DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 1, 2016

Philips Medizin Systeme Boeblingen GmbH
Markus Stacha
Sr. Regulatory Affairs Engineer
Hewlett-packard-str.-2
71034 Boeblingen
Germany

Re: K161531
Trade/Device Name: IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2
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: May 30, 2016
Received: June 2, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Names:

IntelliVue MP2 Patient Monitor:

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 and outside of 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.

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Prescription Use _Yes_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

IntelliVue MP5, MP5T, and MP5SC Patient Monitors:

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, MP5SC and MP5T 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, MP5SC and MP5T 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.

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Indications for Use (continued)

IntelliVue MX400, MX430, MX450, MX500, MX550, MX600, MX700, and MX800 Patient Monitors:

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/MX430/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.

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Indications for Use (continued)

IntelliVue MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 Patient Monitors:

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 MP20/MP30/MP40/MP50 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 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 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 transcutaneous gas measurement (tcGas) 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 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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Indications for Use (continued)

IntelliVue X2 Multi-Measurement Module:

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

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 June 30, 2016.

2. The name and classification of the devices:

Trade name: IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2.

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 MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 with software Rev. M.0 are substantially equivalent to the previously cleared IntelliVue Patient Monitors as shown in the table below:

Modified Devices	Most Recent Predicate	
IntelliVue Model	**IntelliVue Model**	**510(k) No.**
MP2	MP2	K150975
MP5	MP5	K150975
MP5T	MP5T	K150310
MP5SC	MP5SC	K150975
MP20	MP20	K150975
MP30	MP30	K150975
MP40	MP40	K151681
MP50	MP50	K151681
MP60	MP60	K151681
MP70	MP70	K151681
MP80	MP80	K151681
MP90	MP90	K151681
MX400	MX400	K150975
MX430	MX430	K150975
MX450	MX450	K150975
MX500	MX500	K151681
MX550	MX550	K151681
MX600	MX600	K151681
MX700	MX700	K151681
MX800	MX800	K151681
Multi-Measurement Module X2	Multi-Measurement Module X2	K150975

4. Description of the device

The IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 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 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.

The software of the IntelliVue Patient Monitors MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, and MX800, was modified to provide the feature Alarm Advisor.
Legally marketed IntelliVue Patient Monitors provide the features Graphic Trends (displays for configurable time in a graphic form patient measurement data to show how this data develops over time) and Alarm Limits window (displays in a graphic form 15 min trends, alarm limits, and measurement values, and allows operator changing the limits manually on the basis of the displayed information).
In the new software Rev. M.0 of the subject devices MP5 to MX800, these functionalities were combined in one feature called Alarm Advisor in order to display in a graphic format for a configurable time trends, alarm limits, and measurement values and to allow operator changing the alarm limits manually.
Compared to Graphic Trends and Alarm Limits window, Alarm Advisor provides two enhancements: it gives feedback in case of recurring or continuous alarm limit violations in form of a notification and it allows operator to try out new alarm limits before setting them, with the help of the graphical trend information. When an operator tries a new alarm limit, Alarm Advisor shows the effect the new alarm limit would have had on the occurred alarm limit violations. The Alarm Advisor itself does not propose any specific alarm limit values. It also does not make any automatic alarm limit settings.
The combination of existing trending and alarm limit setting features and their enhancement joint in the Alarm Advisor feature, supports clinician in adapting alarm limits more specifically for individual patients.

The software of the IntelliVue Patient Monitors MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800, and the IntelliVue X2 Multi-Measurement Module was additionally modified to support configurable source of QRS tone.
In the previously cleared IntelliVue Patient Monitors, the QRS tone can be derived from either HR or Pulse, depending on which is currently selected as the alarm source. In the modified IntelliVue Patient Monitors software Rev. M.0 this limitation has been eliminated so that the source of the QRS tone is free selectable between HR and Pulse.

5. Intended Use

The modified IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 have the same intended use as the legally marketed predicate devices.

<u>IntelliVue MP2 Patient Monitor:</u>

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 and outside of 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.

IntelliVue MP5, MP5T, and MP5SC Patient Monitors:

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, MP5SC and MP5T 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, MP5SC and MP5T 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 MX400, MX430, MX450, MX500, MX550, MX600, MX700, and MX800 Patient Monitors:

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/MX430/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.

IntelliVue MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 Patient Monitors:

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 MP20/MP30/MP40/MP50 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 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 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 transcutaneous gas measurement (tcGas) 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 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.

<u>IntelliVue X2 Multi-Measurement Module:</u>

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

6. Technological Characteristics

The modifications to the IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 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 in order to provide the features Alarm Advisor and configurable source of QRS tone.
Design, materials, energy source, portability, user interface, 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 MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 have been subject to the following V&V activities:

- Tests as required by Hazard Analysis. All specified pass/fail criteria have been met. The test results confirmed the effectiveness of the implemented design risk mitigation measures.
- Functional tests of the IntelliVue Patient Monitors MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 with the Alarm Advisor feature. All specified pass/fail criteria have been met.
- Functional tests of the IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 with the feature configurable source of QRS tone. All specified pass/fail criteria have been met.

The conducted 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 modified IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 to confirm that the unchanged and not affected functions of the previous software Rev. L.10 also work correctly with the new software Rev. M.0. All specified pass/fail criteria have been met. The regression tests demonstrate that the modified patient monitors work safely, effectively, and correctly in accordance with all specifications and labeling claims.

- Regression tests of the Alarm System of the IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 according to the alarm standard IEC 60601-1-8. All applicable pass/fail criteria have been met.

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 functionality and regression testing at unit, integration, and system level, and safety and performance tests according to the recognized consensus alarm standard.
Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence.
The results demonstrate that the Philips IntelliVue Patient Monitors MP2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800 and the Multi-Measurement Module X2 meet all defined reliability requirements and performance claims.