
IntelliVue Patient Monitors X3 and MX100 – description of the device per 21 CFR 807.92(a) (4)				
The Multi-Measurement Module X3 and the IntelliVue Patient Monitor MX100, 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 X3 and MX100 can interact with the Central Station via LAN or wireless link.

The Multi-Measurement Module X3 and IntelliVue Patient Monitor MX100 are compact, rugged, lightweight monitors with built-in invasive and non-invasive measurements, namely ECG (including arrhythmia and ST), respiration, SpO2, NBP, dual invasive pressure, temperature, and CO2. It can further extend the measurement capabilities when connecting to the legally marketed IntelliVue Multi-Measurement Extensions

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.

1.5 Intended Use and Indication for Use

Intended Use as required per 21 CFR 807.92(a)(5)

Intended Use:

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.

Indications for Use:

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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. It is not intended for home use.

Warning: The monitor is not intended for use in an MRI environment or in an oxygen-enriched environment (for example, hyperbaric chambers).

Contraindications: There are no known contraindications for the IntelliVue MX100/X3 Patient Monitor/Multi-Measurement Module.

1.6 Comparison of Intended Uses for Subject Device and Predicate

The modified Multi-Measurement Module X3 and IntelliVue Patient Monitor MX100 have the same intended use and indications as the legally marketed predicate device.

1.7 Comparison of Technological Characteristics with Predicate Device

Similarities

Item of Comparison	Description/Rationale
Device Design	<ul style="list-style-type: none"> device design of subject devices is the same as for the predicate devices unchanged hardware and architecture monitor hardware entirely unchanged
Materials	<ul style="list-style-type: none"> same materials used as those of the predicate devices biocompatibility aspects do not apply because the devices do not have patient contact biocompatibility aspects of accessories are not affected, because all accessories of the predicate devices remain unchanged
Energy Source	<ul style="list-style-type: none"> Powered by dedicated external power supply or from connected host patient monitor (via MSL interface, X3 only) or from built-in battery devices do not deliver energy to the patients for their function, same as predicate devices
Software/Hardware Features	<ul style="list-style-type: none"> proposed modification does not introduce any new technological hardware features is unchanged from its predicate device measurements of physiological parameters are the same as in the predicate devices



Physiological Parameters	<ul style="list-style-type: none"> existing physiological parameters of the predicate devices remain unchanged is the same as those of its respective predicate device
Performance specifications	<ul style="list-style-type: none"> specifications of all measurement characteristics, including measurement principles, methods, algorithms, and all detailed performance specifications remain unchanged
Operating Principle and Mechanism of Action	<ul style="list-style-type: none"> unchanged from the predicate devices
Human Interface	<ul style="list-style-type: none"> human interface of the IntelliVue X3 and MX100 remain the same
Measurement Accessories	<ul style="list-style-type: none"> all accessories of the predicate devices <ul style="list-style-type: none"> IntelliVue Patient Monitor X3 IntelliVue Patient Monitor MX100 are re-used without any change
Differences	
Software	<ul style="list-style-type: none"> A new software version designated as IntelliVue Software P.01 introduced the following new features: <ul style="list-style-type: none"> New alarm sounds designated as “Philips 2021” sounds. Configurable alarm management, limiting changes in alarm settings to pre-defined authorized personnel. Additionally, the new Software revision will further enhance the following existing features: <ul style="list-style-type: none"> Early Warning Score Validation followed by user identification via Single Sign On Additional SPO2 fallback configuration Additional Lead Diagram presentation for ECG Enhancement of presentation of the global “alarm off” state



Substantial Equivalence Summary		
Operational and technological characteristics form the basis for the determination of substantial equivalence of the subject devices with the legally marketed predicate devices (K182979). The subject devices are substantially equivalent to the predicate devices.		
1.8 Performance Data		
Non-Clinical Tests – Harmonized Standards		
The subject devices have passed all safety tests for demonstrated compliance with the recognized standards below.		
Standard	FDA Recognition #	Title #
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	19-4	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.0	19-8	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6 Edition 3.2	5-132	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8 Edition 2.2 (CSV)	5-131	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62304 Edition 1.1 (CSV)	13-79	Medical device software – Software life cycle processes



Non-clinical Bench Tests
No new issues of safety or effectiveness as compared to the predicate are introduced because of using this device.
Clinical Studies
<p>The subject devices, like the primary predicate devices, did not require clinical trials.</p> <p>Compliance to the FDA Quality System Regulations, FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, software validation, usability validation, and risk management activities have taken place for the subject devices.</p> <p>Based upon the design, intended use, indications for use, classification, usability and safety testing, the subject devices are substantially equivalent to the listed predicate devices.</p> <p><i>No new issues of substantial equivalence are introduced as a result of using this device.</i></p>

1.9 CONCLUSIONS
<p>The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety and electromagnetic compatibility, software verification and validation, human factors, usability and interoperability testing, demonstrate that the modified devices do not raise different questions of safety and effectiveness when compared to the predicate, perform as intended, and have performance characteristics that are substantially equivalent to the predicate devices.</p>

