August 22, 2023

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

Re: K223574
Trade/Device Name: IntelliVue Patient Monitor MX400 (866060), IntelliVue Patient Monitor MX450 (866062), IntelliVue Patient Monitor MX500 (866064), IntelliVue Patient Monitor MX550 (866066)
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, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWQ, GWS, FLL
Dated: November 29, 2022
Received: November 30, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Indications for Use

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

510(k) Number *(if known)*
K223574

Device Name
IntelliVue Patient Monitor MX400 (866060); IntelliVue Patient Monitor MX450 (866062);
IntelliVue Patient Monitor MX500 (866064); IntelliVue Patient Monitor MX550 (866066)

Indications for Use *(Describe)*
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 EC11).
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 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 home use.
The MX400/MX450/MX500/MX550 monitors are additionally intended for use in transport situations within hospital environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Summary

1.1 Submitter

Date Prepared	November 29, 2022
Submitter/Owner	Philips Medizin Systeme Böblingen GmbH FDA Establishment Number 9610816 Hewlett-Packard-Str. 2 71034 Böblingen Germany
Key Contact	Siegfried Breitling Regulatory Affairs Specialist siegfried.breitling@philips.com Phone: +49 151 200 443 77
510(k) Submission Type	This is a traditional 510(k).

1.2 Device

Trade Name	IntelliVue Patient Monitor MX400 IntelliVue Patient Monitor MX450 IntelliVue Patient Monitor MX500 IntelliVue Patient Monitor MX550
Common Name	Multiparameter Patient Monitor
Classification Name	Panel & Name: Cardiovascular Devices Subpart & Division: 21 CFR §870.1025 Regulatory Class: II Classification Product Code: MHX Subsequent Product Codes: MLD, DSJ, DSK, DXN, DRT, DPS, DQA, DSF, MSX, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWQ, GWS, FLL

1.3 Predicate Device

	510(k) No.	***Company***	***Device Name***	***Product Code***
Predicate Device	K182979	Philips	IntelliVue Patient Monitor MX400 IntelliVue Patient Monitor MX450 IntelliVue Patient Monitor MX500 IntelliVue Patient Monitor MX550	MHX DRT, DSI, DSJ, DSK, DXN, MLD, MSX

	K172890	Masimo	SedLine Sedation Monitor	OLW GXY, OLT, OMC, ORT

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

1.4 Device Description

IntelliVue Patient Monitors MX400, MX450, MX500 and MX550 – description of the device per 21 CFR 807.92(a) (4)

The IntelliVue Patient Monitors MX400, MX450, MX500 and MX550 acquire multiple physiological patient signals, display measurement values, waves and trends, generate physiological and technical alarms, provide data recording and support patient data management.

The 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 at the patient bedside vicinity and can also be used during patient transport inside hospitals. The monitors have a color display with touchscreen as a primary input device. They also support a specialized remote control, keyboard and pointing devices such as a mouse. External displays can be connected to a built-in video port to provide an adaptive duplicate image of the primary display. The monitors can interact with several compatible external measuring and auxiliary devices locally at the bedside or in transport situations and with the Central Station via LAN or wireless link.

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 EC11).

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

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The SSC Sepsis Protocol, in the Protocol Watch 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 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 home use. The MX400/MX450/MX500/MX550 monitors are additionally intended for use in transport situations within hospital environments.

1.6 Comparison of Intended Uses for Subject Device and Predicate

The modified IntelliVue MX400, MX450, MX500 and MX550 have the same intended use and indications as the predicate devices. Additionally, the MX500 and MX550 devices inherited the Masimo SedLine *Sedation Monitor indication:*

- 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.

1.7 Comparison of Technological Characteristics with Predicate Device

Similarities	
Item of Comparison	**Description/Rationale**
Device Design	• device design of subject devices is the same as for the predicate devices • unchanged hardware and architecture • monitor hardware entirely unchanged • device design of added external measurements - Masimo SedLine, is identical to their predicate devices

Materials	• same materials used as those of the predicate devices • materials used in the new plug-in module - SedLine (867186), are the same as those of other legally marketed plug-in modules • biocompatibility aspects do not apply because the devices do not have patient contact. • materials used in the added external measurement - Masimo SedLine, are identical to their predicate devices. • biocompatibility aspects of accessories are not affected, because all accessories of the predicate devices remain unchanged
Energy Source	• powered by AC mains or from built-in battery, same as predicate devices • devices do not deliver energy to the patients for their function, same as predicate devices • the added external measurement - Masimo SedLine, does not have its own power supply; It is supplied by its host patient monitor. This is the same as for its predicate device
Software/Hardware Features	• proposed modification does not introduce any new technological hardware features • predicate devices already support plug-in modules, with these modules offering built-in measurements as well as interfaces to external measurements • hardware and software of the added external measurement - Masimo SedLine is unchanged from its predicate device • measurements of physiological parameters are exactly the same as in the predicate devices
Physiological Parameters	• existing physiological parameters of the predicate devices remain unchanged • the added external measurement - Masimo SedLine is the same as those of its respective predicate device
Performance specifications	• specifications of all measurement characteristics, including measurement principles, methods, algorithms, and all detailed performance specifications remain unchanged • performance specifications of the added external measurement - Masimo SedLine remains unchanged
Operating Principle and Mechanism of Action	• unchanged from the predicate devices

Human Interface	• human interface of the IntelliVue MX400, MX450, MX500 and MX550 remain exactly the same • the newly added external measurement - Masimo SedLine does not have a human interface of its own
Measurement Accessories	• all accessories of the predicate devices - IntelliVue Patient Monitor MX400 - IntelliVue Patient Monitor MX450 - IntelliVue Patient Monitor MX500 - IntelliVue Patient Monitor MX550 • as well as those of the added external measurement - Masimo SedLine are re-used without any change
Differences	
Hardware	• one new plug-in module - SedLine (product number 867186)is created, which acts as a digital communication interface between the IntelliVue Patient Monitors MX400/MX450/MX500/MX550 and the external Masimo measurement devices • the new plug-in module does not alter or modify the contents of the transferred data • the new plug-in module also provides electrical isolation for both power and communication between patient monitor and the external SedLine measurement device; the patient isolation circuit is the same as for other legally marketed plug-in modules for the IntelliVue patient monitor family • the predicate external measurement device - Masimo SedLine also connects to a host monitor / backboard device using an isolated digital interface, where the isolation must be provided by that host monitor / backboard device; the new plug-in module 867186 provides exactly this isolated digital interface as optional plug-in module, specialized for the IntelliVue Patient Monitors MX400, MX450, MX500 and MX550

Software	• The software of the subject devices IntelliVue MX400, MX450, MX500 and MX550 has been extended so that the new plug-in module will be accepted as compatible and the physiological data provided by the Masimo SedLine measurement device will be displayed on the patient monitor screen. • Additionally, a new software version designated as IntelliVue Software P.01 introduced the following new features: - New alarm sounds designated as "Philips 2021" sounds. - 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. • Additionally, the new Software revision will further enhance the following existing features: - Early Warning Score Validation followed by user identification via Single Sign On - Additional SPO2 fallback configuration - Additional Lead Diagram presentation for ECG - Enhancement of presentation of the global "alarm off" state
Physiological Parameters	• For marketing reasons, the proposed modification does not provide the parameters and graphical presentations • DSA (SedLine) which the predicate device is providing.

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.

1.8 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 #
IEC 62304 Edition 1.1 2015-06 consolidated version	13-79	Medical device software – Software life cycle processes
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 4.0 2014-02	19-8	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	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
60601-1-6 Edition 3.1 2013-10	5-89	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Non-clinical Bench Tests
No new issues of substantial equivalence are introduced because of using this device
Clinical Studies
The subject devices, like the primary predicate devices, did not require clinical trials. Any clinical studies performed for the Masimo SedLine parameter are still valid as the measurements are not modified; they are only being connected to an additional host patient monitor. 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.