September 2, 2025

Philips Medizin Systeme Böblingen GmbH
Monica Da Silva
Principal Regulatory Affairs Specialist
Hewlett-Packard-Str. 2
Boeblingen, 71034
Germany

Re: K250453
Trade/Device Name: IntelliVue Patient Monitor 6100 (6100); IntelliVue Patient Monitor 6300 (6300); IntelliVue Patient Monitor 6500 (6500)
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, MLD, DSJ, DSK, DXN, DRT, DPS, DQA, DSF, MSX, CCK, BZQ, FLL
Dated: August 25, 2025
Received: August 25, 2025

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

Submission Number *(if known)*

K250453

Device Name

IntelliVue Patient Monitor 6100 (6100);
IntelliVue Patient Monitor 6300 (6300);
IntelliVue Patient Monitor 6500 (6500)

Indications for Use *(Describe)*

Intended Use:
The devices are 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:
The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are only for use on one patient at a time.
The monitors are not therapeutic devices.
Caution: The monitors are for prescription use only.

The ECG measurement is indicated to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is indicated for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is indicated for use with adult patients only.
The derived measurement Pulse Pressure Variation (PPV) is indicated 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 Predictive Temperature module is indicated to provide an accurate prediction of patient temperature using the oral, axillary, or rectal body sites, or to provide an actual temperature reading in the continuous monitor mode to adult and pediatric patients.
The NanoPod capnography module is indicated to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is indicated for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport.
The NanoPod capnography module provides the clinician with an integrated pulmonary index (IPI). The IPI is based on end tidal carbon dioxide, respiration rate, oxygen saturation and heart rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status. The Integrated Pulmonary Index (IPI) is indicated 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.

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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510(k) Summary

1.1 Submitter

Date Prepared	February 14, 2025
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 Monica.dasilva@philips.com Phone: +49 175 3293 046
510(k) Submission Type	Traditional 510(k)

1.2 Device

Trade Name	IntelliVue Patient Monitor 6100 IntelliVue Patient Monitor 6300 IntelliVue Patient Monitor 6500
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***
	K223574	Philips	IntelliVue Patient Monitor MX550	MHX

The subject devices are substantially equivalent to the legally marketed predicate devices.

1.4 Device Description

IntelliVue Patient Monitors 6100, 6300, 6500 – description of the device per 21 CFR 807.92(a) (4)

The new IntelliVue Patient Monitors 6100 (867311), 6300 (867313) and 6500 (867315) are display units with built-in CPUs. They integrate a TFT LCD flat panel display with dimensions of 10’ for model

6100 and 6300 and 15' for the 6500 model). All Monitors are outfitted with a touchscreen interface as a primary input for the device. They also support data input devices such as a dedicated remote control, keyboard and pointing devices such as a mouse.

The new patient monitors have integrated measurements such as ECG/Resp, SpO2, NIBP, IBP and Temperature. In addition to their integrated measurements, these devices can also connect to other external measurement modules through their FlexLink connector. The FlexLink connector serves as an interface between the 6100, 6300 and 6500 Patient Monitors and Medtronic's Microstream™ CO2 NanoPod as well as the Predictive Temperature Module.

The new Patient Monitors run on mains power or on the internal battery. They serve as stationary patient monitors and can also be used as portable patient monitors in hospital transport only.

The new Patient Monitors can communicate with the Philips Central Station (aka Patient Information Center iX, last cleared with K211900) as well as with Philips XDS Software, which is intended for use as an independent display replicating the Patient Monitors screen. They are outfitted with an ECG-Out connector, which may be used to synchronize (via an analog ECG signal output) a connected external device such as a defibrillator, CT scan or Intra-aortic Balloon Pump.

1.5 Intended Use and Indication for Use

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

Intended Use:

The devices are 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:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitors are only for use on one patient at a time.
The monitors are not therapeutic devices.
Caution: The monitors are 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 SSC Sepsis Protocol, in the Protocol Watch clinical decision support tool, is indicated for use with adult patients only.

The derived measurement Pulse Pressure Variation (PPV) is indicated 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 Predictive Temperature Module is indicated to provide an accurate prediction of patient temperature using the oral, axillary, or rectal body sites, or to provide an actual temperature reading in the continuous monitor mode to adult and pediatric patients.

The NanoPod capnography module is indicated to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is indicated for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport.

The NanoPod capnography module provides the clinician with an integrated pulmonary index (IPI). The IPI is based on end tidal carbon dioxide, respiration rate, oxygen saturation and heart rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The Integrated Pulmonary Index (IPI) is indicated 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.

1.6 Comparison of Intended Uses for Subject Device and Predicate

The new IntelliVue Patient Monitors 6100, 6300, 6500 have the same intended use as the predicate device IntelliVue Patient Monitor MX550. The subject and predicate device are intended for monitoring, recording and alarming of physiological parameters for adults, pediatrics and neonates. Subject and predicate device are intended for use by trained healthcare professionals in a hospital environment.

For the most part the subject device has the same indications for use as the predicate device. Due to the subject device's compatibility with the Predictive Temperature Module and Medtronic's Microstream™ CO2 NanoPod additional indications for use were added to the subject device's indication for use:

- The Predictive Temperature Module is indicated to provide an accurate prediction of patient temperature using the oral, axillary, or rectal body sites, or to provide an actual temperature reading in the continuous monitor mode to adult and pediatric patients.
- The NanoPod capnography module is indicated to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is indicated for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport.

  The NanoPod capnography module provides the clinician with an integrated pulmonary index (IPI). The IPI is based on end tidal carbon dioxide, respiration rate, oxygen saturation and heart rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

1.7 Comparison of Technological Characteristics with Predicate Device

Item of Comparison	Description/Rationale
Similarities	
Device Design	• Subject device is designed for stationary and in-hospital transport use as the predicate device. • Subject device runs on IntelliVue Software, which is the same software platform available in the predicate device. • Subject device is designed with integrated measurements ECG/Resp, SpO2, NIBP, IBP and Temperature, which can also be displayed in the predicate device when connected to external measurements modules.
Energy Source	• Subject device is powered by AC mains or from built-in battery, as the predicate device. • Subject and predicate device do not deliver energy to patients.
Software/Hardware Features	• Subject device does not introduce any new technological hardware features. • Measurements offered by the subject device are also offered by the predicate device via its compatibility with external measurement modules. • Software features introduced with IntelliVue Software version R, rely on well-established software platform and architecture which was iteratively developed from the version available in the predicate device.
Physiological Parameters	• Measurements embedded in subject device are existing physiological parameters which are also displayed on the predicate device through its connectivity with external measurements.
Performance specifications	• Specifications of all measurement characteristics, including measurement principles, methods, algorithms, and all detailed performance specifications are unchanged from existing IntelliVue Patient Monitors i.e. reference device (IntelliVue X3) • Performance specifications of the external measurement that are compatible with the subject device remain unchanged from their original clearance i.e. Medtronic's Microstream™ CO2 NanoPod (K213911) and SureTemp® Plus (K030580) for the Predictive Temperature Module.
Operating Principle and Mechanism of Action	• Operating principle and mechanism of action from subject device is unchanged from the predicate device.

1.7 Comparison of Technological Characteristics with Predicate Device

Item of Comparison	Description/Rationale
Human Interface	• human interface of the new IntelliVue Patient Monitors 6100, 6300 and 6500 leverages from the well established IntelliVue Software, which also runs on the predicate device.
Measurement Accessories	• Accessories applied to the predicate device are compatible with the subject devices.
Differences	
Device Design	• Subject device benefits of updated electronic components when compared to predicate device. • Subject device integrates a new Philips proprietary FlexLink connector
Materials	• Subject device is outfitted with chemically strengthened glass when compared to predicate device • Subject device is outfitted with modified plastic to better withstand disinfectant agents.
Physiological Parameters	• Subject device is compatible with external measurements with previously cleared technologies i.e. Medtronic's Microstream™ CO2 NanoPod (K213911) and SureTemp® Plus (K030580) for the Predictive Temperature Module.
Measurement Accessories	• Subject device introduces a new Predictive Temperature FlexLink Cable (P/N 453564951751).
Software	• The IntelliVue Software version R.00.01 that is embedded in the subject device introduces: o the integration of new hardware components and functional elements for the subject device such as display resolution and compatibility with other medical devices i.e. Medtronic's Microstream™ CO2 NanoPod (P/N 989803209661) and the Predictive Temperature Module (P/N 867394) o optimizations to user interface and cybersecurity (i.e *"Issue Helper Window"*, *"My Apps Window"*, *"Extended Alarm Logging"* etc..) and o new applications such as the *"Clinical Monitoring Analytics"*

1.8 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. The subject devices are substantially equivalent to the predicate devices.

1.9 Performance Data

Clinical Tests – Harmonized Standards

The subject devices have passed all safety tests for demonstrated compliance with the recognized standards below.

Standard	FDA Recognition #	Title #
IEC 60601-1:2005 incl. AMD1:2012 and AMD2:2020	19-49	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 60601-2-25:2011	3-105	Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of electrocardiographs.
IEC 60601-2-27:2011	3-126	Medical electrical equipment – Part 2: Particular Requirements for the Safety, Including Essential Performance of Electrocardiographic Monitoring Equipment.

IEC 80601-2-30:2018	3-123	Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
IEC 60601-2-34:2011	3-115	Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment.
ISO 80601-2-55:2018	1-140	Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors.
ISO 80601-2-56:2017 incl. AMD1:2018	6-421	Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
ISO 80601-2-61:2017 incl. COR1:2018	1-139	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 62304:2006 incl. AMD1: 2015	13-79	Medical device software Software life-cycle processes
IEC 62133-2:2017 incl. AMD1: 2021	19-33	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
UL 2054	19-11	Household and Commercial Batteries

Non-clinical Bench Tests
No new issues of safety or effectiveness as compared to the predicate are introduced with the new IntelliVue Patient Monitors 6100, 6300, 6500.
Clinical Studies
The subject devices, like the predicate device, did not require any clinical trials. The 510(k) included clinical data from Philips initiated laboratory tests with the intent to demonstrate the accuracy performance of the Philips FAST PicoSAT X SpO2 technology. The activities involved in the development and release of the subject device are compliant with FDA Quality System Regulations, FDA recognized standards, FDA guidance documents and harmonized standards. The subject device was subjected to several verification and validation activities, usability validation and risk management activities. Based upon the design, intended use, indications for use, classification, usability and safety testing, the subject devices are substantially equivalent to the predicate device.

1.10 CONCLUSION

Substantial equivalence assessment, based on non-clinical bench testing, electrical safety, electromagnetic compatibility, software verification and validation, human factors, interoperability testing and clinical tests (for Philips FAST PicoSAT X SpO2 technology), demonstrate that the new IntelliVue Patient Monitors 6100, 6300 and 6500 do not raise different questions of safety and effectiveness when compared to their predicate device IntelliVue Patient Monitor MX550. The new IntelliVue Patient Monitors 6100, 6300 and 6500 perform as intended and have performance characteristics that are substantially equivalent to IntelliVue Patient Monitor MX550.