December 19, 2023

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

Re: K231671
Trade/Device Name: IntelliVue Patient Monitor MX750 (866471), IntelliVue Patient Monitor MX850 (866470), IntelliVue 4-Slot Module Rack FMX-4 (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, BZC, BZQ, CBQ, CBR, CBS, CCK, CCL, DPS, DQA, DRT, DSF, DSJ, DSK, DXN, FLL, GWQ, GWS, KLK, KOI, LKD, MLD, MSX, NHO, NHP, NHQ
Dated: November 17, 2023
Received: November 17, 2023

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231671

Device Name

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

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.
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.

The noninvasive Masimo O3 Regional Oximeter System and accessories are intended 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 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.

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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K231671 510(k) Summary

Submitter/Owner	Philips Medizin Systeme Böblingen GmbH FDA Establishment Number 9610816 Hewlett-Packard-Str. 2 71034 Böblingen Germany Phone: +49 151 40903561
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

Predicate Device

K221348 is the primary predicate device.

510(k) No.	*Company*	*Device Name*	*Product Code*
K221348	Philips	IntelliVue Patient Monitor MX750 IntelliVue Patient Monitor MX850 IntelliVue 4-Slot Module Rack FMX-4	MHX

Intended Use and Indications for Use The modified IntelliVue Patient Monitors MX750 and MX850 have the same intended use and indications as the legally marketed predicate device.	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. The noninvasive Masimo O3 Regional Oximeter System and accessories are intended 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 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.

Summary of Reason for Notification	The reason for this traditional 510(k) submission is to: Notify FDA on modifications carried out on the IntelliVue Software, which is the software platform common to the legally marketed Philips IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4 (K221348). The software changes resulted in a new IntelliVue Software version, bringing these devices to software version P.01.

1. Description of the Subject Devices: IntelliVue Patient Monitors MX750/MX850 and IntelliVue 4-Slot Module Rack FMX-4

All features and technological characteristics of the primary predicate IntelliVue Patient Monitors MX750 (866471), MX850 (866470) and IntelliVue 4-Slot Module Rack FMX-4 (866468) remain unchanged and are still applicable to the IntelliVue Patient Monitors, subject of this submission.

The proposed modifications for the IntelliVue Patient Monitors MX750/MX850 and IntelliVue 4-Slot Module Rack FMX-4 include:

1) A new software version, designated as IntelliVue Software P.01. The new software version introduces following new features:
    - New alarm sounds designated as “Philips 2021” sounds, based on a joint development of Philips and Sen Sound researchers who focus on transforming the experience of sound in healthcare.
    - New Visual Patient feature, which displays patients’s vital signs in an animated patient avatar alongside the conventional vital sign waveforms and numerics.
    - configurable alarm management, limiting changes in alarm settings to pre-defined authorized personnel.

It further enhances following existing features

- Manual Selection of QRS /Pulse Tone
- Introduction of Lead Diagram for ECG
- Enhancement of Visual Presentation for “Global Alarm Off” State

Table 1 - Device Identifying Information

Model Number	Product Name / Description
866471	IntelliVue Patient Monitor MX750
866470	IntelliVue Patient Monitor MX850
866468	IntelliVue 4-Slot Module Rack FMX-4

1.1 Discussion of Similarities and Differences

Intended Use and Indications for Use

Intended use and indications for use of the modified IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4 are the same as those of the primary predicate IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4 .

Environment of Use, Intended Users

All subject and predicate devices are intended for use inside hospital environments.

All subject and predicate devices are for use by trained healthcare professionals.

In summary, the environment of use and intended users of the subject devices IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4 is the same as those of their predicate devices.

Technological Characteristics

The device design, materials and energy sources of the modified IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4 are the same as those of their predicate IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4.

The software of the IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4 was slightly changed in order to:

- further enhance some of the existing functionalities, i.e re-design of existing alarm sounds (adding the Philips 2021 sounds), enabling the user authentication capability, limiting the access to Early Warning Score (EWS) data and allow for user validation of the data by means of authentication, additional configuration for manual selection of QRS /Pulse Tone, additional lead diagram for ECG and the enhanced presentation of the “Global Alarm off” state.
- include an additional form of vital signs presentation, which presents physiological parameters in a more intuitive way, by means of an animated patient avatar i.e Visual Patient feature.

Other key technological features

The proposed modification does not introduce any new hardware features.

Operating principle, mechanisms of action and human interface are unchanged from the predicate devices.

All accessories of the legally marketed predicate devices IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4 are re-used without any change.

The physiological measurements of the legally marketed IntelliVue Patient Monitors MX750/MX850 and their designated FMX-4 remain unchanged.

Performance specifications of all supported measurements remain unchanged by the proposed modification.

In summary, key technological features are mostly unchanged, and the modifications do not raise any different questions of safety and effectiveness as compared to the predicate device.

2. Summary of Performance Testing

The following table provides an overview how the proposed modification has been verified:

Table 1 - Summary of Performance Testing

Test Name	Test Description	Attachments	Result
Electrical Safety Testing	Tested to recognized consensus standards IEC 60601-1	*"IEC 60601-1 Test Report"* TR: 282234-TL4-1	PASSED
	IEC 60601-1-8	*"IEC 60601-1-8 Test Report"* TR: 291778-TL4-16	
	IEC 62304	*"IEC 62304 Test Report"* TR: 291778-TL4-20	
EMC Testing	Tested to recognized consensus standard IEC 60601-1-2 Tested against common EM emitters	*"EMC Test Report"* TR: 2021113-02-I	PASSED
Wireless Coexistence	Test sensitivity of patient monitors to common interferers	*"Wireless Coexistence Test Report"*	PASSED
Software Integration Testing	Test of new functionality integration into existing software infrastructure	*"Test Report for Integration Testing"*	PASSED
Software Testing	Test of new software functionality	*"Test Report for System Requirements Testing"* *"Test Report for Safety Risk Assessment"* *"Test Report for Regression Testing"* *"Test Report for Security Risk Assessment"* *"Test Report for Compatibility Testing"*	PASSED
Essential Performance Testing	Tests verifying that essential performance requirements are met.	For Patient Monitors: *"Monitor EP Verification Report1"* *"Monitor EP Verification Report2"*	PASSED
Human Factors	Test of device usability	*"Human Factors Engineering Report"*	PASSED

Table 3 - Summary of non-clinical and clinical testing

Non-clinical Bench Tests
No new issues of safety or effectiveness as compared to the predicate are introduced because of using this device.
Clinical Studies
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.*