February 3, 2023

Philips Medizin Systeme Böblingen GmbH
Stefan Breuer
Senior Regulatory Affairs Engineer
Hewlett-Packard Str. 2
Böblingen, BW 71034
Germany

Re: K221348
Trade/Device Name: IntelliVue Patient Monitor MX750 (866471); IntelliVue Patient Monitor MX850 (866470)
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
Dated: May 12, 2022
Received: January 4, 2023

Dear Stefan Breuer:

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,

for Shruti N. Mistry -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.*

510(k) Number *(if known)*
K221348

Device Name
IntelliVue Patient Monitor MX750 (866471);
IntelliVue Patient Monitor MX850 (866470)

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 intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.
The monitors are only for use on one patient at a time. They are not intended for use in transport situations. They are not intended for home use. 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.

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

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

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

***510(k) Summary***

## 1.1 Submitter

| | |
|---|---|
| **Date Prepared** | April 27, 2022 |
| **Submitter/Owner** | Philips Medizin Systeme Böblingen GmbH<br>FDA Establishment Number 9610816<br>Hewlett-Packard-Str. 2<br>71034 Böblingen<br>Germany<br>Phone: +49 151 1961 5514<br>Fax: +49 7031 463 2442 |
| **Key Contact** | Stefan Breuer<br>Senior Regulatory Affairs Engineer<br>Stefan.Breuer@philips.com |
| **510(k) Submission Type** | This is a traditional 510(k). |

## 1.2 Device

| | |
|---|---|
| **Trade Name** | IntelliVue Patient Monitor MX750<br>IntelliVue Patient Monitor MX850 |
| **Common Name** | Multiparameter Patient Monitor |
| **Classification Name** | Panel & Name: Cardiovascular Devices<br>Subpart & Division: 21 CFR §870.1025<br>Regulatory Class: II<br>Product Code: MHX |

## 1.3 Predicate Device

| | ***510(k) No.*** | ***Company*** | ***Device Name*** | ***Product Code*** |
|---|---|---|---|---|
| **Primary Predicate Device** | K210906 | Philips | IntelliVue Patient Monitor MX750<br>IntelliVue Patient Monitor MX850 | MHX |
| **Reference Devices** | K162603 | Masimo | O3 Regional Oximeter System | MUD |
| | K123043 | Masimo | Infrared Mainstream (IRMA) CO2 Gas Analyzer | CCK |
| | K171121 | Masimo | Infrared Sidestream (ISA) CO2 Gas Analyzer | CCK |
| | K172890 | Masimo | SedLine Sedation Monitor | OLW |

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

## 1.4 Device Description

**IntelliVue Patient Monitors MX750 and MX850** – 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 Indication for Use

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

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 intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.
The monitors are only for use on one patient at a time. They are not intended for use in transport situations. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.
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The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
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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.

### 1.6 Comparison of Intended Uses for Subject Device and Predicate

The modified IntelliVue MX750 and MX850 have the same intended use and indications as the predicate devices, with the addition of the following paragraphs, which have been adopted without change from the predicate devices Masimo O3 Regional Oximeter System and Masimo SedLine Sedation Monitor:

- 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.

Adding compatibility to Masimo IRMA CO2 and ISA CO2 does not affect the intended use or indications for use of the IntelliVue MX750 and MX850. The predicate devices IntelliVue MX750 and MX850 have already been able to measure Mainstream CO2 and Sidestream CO2 using measurement modules of the same technologies as the subject devices. Therefore, adding compatibility to Masimo IRMA CO2 and ISA CO2 merely gives the customer a broader choice of CO2 measurements, but does not add indications for use or intended uses to the IntelliVue MX750 and MX850.

## 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<br>• unchanged hardware and software architecture<br>• monitor hardware entirely unchanged<br>• device design of added external measurements<br>– Masimo O3 Regional Oximeter System<br>– Masimo IRMA CO2 and ISA CO2<br>– Masimo SedLine<br>is identical to their predicate devices |

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| Materials | • same materials used as those of the predicate devices<br>• materials used in the new plug-in modules<br>– O3 (867184)<br>– CO2 (867185)<br>– SedLine (867186)<br>are the same as those of other legally marketed plug-in modules<br>• biocompatibility aspects do not apply because the devices do not have patient contact.<br>• materials used in the added external measurements<br>– Masimo O3 Regional Oximeter System<br>– Masimo IRMA CO2 and ISA CO2<br>– Masimo SedLine<br>are identical to their predicate devices.<br>• biocompatibility aspects of accessories are not affected, because all accessories of the predicate devices remain unchanged |
| Energy Source | • powered by AC power, same as predicate devices<br>• devices do not deliver energy to the patients for their function, same as predicate devices<br>• the added external measurements<br>– Masimo O3 Regional Oximeter System<br>– Masimo IRMA CO2 and ISA CO2<br>– Masimo SedLine<br>• do not have their own power supply; they are supplied by their host patient monitor. This is the same as for their predicate devices |
| Software/Hardware Features | • proposed modification does not introduce any new technological hardware or software features<br>• predicate devices already support plug-in modules, with these modules offering built-in measurements as well as interfaces to external measurements<br>• hardware and software of the added external measurements<br>– Masimo O3 Regional Oximeter System<br>– Masimo IRMA CO2 and ISA CO2<br>– Masimo SedLine<br>is unchanged from their predicate devices<br>• measurements of physiological parameters are exactly the same as in the predicate devices |

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| Physiological Parameters | • existing physiological parameters of the predicate devices remain unchanged<br>• the added external measurements<br>– Masimo O3<br>– Masimo IRMA CO2 and ISA CO2<br>– Masimo SedLine<br>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<br>• performance specifications of the added external measurements<br>– Masimo O3<br>– Masimo IRMA CO2 and ISA CO2<br>– Masimo SedLine<br>remain unchanged |
| Operating Principle and Mechanism of Action | • unchanged from the predicate devices |
| Human Interface | • human interface of the IntelliVue MX750 and MX850 remains exactly the same<br>• the newly added external measurements<br>– Masimo O3<br>– Masimo SedLine<br>do not have a human interface of their own; the<br>– Masimo IRMA CO2<br>– Masimo ISA CO2<br>only have a status LED. Data presentation and user control are done through the connected host monitor, same as for their predicate devices |
| Measurement Accessories | • all accessories of the predicate devices<br>– IntelliVue Patient Monitor MX750<br>– IntelliVue Patient Monitor MX850<br>• as well as those of the added external measurements<br>– Masimo O3<br>– Masimo IRMA CO2 and ISA CO2<br>– Masimo SedLine<br>• are re-used without any change |

| Differences | |
|---|---|
| Hardware | • three new plug-in modules<br>– O3 (product number 867184)<br>– CO2 (product number 867185)<br>– SedLine (product number 867186)<br>are created, which act as a digital communication interface between the IntelliVue Patient Monitors MX750/MX850, and the external Masimo measurement devices<br>• the CO2 plug-in module interfaces both CO2 gas analyzers: IRMA CO2 and ISA CO2<br>• the new plug-in modules do not alter or modify the contents of the transferred data<br>• the new plug-in modules also provide electrical isolation for both power and communication between patient monitor and the external O3, IRMA CO2, ISA CO2 and SedLine measurement devices; the patient isolation circuit is the same as for other legally marketed plug-in modules for the IntelliVue patient monitor family<br>• the predicate external measurement devices<br>– Masimo O3<br>– Masimo IRMA CO2 and ISA CO2<br>– Masimo SedLine<br>• also connect to a host monitor / backboard device using an isolated digital interface, where the isolation has to be provided by that host monitor / backboard device; the new plug-in modules 867184, 867185 and 867186 provide exactly this isolated digital interface as optional plug-in modules, specialized for the IntelliVue Patient Monitors MX750 and MX850 |
| Software | • The software of the subject devices IntelliVue MX750 and MX850 has been extended so that the new plug-in modules will be accepted as compatible and the physiological data provided by the Masimo O3, IRMA CO2, ISA CO2 and SedLine measurement devices will be displayed on the patient monitor screen. |
| Physiological Parameters | • For marketing reasons, the proposed modification does not provide the parameters and graphical presentations<br>– Delta SpO2 / ΔSpO2 (O3)<br>– DSA (SedLine)<br>which the predicate devices are providing. |

| **Substantial Equivalence Summary** |
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| 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)2021 and A1:2012 | 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 |
| IEC60601-1-8 Edition 2.1 2012-11 | 5-76 | 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 |
| ISO 80601-2-55 Second edition 2018-02 | 1-140 | Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors |

| **Non-clinical Bench Tests** |
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| There were no new questions of safety or effectiveness introduced as a result of using this device. |
| **Clinical Studies** |
| The subject devices, like the primary predicate devices, did not require clinical trials.<br>Any clinical studies performed for the Masimo O3, IRMA CO2, ISA CO2 and SedLine parameters are still valid as the measurements are not modified; they are only being connected to an additional host patient monitor.<br><br>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.<br><br>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.<br><br>*There were no new questions of safety or effectiveness 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 and usability 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.