February 6, 2026

Philips Medizin Systeme Boeblingen GmbH
Siegfried Breitling
Senior Regulatory Affairs Specialist
Hewlett-Packard-Strasse 2
Boeblingen, BW 71034
Germany

Re: K252726
Trade/Device Name: IntelliVue Multi-Measurement Module X3 (867030); IntelliVue Patient Monitor MX100 (867033); IntelliVue MMX (867036)
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: January 9, 2026
Received: January 9, 2026

Dear Siegfried Breitling:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 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

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252726

Device Name
IntelliVue Multi-Measurement Module X3, IntelliVue Patient Monitor MX100 and IntelliVue MMX.

Indications for Use *(Describe)*
IntelliVue Patient Monitors X3 and MX100:

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.

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.

Indications 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.
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.

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.

IntelliVue MMX:

Intended use:

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

Indications for use:

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 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 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.

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510(k) Summary

510(k) Summary

1.1 Submitter

Date Prepared	August 25, 2025
Submitter/Owner	Philips Medizin Systeme Böblingen GmbH FDA Establishment Number 9610816 Hewlett-Packard-Str. 2 71034 Böblingen Germany
Key Contact	Daniel Potocic Regulatory Affairs Specialist daniel.potocic@philips.com Phone: +4970314632626
510(k) Submission Type	This is a traditional 510(k).

1.2 Device

Trade Name	IntelliVue Multi-Measurement Module X3 IntelliVue Patient Monitor MX100 IntelliVue MMX
Common Name	Multiparameter Patient Monitor
Classification Name	Panel & Name: Cardiovascular Devices Subpart & Division: 21 CFR §870.1025 Regulatory Class: II Product Code: MHX, DQA, DRT, DSI, DSJ, DXN, FLL, MLD

1.3 Predicate Device

Predicate Device	***510(k) No.***	***Company***	***Device Name***	***Product Code***
	K230604	Philips	IntelliVue Multi-Measurement Module X3	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.

IntelliVue MMX – description of the device per 21 CFR 807.92(a) (4)

The 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 Multi-Measurement Module MMX provides multiple non-invasive and invasive measurements: ECG (including arrhythmia and ST), respiration, SpO2, NBP, dual invasive pressure, temperature, and CO2.

1.5 Intended Use and Indication for Use

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

<u>Intended Use (X3/ MX100)</u>:
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.

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.

<u>Indications for Use (X3/ MX100):</u>

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.
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.

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.

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

Indications for Use (MMX):
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 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 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.

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 as the legally marketed predicate device.

The MMX intended use contains additional text stating that the MMX is not a stand-alone device and sends measurement data to the connected Monitors.
Despite the slight difference in text, the intended use of the MMX is in its essence the same as that of X3 (predicate device).

1.7 Comparison of Technological Characteristics with Predicate Device

Similarities

Item of Comparison	**Description/Rationale**
Device Design	• The device design of the subject devices is equivalent to the predicate device. • The changes proposed in this 510(k) do not modify the hardware and architecture of the devices.
Materials	• The changes proposed in this 510(k) do not modify the material used in previous versions of the device (predicate device). • 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 device remain unchanged

Energy Source	• Powered by dedicated external power supply (X3 and MX100) or from connected host patient monitor (via MSL interface, X3 and MMX) or from built-in battery (X3 and MX100) • devices do not deliver energy to the patients for their function, same as predicate device • The changes proposed in this 510(k) are unrelated to the energy source of the devices
Hardware Features	• proposed modification does not introduce any new technological hardware features. Hardware is unchanged from its predicate device
Physiological Parameters	• The changes proposed in this 510(k) are unrelated to any existing physiological parameters. No changes were performed in the measurement capabilities of the devices.
Performance specifications	• specifications of all measurement characteristics, including measurement principles, methods, algorithms, and all detailed performance specifications remain unchanged
Operating Principle and Mechanism of Action	• unchanged from the predicate device
Human Interface	• human interface remains the same
Measurement Accessories	• all accessories of the predicate device - IntelliVue Patient Monitor X3 - IntelliVue Patient Monitor MX100 - IntelliVue MMX are re-used without any change
Differences	
Software	• The software of the subject devices was slightly changed when compared to its predicate device, to: ○ further enhance some of the existing functionalities: enabling faster initiation of the STAT mode during NBP measurements For the Multi-Measurement Module X3 and IntelliVue Patient Monitor MX100 only: ○ modifying the factory default for the NBP, recording more alarm logging information, disabling the configuration of the “AlarmsOffAtStart” feature, allowing connections with 100Mbps speeds and enhancing the existing visual indications in the case of speaker malfunction.

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 device (K230604). The subject devices are substantially equivalent to the predicate device.

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 60601-1-2:2014 incl. AMD1:2020	19-36	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2010 incl. AMD1:2013 and AMD2:2020	5-132	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 60601-1-8:2006 incl. AMD1:2012 and AMD2:2020	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 62304:2006 incl. AMD1: 2015	13-79	Medical device software Software life-cycle processes

Non-clinical Bench Tests
No new issues of safety or effectiveness are introduced with the changes proposed for the IntelliVue X3, MX100 and MMX compared to the predicate.
Clinical Studies
The subject devices, like the primary predicate device, did not require clinical trials.

1.9 CONCLUSIONS

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety and electromagnetic compatibility assessments, software verification and validation, 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 device.