November 10, 2025

Philips Medizin Systeme Böblingen GmbH
Alicia Honemeyer
Regulatory Affairs Specialist
Hewlett-Packard-Str. 2
Böblingen, BW 71034
Germany

Re: K251702
Trade/Device Name: IntelliVue Patient Monitor MX750; IntelliVue Patient Monitor MX850; IntelliVue 4-Slot Module Rack FMX-4 (866471 866470 866468)
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, DQK, DRT, DPS, DQA, DSF, MSX, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWQ, GWS, FLL
Dated: October 10, 2025
Received: October 10, 2025

Dear Alicia Honemeyer:

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

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.	K251702

Please provide the device trade name(s).

IntelliVue Patient Monitor MX750
IntelliVue Patient Monitor MX850
IntelliVue 4-Slot Module Rack FMX-4 (866471
866470
866468)

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 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. 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 EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The transcutaneous gas measurement (tcGas) with the M1018A plug-in module is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended 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 intended for use with adult patients only.
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 IntelliVue NMT is intended 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 intended 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 non-invasive 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 intended 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 intended 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 Edwards FloTrac solution offers continuous assessment of hemodynamic parameters. It is indicated to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting. It is indicated for use in adult critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. The Edwards FloTrac solution is indicated to be used in the operating room, intensive care unit, and emergency room.

The monitors are intended for use by trained healthcare professionals in a hospital environment.
They are not intended for home use.
The monitors are additionally intended for use in transport situations within hospital environments.

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

510(k) Summary

510(k) Summary

1.1 Submitter

Date Prepared	Oct 02nd, 2025
Submitter/Owner	Philips Medizin Systeme Böblingen GmbH FDA Establishment Number 9610816 Hewlett-Packard-Str. 2 71034 Böblingen Germany
Key Contact	Alicia Honemeyer Regulatory Affairs Specialist alicia.honemeyer@philips.com Phone: +49 7031 463 1707
510(k) Submission Type	This is a traditional 510(k).

1.2 Device

Trade Name	IntelliVue Patient Monitor MX750 IntelliVue Patient Monitor MX850 IntelliVue 4-Slot Module Rack FMX-4
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

	510(k) No.	***Company***	***Device Name***	***Product Code***
Predicate Device	K231671	Philips	IntelliVue Patient Monitor MX750 IntelliVue Patient Monitor MX850 IntelliVue 4-Slot Module Rack FMX-4	MHX
	K180881	Edwards Lifesciences	HemoSphere Advanced Monitor, HemoSphere Swan-Ganz Module, HemoSphere Oximetry Cable, HemoSphere Pressure Cable, Acumen Hypotension Prediction Index feature	DQK

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

1.4 Device Description

IntelliVue Patient Monitors MX750/MX850 and IntelliVue 4-Slot Module Rack FMX-4– description of the device per 21 CFR 807.92(a) (4)

The IntelliVue Patient Monitors MX750 and MX850 acquire multiple physiological patient signals, display measurement values, waves and trends, generate physiological and technical alarms, provide data recording and support patient data management. They operate with the external Measurement Modules and the IntelliVue 4-Slot Module Rack FMX-4, which establishes the connection between the individual plug-in measurement modules and the MX750 and MX850 monitors.

The monitors support multiple non-invasive and invasive measurements such as ECG, arrhythmia, ST, QT, SpO2, respiration rate, pulse rate, heart rate, invasive and non-invasive blood pressure, temperature, CO2, tcpO2/ tcpCO2, C.O., CCO, intravascular SO2, SvO2, ScvO2, EEG, BIS, NMT, and gas analysis.

The monitors offer a monitoring solution optimized for the surgical, cardiac, medical and neonatal care environments. They are located in the patient vicinity at the bedside. These devices have a color display with a touch-screen as a primary input device. They also support keyboard and pointing devices such as a mouse.

The monitor models MX750 and MX850 differ mainly in size. While MX750 has a 19” flat panel display, MX850 has a 22” display.

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.
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 EC 11).

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended 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 intended for use with adult patients only.

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 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 IntelliVue NMT Module is intended to be used as an objective neuromuscular transmission monitor, using accelerometry for measuring the muscle contraction following an electrical stimulation of a peripheral nerve. The NMT Module is intended 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.

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The Edwards FloTrac solution offers continuous assessment of hemodynamic parameters. It is indicated to be used by qualified personnel or trained clinicians in a critical care environment in a

hospital setting. It is indicated for use in adult critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. The Edwards FloTrac solution is indicated to be used in the operating room, intensive care unit, and emergency room.

The monitors are intended for use by trained healthcare professionals in a hospital environment.
They are not intended for use in transport situations.
They are not intended for home use.

1.6 Comparison of Intended Uses for Subject Device and Predicate

The IntelliVue Patient Monitors MX750/MX850 and the IntelliVue 4-Slot Module Rack FMX-4 have the same intended use as their predicate device.

Additionally, the MX750/MX850 and the IntelliVue 4-Slot Module Rack FMX-4 models inherited the Hemosphere Advanced Monitor indication:

- *The Edwards FloTrac solution offers continuous assessment of hemodynamic parameters. It is indicated to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting. It is indicated for use in adult critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. The Edwards FloTrac solution is indicated to be used in the operating room, intensive care unit, and emergency room.*

1.7 Comparison of Technological Characteristics with Predicate Device

Similarities

Item of Comparison	**Description/Rationale**
Device Design	• The hardware design of the subject device is the same as that of the predicate device. • device design of added Edwards Lifesciences external measurement devices composed of the FloTrac Pressure Cable-Philips and FloTrac sensor is equivalent to their predicate devices • Subject and predicate device run on IntelliVue Software (version R.00), which is also the software platform available in the predicate device (version P.01.).

Materials	• 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	• 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 • added external Edwards Lifesciences devices do not have their own power supply; it is supplied by the host monitor. This is the same as for their predicate devices.
Software/Hardware Features	• Proposed modification does not introduce any new technological hardware features. • Measurements offered by the subject device are also offered by the predicate device. Subject and predicate devices have the same interfaces. • Software features introduced for the proposed IntelliVue Software version R.00.01, rely on a well-established software platform and architecture which was iteratively developed from the version available in the predicate device. • Hardware and Software of the added external Edwards Lifesciences devices are equivalent to their predicates. • measurements of physiological parameters are the same as in the predicate devices.
Physiological Parameters	• The subject device supports the same measurement modules as the predicate device, except for: ○ the newly added plug-in module for FloTrac (with P/N 867409) • Measurement Modules M1019A (Gas Module), M1013A (Gas Module), M1014A (Spirometry Module) are no longer supported by the subject device. Previous versions (incl. predicate device) of MX750/MX850 and FMX-4 were compatible with these modules. • existing physiological parameters of the predicate devices remain unchanged • the physiological parameters of the added external Edwards Lifesciences devices are the same as those of their respective predicate 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 devices

Human Interface	• The human interface of the IntelliVue MX750/MX850 and the FMX-4 remain the same. Data presentation and user control of the new plug-in module for FloTrac (with P/N 867409) are done through the Patient Monitors (MX750/MX850 with the FMX-4). This is unchanged from how the predicate device supports and operates with other plug-in measurements (K231671). The addition of the user interfaces for the FloTrac module do not influence the patient monitors´ user interface or the user interaction with the patient monitors. • The human interfaces of added Edwards Lifesciences devices are unchanged to their predicates.
Measurement Accessories	• all accessories of the predicate devices - IntelliVue Patient Monitor MX750 - IntelliVue Patient Monitor MX850 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, i.e enabling fast access of applications, recording more alarm logging information, disabling the configuration of the "AlarmsOffAtStart" feature, modifying the factory default for the NBP, enhancing the existing visual indications in the case of speaker malfunction, transmitting alarm limits of more numerics to the central station, introducing the clinical analytics framework into the Software infrastructure. ○ extend its capability, so that the subject devices accept the physiological data provided by the Edwards FloTrac as compatible and display the FloTrac measurement on these patient monitors' screen, i.e compatibility with new FloTrac Plug-in Module.

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 (K231671). 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 4.1	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 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 are introduced because of using this device.
Clinical Studies
The subject devices, like the primary predicate devices, did not require clinical trials. 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. 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. *No new issues of substantial equivalence are introduced as a result of using this device.*

1.9 CONCLUSIONS

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.