October 7, 2021

Philips Medizin Systeme Boeblingen GmbH
Monica Silva
Sr. Regulatory Affairs Engineer
Hewlett-Packard-Strasse 2
Boeblingen, Baden-Wuerttemberg 71034
Germany

Re: K210906
Trade/Device Name: IntelliVue Patient Monitors MX750 and MX850 and IntelliVue 4-Slot Module Rack FMX-4
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: September 3, 2021
Received: September 7, 2021

Dear Monica Silva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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 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)*
K210906

Device Name
IntelliVue Patient Monitors MX750 and MX850 and IntelliVue 4-Slot Module Rack FMX-4.

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.

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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PHILIPS

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. Submitter of this premarket notification

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This summary was prepared on March 23, 2021.

2. The name and classification of the devices:

Trade name: IntelliVue Patient Monitors MX750 and MX850 and IntelliVue 4-Slot Module Rack FMX-4.

Common name: Multiparameter Patient Monitor.

Classification:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2700, II	DQA	Oximeter

Device Panel	Classification	ProCode	Description
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2300 II	MSX	System, Network and Communication, Physiological Monitors
Anesthesiology Devices	§868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	§868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	§868.1880, II	BZC	Data calculator Pulmonary-function
	§868.2375, II	BZQ	Monitor, Breathing Frequency
	§868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	§868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
	§868.2775 II	KOI	Electrical peripheral nerve stimulator
Neurological Devices	§882.1400, II	GWQ	Electroencephalograph
	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalograph Signal
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical

3. Philips IntelliVue Patient Monitors MX750, MX850 are substantially equivalent to the previously cleared, primary predicate device, Philips IntelliVue Patient Monitor MX800 marketed pursuant to K161531.

   Philips IntelliVue 4-Slot Module Rack FMX-4 is substantially equivalent to the previously cleared Philips IntelliVue 4-Slot Module Rack FMS-4 marketed pursuant to K110622.

4. Description of the device

Hardware and software modifications carried out on the legally marketed device IntelliVue Patient Monitor MX800 and its IntelliVue 4-Slot Module Rack FMS-4, resulted in new models, the IntelliVue Patient Monitors MX750, MX850 and their 4-Slot Module Rack FMX-4, the subject of this submission.

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, Sv02, 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. Whilst MX750 has a 19” flat
panel display, MX850 has a 22” display.

Modifications:
Standard hardware components of the almost 10 years old predicate MX800, like flat panel display, touch screen, CPU, video board, and memory have been replaced in the MX750 and MX850 by state of the art electronic components. Two additional features, the NFC reader and adaptive lighting through the Ambient Light Sensor, have been implemented into the new MX750 and MX850 monitors.
The hardware of the new 4-Slot Module Rack FMX-4 is very similar to that of its 8 years old predicate 4-Slot Module Rack FMS-4. The new FMX-4 has the same housing, which is made of the same material as FMS-4 but has a slightly different shade of color (same shade of color as the new MX750 and MX850 monitors). The FMX-4 has a new Printed Circuit Assembly with standard hardware components like CPU and memory being replaced by state of the art electronic components.

The software modifications comprise the following changes:
- Support of the new state-of-the-art electronic components.
- Modified elements of the Graphical User Interface.
- Implementation of a feature called Electronic Strip Recording. This feature allows electronic strips that can be reviewed on the monitor and printed out as a report on the printer.
- Modification of the existing feature Remote Applications to support HTML5 and PDF format.

None of the described modifications represents any change to the fundamental technology of the predicate device.

5. Intended Use

The intended use and indications for use of the Philips IntelliVue Patient Monitors MX750, MX850 and their IntelliVue 4-Slot Module Rack FMX-4, have not changed from the legally marketed predicate device IntelliVue Patient Monitor MX800 and the respective IntelliVue 4-Slot Module Rack FMS-4 as a result of the modifications.

IntelliVue Patient Monitors MX750 and MX850 and IntelliVue 4-Slot Module Rack FMX-4.

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

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IntelliVue 4-Slot Module Rack FMX-4

The 4-Slot Module rack FMX-4 is intended to connect up to four particular plug-in physiological measurement modules to the dedicated host patient monitors.

6. Comparison of Technological Characteristics with Predicate Device

	Primary Predicate Device	**Subject Devices**
Comparative Characteristics	**Philips IntelliVue Patient Monitors MX800 (K161531)**	**Philips IntelliVue Patient Monitors MX750 and MX850**
Hardware Aspects		
Hardware Design	Monitors with display and CPU integrated in one housing and connectable to dedicated external measurement modules.	**Same**
Material	Housing: PC ABS + PC Front side: Glass with foil On/Off Button: Silicone	Housing: PBT + PC Front side: Chemically strengthened Glass On/Off Button: Same
Display	Size: 19” Resolution: WSXGA+ (1680 x 1050)	Size: MX750: 19” MX850: 22” Resolution: MX750: 1920 x 1080 (Full HD) MX850: 1920 x 1080 (Full HD)
Touchscreen Technology	Resistive touchscreen	Capacitive touchscreen
Hardware Visual Alarm Indicators	Lamp indicators: 1 color coded alarm indicator lamp (red, yellow, cyan) 1 color coded alarm indicator lamp (red, yellow)	**Same**

	Primary Predicate Device	Subject Devices
Comparative Characteristics	**Philips IntelliVue Patient Monitors MX800 (K161531)**	**Philips IntelliVue Patient Monitors MX750 and MX850**
	1 color coded „alarms off" lamp (red, yellow)	
Alarm Loudspeaker	Loudspeaker technology: dynamic loudspeaker	**Same**
Energy Type	Powered by AC mains	**Same**
Physiological Measurements		
Internal (built-in) Physiological Measurements	None	**Same**
Supported external Measurement Modules	– Multi-Measurement Modules directly connected to the patient monitor (including) o Measurement Extensions attached to the Multi-Measurement Modules – Measurement Modules directly connected to the patient monitor • – Measurement Modules connected to a host patient monitor via the dedicated Flexible Module Racks.	**Same**
Supported dedicated Flexible Module Racks	– 8-Slot Module Rack FMS-8 (M8048A) • • • – 4-Slot Module Rack FMS-4 (865243)	– 8-Slot Module Rack: not supported. Instead, supports two simultaneous 4-Slot Module Racks FMX-4 (866468). • – 4-Slot Module Rack FMS-4 (865243) not supported, substituted by FMX-4.
Connectivity features		
Wireless Interfaces	WLAN 2.4 and 5 GHz, IEEE 802.11 a/b/g/n Short Range Radio (SRR) 2.4 GHz, ITS 2.4 GHz ISM, ITS 1.4 GHz WMTS Near Field Communication Interface (NFC): not supported	WLAN/Radio Module: **Same** Short Range Radio (SRR): not supported ITS 2.4 GHz ISM: not supported ITS 1.4 GHz WMTS: not supported

	Primary Predicate Device	Subject Devices
Comparative Characteristics	**Philips IntelliVue Patient Monitors MX800 (K161531)**	**Philips IntelliVue Patient Monitors MX750 and MX850**
		Near Field Communication Interface (NFC): Technology: NFCIP-1, NFCIP-2 protocol, ISO/IEC 14443A, ISO/IEC 14443B Frequency: 13.56 MHz. FCC ID : PQC-NFCBV1
Wired Interfaces	LAN IEEE 802.3 100MBit RS232/MIB ISO/IEEE 11073-30200 USB 2.0 ECG-Out Basic Nurse Call Relay Flexible Nurse Call Relay Proprietary measurement Link (MSL) Video Interface DVI analog & digital.	**Same,** except for not supported Video Interface DVI analog & digital.
Integrated PC	iPC (cleared with K101449) Feature that allows for a computer functionality within the monitor, so that the user can use standard applications as for i.e Web browser.	**Same**
Supported Remote Display Application	Philips IntelliVue XDS solution	**Same**
Strip Recording	Paper-strip recorders M1116B and M1116C	**Same,** additionally electronic-strip recording in print database.
Remote Applications	Access to pre-configured applications made available by hospital, hosted remotely on the Philips Application Server utilizing Citrix Presentation Server™ and displayed and operated on the MX800 patient monitor.	**Same,** but instead of Citrix Presentation Server™, Citrix® Xen App® and standard web application servers are used. With this modification the HTML5 and PDF format are provided.
Human Interface (HIF)		
Elements that provide information to the user	Indicator lights, display, visual and audible alarms.	**Same**
Graphic user interfaces of device	Selection of screen elements Use touch screen to operate monitor Moving windows Use of SmartKeys	**Same**
Hardware components that the user handles to control device operation	Touchscreen: Yes Remote control: Yes USB Pointing devices: mouse, trackball, keyboard, Barcode Reader	**Same**, except not supported remote control.
Mechanical and Environmental specifications, Safety and EMC compliance, Biocompatibility		

	Primary Predicate Device	Subject Devices
Comparative Characteristics	**Philips IntelliVue Patient Monitors MX800 (K161531)**	**Philips IntelliVue Patient Monitors MX750 and MX850**
Robustness	Mechanical Strength testing as per IEC 60601-1: 1988 + A1: 1991 + A2: 1995. Additionally mechanical Class 7M1	**Same**
Environmental Specifications	- Operating Temperature Range: 0 to 40°C (32 to 100 °F) or 0 to 35°C (32 to 95 °F) when equipped with the iPC - Storage Temperature Range: -20 to 60 °C (-4 to 140°F) - Operating Humidity Range: 15% to 95% RH, non-condensing - Storage Humidity Range: 5% to 95% RH - Operating Altitude Range: -500 to 3000 m (-1600 to 10000 ft) - Storage Altitude Range: -500 to 4600 m (-1600 to 15000 ft) - Ingress Protection: IPX1	**Same** environmental specifications. Ingress Protection: IP21
Biocompatibility	N/A, no patient contact	**Same**
EMC and Electrical Safety	EMC: IEC 60601-1-2: 2014 (Ed.4) Safety: IEC 60601-1 (3rd Ed.) + Cor.1:2006 + Cor.2:2007 + A1:2012 and ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	EMC: **Same** Safety: **Same**

7. Summary of V&V activities

The modified IntelliVue Patient Monitors MX750, MX850 and the IntelliVue 4-Slot Module Rack FMX-4 with the current software Revision N.01 have been subject to the following V&V activities:

- Testing according to the recognized consensus standard:
  - AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012 (Ed. 3.1)
  - IEC 60601-1-2:2014 (Ed. 4)
  - IEC 60601-2-23:2011 (Ed.3)
  - IEC 60601-2-25:2011 (Ed. 2)
  - IEC 60601-2-27:2011(Ed. 3)
  - IEC 80601-2-30:2009 (Ed. 1.1) and A1:2013
  - IEC 60601-2-34:2011(Ed.3)
  - ISO 80601-2-55:2018 (Ed. 2)
  - ISO 80601-2-56:2017 (Ed. 2) and A1:2018

- ISO 80601-2-61:2017 (Ed. 2) and Corr1:2018
- IEC 60601-1-8:2006 (Ed. 2.1) and A1:2012

All applicable requirements have been met.

- Compliance with the recognized consensus process standards:
  - IEC 62304:2006 (Ed. 1.1) and A1:2015
  - IEC 60601-1-6:2010 (Ed.3.1) and A1:2013

  All applicable requirements have been met.

• The determination of substantial equivalence is also based on an assessment of the following testing:

- Environmental Testing encompassing:
  - Mechanical Testing: Shock, vibration, and free fall to simulate the environment of use during stationary use and patient transport inside of hospitals, according to the IEC TR60721-4-7 Class 7M1 and IEC 60068-2-xx standard series.
  - Temperature and humidity testing to simulate the climatic conditions during device operation in hospital environments and during storage.

- Human Factors Engineering Testing

  The modified Graphical User Interface elements were evaluated and improved iteratively during the design phase conducting several formative usability evaluations, as per FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" issued on February 3, 2016. These included established usability engineering methods such as focus groups, expert reviews and usability tests using user interface prototypes. User feedback was translated into iterative user interface improvements. All specified test requirements have been met and no new hazards have been identified.

- WLAN Coexistence Testing

  The specified pass/fail criteria has been met.

- Software tests for:
  - Safety risk assessment requirements.
  - Software specifications requirements.
  - Security risk requirements.

  All tests have been passed.

8. Conclusion

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the specific predicates.

V&V testing comprised well-established software tests, safety and essential performance tests, and human factors engineering tests.

Test methods and acceptance criteria were the same as those for the predicate devices and test results showed substantial equivalence with respect to safety and effectiveness.

The results demonstrate that the Philips IntelliVue Patient Monitors MX750, MX850 and the IntelliVue 4-Slot Module Rack FMX-4 meet all defined reliability requirements and performance claims.