November 19, 2019

Philips Medizin Systeme Boeblingen GmbH
Markus Stacha
Sr. Regulatory Affairs Engineer
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany

Re: K182979
Trade/Device Name: IntelliVue Patient Monitors MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800, MP5, MP5SC, Multi-Measurement Module X3
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, DSI, MLD, DSJ, DSK, DXN, DXG, KRB, DRQ, DRT, DPS, MLC, DRW, KRC, DRJ, DQA, DSB, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWR, GWS, FLL
Dated: September 10, 2019
Received: September 16, 2019

Dear Markus Stacha:

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,

Jessica E. Paulsen
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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K182979

Device Name: IntelliVue Patient Monitors MP5 and MP5SC

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 MP5 and MP5SC monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment.
The MP5 and MP5SC when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

Continued on next page

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.

Indications for Use for IntelliVue Patient Monitors MP5 and MP5SC (continued)

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.
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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K182979

Device Name: IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3

Indications for Use *(Describe)*

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitor is intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.
The monitor is also intended for use during patient transport inside the hospital environment.
The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.

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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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Indications for Use for IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3 (continued)

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The 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 which are mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K182979

Device Name: IntelliVue Patient Monitors MX400, MX430, MX450, MX500, MX550, MX700, MX800

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 MX400/MX450/MX500/MX550 monitors are additionally intended for use in transport situations within hospital environments.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

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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)

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PRAStaff@fda.hhs.gov

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Indications for Use for IntelliVue Patient Monitors MX400, MX430, MX450, MX500, MX550, MX700, MX800 (continued)

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.
The transcutaneous gas measurement (tcGas) with the M1018A plug-in module is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.
The IntelliVue NMT 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.

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510(k) Summary

This summary of 510(k) 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

Markus Stacha
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany
Tel: +49 7031 463-2840 Fax: +49 7031 463-2442
e-mail: markus.stacha@philips.com

This summary was prepared on November 19, 2019.

2. The name and classification of the devices:

Trade name: IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi-Measurement Module X3.

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	DSI	Detector and alarm, arrhythmia
	§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
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation

Device Panel	Classification	ProCode	Description
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
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	GWR	Electroencephalograph
	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalograph Signal
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical

3. The modified Philips IntelliVue Patient Monitors MP5, MP5SC, MX400, MX430, MX450, MX500, MX550, MX700, MX800 with software Rev. N.0, are substantially equivalent to the previously cleared IntelliVue Patient Monitors MP5, MP5SC, MX400, MX430, MX450, MX500, MX550, MX700, MX800, marketed pursuant to K161531.
The modified Philips IntelliVue Patient Monitor MX100 and IntelliVue Multi-Measurement Module X3 with software Rev. N.0 are substantially equivalent to the previously cleared IntelliVue Patient Monitor MX100 and IntelliVue Multi-Measurement Module X3, marketed pursuant to K171801 and K181314.

4. Description of the device

The IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi-Measurement Module X3 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, Sv02, ScvO2, spirometry, 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. Several monitor models can also be used mobile, during patient transport inside or outside of hospitals.
The monitors have a color display with touch-screen and/or keys and a navigation point as a primary input device. They also support further local input devices such as specialized remote control, keyboard, and 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.

With the current software Rev. N.0 the following modifications have been introduced:

- Implementation of the existing feature Alarm Advisor into the IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3.
  Alarm Advisor provides feedback on recurring and continuous alarm limit violations based on configured criteria. The information provided by the Alarm Advisor supports device operator in adapting alarm limits more specifically.
  This is the same functionality as that in other IntelliVue Patient Monitors: MP5, MP5SC, MX400, MX430, MX450, MX500, MX550, MX700, and MX800 (cleared with K161531).

- Modification of a few specific elements of the Graphical User Interface (GUI) of the IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800, and the IntelliVue Multi-Measurement Module X3:
  - The key ‘Silence’ has been renamed to ‘Acknowledge’,
  - A new default configuration for the Pause/Switch off of alarms via ‘Acknowledge’ key combined with a specific pop-up window has been added to all monitor models,
  - New default configurations of visual alarm indicators with other colors and flashing behavior of the alarm numerics and limits have been added.

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5. Intended Use

The modified IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi-Measurement Module X3 have the same intended use and indications for use as the legally marketed predicate devices.

IntelliVue Patient Monitors MP5 and MP5SC:

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 MP5 and MP5SC monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment. The MP5 and MP5SC when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.
The monitors are only for use on one patient at a time. 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 EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.
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.

IntelliVue Patient Monitor MX100 and Multi-Measurement Module X3

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitor is intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.
The monitor is also intended for use during patient transport inside the hospital environment.

The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The 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 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.

IntelliVue Patient Monitors MX400, MX430, MX450, MX500, MX550, MX700, and MX800:

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 MX400/MX450/MX500/MX550 monitors are additionally intended for use in transport situations within hospital environments.
The monitors are only for use on one patient at a time. 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.
The transcutaneous gas measurement (tcGas) with the M1018A plug-in module is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.
The IntelliVue NMT 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.

6. Technological Characteristics

The modifications to the IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi-Measurement Module X3 are limited to some minor software changes that do not affect technological characteristics of the devices. The common software of the devices has slightly been modified to add the feature Alarm Advisor to the models MX100 and X3 and to optimize the Graphical User Interface in the area of alarm controls and visualization.
Design, materials, energy source, portability, radio technology, measurement principle, and all physical, environmental, and performance specifications of the devices remain all unchanged.

7. Summary of V&V activities

The modified IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi-Measurement Module X3 with the current software Revision N.0 have been subject to the following V&V activities:

- Testing as required by the Hazard Analysis. All specified pass/fail criteria have been met. The test results confirmed the effectiveness of the implemented design risk mitigation measures.
- Testing according to the recognized consensus standard:
  - IEC 60601-1-8: 2012 (Ed. 2.1) (Alarms)

  All applicable requirements have been met.
- Compliance with the recognized consensus process standards:
  - AAMI ANSI IEC 62304:2006 (Ed. 1) (Software life cycle processes)
  - IEC 60601-1-6: 2013 (Ed. 3.1) (Usability).

  The modified devices are compliant with all applicable requirements of the above stated process standards.

- Usability and User Preference Testing
  The features of the current software Revision N.0 were evaluated and improved iteratively during the design phase conducting several formative usability evaluations. They included established usability engineering methods like 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.

- Integration tests, functional system level tests, and regression system level tests:

  - Integration Level tests of the IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi Measurement Module X3. All tests have been passed.
    These tests demonstrate that all individual software modules for the current software Revision N.0 have been successfully combined and bundled into one software package.
  - Functional tests of the IntelliVue Patient Monitor MX100 and IntelliVue Multi Measurement Module X3 with feature Alarm Advisor at System Level. All tests have been passed.
  - Functional tests of the IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi Measurement Module X3 with the feature blinking behavior of numerics at System Level. All tests have been passed.
  - Functional tests of the IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi Measurement Module X3 with the feature Alarm Acknowledge at System Level. All tests have been passed.
  - Functional tests of the IntelliVue Patient Monitors MP5, MP5SC, MX400, MX430, MX450, MX500, MX550, MX700, MX800 with the feature Pause/Switch off Alarms at System Level. All tests have been passed.
    The performed functional tests demonstrate that the new features in the IntelliVue Patient Monitors are correctly presented on the display, can be correctly operated, controlled, configured, and function as specified and according to the labeling claims.
  - Regression tests of the IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi Measurement Module X3 at System Level.
    The performed regression tests demonstrate that the unchanged and not affected functions also work correctly and in accordance with all specifications and labeling claims in the modified software.

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 functionality and regression tests at integration and system level, safety and essential performance tests, and usability tests.
Test methods and acceptance criteria were the same as those for the predicate devices and test results showed substantial equivalence.
The results demonstrate that the Philips IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX430, MX450, MX500, MX550, MX700, MX800 and IntelliVue Multi-Measurement Module X3 meet all defined reliability requirements and performance claims.