March 30, 2026

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

Re: K253654
Trade/Device Name: IntelliVue Measurement Rack 6000 (867317)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MSX, DSJ, DSK, DQA, DSF, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, KOI, GWQ, GWS, MUD, FLL
Dated: December 16, 2025
Received: December 17, 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 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

| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K253654 ? |
|---|---|

Please provide the device trade name(s). ?

IntelliVue Measurement Rack 6000 (867317)

Please provide your Indications for Use below. ?

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 devices 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.
BIS is indicated for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is indicated for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
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 IntelliVue NMT is indicated to be used as an objective neuromuscular transmission monitor that measures the muscle response to electrical stimulation of a peripheral nerve. The NMT Module is indicated to be used with adult 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 during both no motion and motion conditions, and for patients who are well or poorly perfused.
The noninvasive Masimo O3 Regional Oximeter System and accessories are indicated for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥ 40 kg and on pediatrics >5 kg and <40 kg in healthcare environments.
The SedLine Sedation Monitor is indicated to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents. The agents include: Alfentanil, Desflurane,

Fentanyl. Isoflurane, Nitrous Oxide, Propofol, Remifentanil, and Sevoflurane. The Sedline Sedation Monitor is indicated for use with adult patients (18 years of age and older) in the operating room (OR), intensive care unit (ICU), and clinical research laboratory.
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.

| | | |
|---|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) | ? |

| *510(k) Summary* | | | | |
|---|---|---|---|---|
| 1.1 Submitter | | | | |
| **Date Prepared** | November 17, 2025 | | | |
| **Submitter/Owner** | Philips Medizin Systeme Böblingen GmbH<br>FDA Establishment Number 9610816<br>Hewlett-Packard-Str. 2<br>71034 Böblingen<br>Germany | | | |
| **Key Contact** | Monica da Silva<br>Principal Regulatory Affairs Specialist<br>Monica.dasilva@philips.com<br>Phone: +49 175 3293 046 | | | |
| **510(k) Submission Type** | Traditional 510(k) | | | |
| 1.2 Device | | | | |
| **Trade Name** | IntelliVue Measurement Rack 6000 | | | |
| **Common Name** | Measurement Rack | | | |
| **Classification Name** | Panel & Name: Cardiovascular Devices<br>Subpart & Division: 21 CFR §870.2300<br>Regulatory Class: II<br>Product Code: MSX<br>Associated Product Code(s): DSJ, DSK, DQA, DSF, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, KOI, GWQ, GWS, MUD, FLL | | | |
| 1.3 Predicate Device | | | | |
| **Predicate Device** | ***510(k) No.*** | ***Company*** | ***Device Name*** | ***Product Code*** |
| | K251702 | Philips | IntelliVue 4-Slot Module Rack FMX-4 | MHX[1] |
| | Associated Product Code(s): DSJ, DSK, DQA, DSF, MSX, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, KOI, GWQ, GWS, MUD, FLL | | | |
| The subject devices are substantially equivalent to the legally marketed predicate devices. | | | | |

[1] MHX as FMX-4 has been submitted with the respective Patient Monitors (IntelliVue Patient Monitors MX750 and MX850 which support arrhythmia detector and alarm). MHX is not a Module Rack specific product code.

## 1.4 Device Description

**IntelliVue Measurement Rack 6000** – description of the device per 21 CFR 807.92(a) (4)

The IntelliVue Measurement Rack 6000 (MR6000) is a hardware component designed with four slots that allow connection to the existing IntelliVue Plug-in Measurement Modules. The MR6000 establishes communication between the already cleared individual Plug-in Measurement Modules and the IntelliVue Patient Monitors 6100, 6300 and 6500.
The MR6000 enables the IntelliVue Patient Monitors (PM6100, PM6300 and PM6500) to scale up measurement capabilities, as it serves as an interface between the Patient Monitors and the currently distributed IntelliVue Plug-in Measurement Modules.
The MR6000 is connected to the IntelliVue Patient Monitor models 6100, 6300, 6500 via the measurement link cable (*MLink*).
The MR6000 has its own power supply with its own mains connection.

## 1.5 Intended Use and Indication for Use

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

The IntelliVue Measurement Rack 6000 (MR6000) is an accessory to IntelliVue Patient Monitors 6100, 6300, 6500. The MR6000 therefore leverages from the intended use of the Patient Monitors (with which it interoperates). With the interoperability between the MR6000 and the IntelliVue Patient Monitors 6100, 6300, 6500 (K250453) the indications for use will be extended to include references to the existing (and unchanged) Plug-in Measurement Modules already available in the market.

The ***bold*** marked text below, represents the indications for use text being ***added*** due to the MR6000 capabilities when connected to the Patient Monitors 6100, 6300, 6500.

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.

Indication for Use

The devices 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.
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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).

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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.

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***The noninvasive Masimo O3 Regional Oximeter System and accessories are indicated for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥ 40 kg and on pediatrics >5 kg and <40 kg in healthcare environments.***

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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.
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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 MR6000 performs the same role for the Patient Monitors 6100, 6300, and 6500 as the FMX-4 (predicate device) does for the MX750 and MX850 Patient Monitors - enabling interoperability with the Plug-in Measurement Modules.

The FMX-4 supports the same IntelliVue Plug-in Measurement Modules as the MR6000 and therefore their Intended Use and Indications for Use are identical.

## 1.7 Comparison of Technological Characteristics with Predicate Device

| **Item of Comparison** | **Description/Rationale** |
|---|---|
| **Similarities** | |
| Device Design | • Subject device (MR6000) and predicate device (FMX-4) are designed for stationary use in hospital environments.<br>• The currently distributed Plug-in Measurement Modules supported by the subject device (MR6000) are also supported by the predicate device (FMX-4). |
| Materials | • The material used in the housing of the subject (MR6000) and predicate (FMX-4) device are similar, composed of plastic components resistant to disinfectant agents. |
| Software/Hardware Features | • Subject (MR6000) and predicate (FMX-4) devices run on IntelliVue Software, sharing common software platform and applications. |
| Physiological Parameters | • The Plug-in Measurement Modules supported by the subject device (MR6000) are also compatible with the predicate device (FMX-4), therefore the devices support the same physiological measurements. |

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|---|---|
| Performance specifications | • Performance specifications between predicate (MR6000) and subject (FMX-4) device are the same as they provide the same function and support the same Plug-in Measurement Modules. |
| Operating Principle and Mechanism of Action | • Operating principle and mechanism of action from subject device (MR6000) is unchanged from the predicate device (FMX-4). |
| Measurement Accessories | • Accessories applied to the predicate device (FMX-4) are compatible with the subject device (MR6000). |
| **Differences** | |
| Device Design | • Subject device (MR6000) benefits of updated electronic components when compared to predicate device (FMX-4).<br>• Subject device (MR6000) integrates a MLink connector that establishes connectivity to the compatible Patient Monitors while the predicate device (FMX-4) integrates the MSL connector to connect to the compatible Patient Monitors.<br>• Subject device (MR6000) is intended to operate with IntelliVue Patient Monitor models 6100, 6300 and 6500 while the predicate device (FMX-4) is compatible with the IntelliVue Patient Monitor models MX750 and MX850. |
| Human Interface | • The subject device (MR6000) has a direct power supply, connected to the mains. The independent power supply of the MR6000 device allowed for the integration of a *"power button"*, this facilitates switching between standby and operating mode when the MR6000 is not being used. This is not available on the predicate device (FMX-4). |
| Energy Source | • Subject device (MR6000) is powered by AC mains while the predicate device (FMX-4) is powered by its compatible Patient Monitors MX750 or MX850. |

## 1.8 Substantial Equivalence Summary

Operational and technological characteristics form the basis for the determination of substantial equivalence of the subject device (MR6000) with the legally marketed predicate device (FMX-4). The subject device (MR6000) is substantially equivalent to the predicate device (FMX-4).

## 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 60601-1-6:2020 | 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 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 | 1-139 | Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential |

| | | |
|---|---|---|
| incl. COR1:2018 | | performance of pulse oximeter equipment |
| IEC 62304:2006<br>incl. AMD1: 2015 | 13-79 | Medical device software Software life-cycle processes |

**Non-clinical Bench Tests**

No new issues of safety or effectiveness compared to the predicate are introduced with the MR6000.

**Clinical Studies**

The subject devices MR6000 did not require any clinical trials.

## 1.10 CONCLUSION

Substantial equivalence assessment, based on electrical safety, electromagnetic compatibility, software verification and validation, human factors and interoperability testing demonstrate that the MR6000 does not raise different questions of safety and effectiveness when compared to its predicate device FMX-4. The MR6000 performs as intended and has performance characteristics that are substantially equivalent to FMX-4.