DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 23, 2016

Philips Medizin Systeme Boeblingen Gmbh
Mr. Michael Asmalsky
Senior Regulatory Affairs Engineer
Hewlett-Packard Str. 2
Boeblingen, Baden Wuerttemberg, 71034 DE

Re: K150975
Trade/Device Name: Philips IntelliVue MP2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX450, MX500, MX550, MX600, MX700 and MX800 patient monitors with software revision L.02 and the Philips IntelliVue X1(M3001AL) and X2 Multi-Measurement Module with software revision L.02
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, DSJ, DSK, DXN, DXG, KRB, DRQ, DRT, DPS, MLC, DRW, KRC, DRJ, DQA, DSB, DPZ, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWR, GWS, FLL
Dated: May 21, 2015
Received: May 26, 2015

Dear Mr. Michael Asmalsky,

This letter corrects our substantially equivalent letter of June 25, 2015.

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

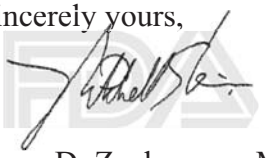
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 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" (21CFR 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
MP2 Patient Monitor

510(k) Number (if known):_____

Device Name:

Philips IntelliVue MP2 Patient Monitor, software revision L.02:

The Philips IntelliVue MP2 is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.

The Philips IntelliVue MP2 is intended to be used for monitoring and recording of, and to generate alarms, for, multiple physiological parameters of adults, pediatrics, and neonates. It is intended for use by trained healthcare professionals in a hospital environment.

The MP2 is also intended for use during patient transport inside and outside of the hospital environment.

The MP2 is only for use on one patient at a time. They are not intended for home use. Not a therapeutic device. The Philips IntelliVue MP2/X2 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.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use
X2 Multi-Measurement Module

510(k) Number (if known):_____

Device Name:

Philips IntelliVue X2 Multi-Measurement Module, software revision L.02:

The Philips IntelliVue X2 is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.

The X2 is intended to be used for monitoring and recording of, and to generate alarms, for, multiple physiological parameters of adults, pediatrics, and neonates. It is intended for use by trained healthcare professionals in a hospital environment.

The X2 is also intended for use during patient transport inside and outside of the hospital environment.

The Philips IntelliVue X2 is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The Philips IntelliVue X2 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.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use
MP5 and MP5SC Patient Monitor

510(k) Number (if known):_____

Device Name:

Philips MP5 and MP5SC IntelliVue patient monitors, software revision L.02:

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.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

MX400, MX450, MX500, MX550, MX600, MX700 and MX800 Patient Monitor

510(k) Number (if known):_____

Device Name:
IntelliVue MX400, MX450, MX500, MX550, MX600, MX700 and MX800 Patient Monitors, software revision L.02:

The monitors are indicated for use by healthcare 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 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) 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.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use
MP20-90 Patient Monitor

510(k) Number (if known):_____

Device Name: Philips MP20, MP30, MP40, MP50, MP60, MP70, MP80 and MP90 IntelliVue patient monitors, software revision L.02.

IntelliVue MP20 – MP90 Patient Monitor:

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.

Prescription Use		Over-The-Counter Use	
___Yes__	AND/OR	(21 CFR 807 Subpart C)	__No___
(Part 21 CFR 801 Subpart D)			

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Indications for Use Addendum for
Masimo rainbow SET ® Measurement in IntelliVue

510(k) Number (if known):_____

Device Name: IntelliVue MP2 and MP5/MP5SC Patient Monitor and IntelliVue X1(M3001AL) and X2 Multi-Measurement Modules :

The Indications for Use as specified for the IntelliVue patient monitor applies.

The Masimo rainbow SET measurement is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), 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.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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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.) The submitter of this premarket notification is:

Michael Asmalsky
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e-mail: michael.asmalsky@philips.com

This summary was prepared on April 9th, 2015.

2.) The trade names/proprietary names of the devices are:
the Philips IntelliVue MP2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX450, MX500, MX550, MX600, MX700 and MX800 patient monitors with software revision L.02 and the Philips IntelliVue X1(M3001AL) and X2 Multi-Measurement Module with software revision L.02.

The common/usual names are: Patient Monitoring Devices

The Classification names are as follows:

Device Panel	Classification	ProCode	Device Description
Cardiovascular Devices	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§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
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance

Device Panel	Classification	ProCode	Device Description
	§870.2700, II	DPZ	Oximeter, ear
	§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
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical
Neurological Devices	§882.1400, II	GWR	Electroencephalograph
	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3.) The modified devices Philips IntelliVue Patient Monitors MP2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX400, MX450, MX500, MX550, MX600, MX700, MX800 and IntelliVue X1(M3001AL) and X2 Multi-Measurement Module with software Rev. L.02 are substantially equivalent to the previously cleared IntelliVue Patient Monitors MX400, MX450, MX500, and MX550 software Rev. K.20 marketed pursuant to K141015, K130849 and K131872 and the IntelliVue Patient Monitors MP2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX600, MX700, MX800 and IntelliVue X2 Multi-Measurement Module software Rev.J.08 marketed pursuant to K122439, K120366, K113441, K113657, K110474, K110622, K102562, K101449, K100939, K093268, K091927, K083517, K082633, K081793, K072020, K071426, K063315, K063725, K062283, K062392, K061610, K061052, K060541, K060221, K053522, K052801, K051106, K050762, K050141, K042845, K041235, K040304, K032858, K031481, K030038 and K021788.

The modified Philips X1 (M3001AL) and X2 Multi-Measurement Modules and Philips MP2 and MP5/MP5SC patient monitors are substantially equivalent to the legally marketed predicate Philips Philips

K102562, K101449, K100939, K093268, K091927, K083517, K082633, K081793, K072020, K071426, K063315, K063725, K062283, K062392, K061610, K061052, K060541, K060221, K053522, K052801, K051106, K050762, K050141, K042845, K041235, K040304, K032858, K031481, K030038 and K021788

and to the currently legally marketed IntelliVue patient monitor MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 or MX800 with a Masimo rainbow SET® Radical 7 Pulse CO-Oximeter (as cleared with K120657) connected via the M1032A Vuelink interface.

4.) Description of the Devices:

The subject devices Philips IntelliVue Patient Monitor family comprises the multi-parameter patient monitor models: IntelliVue Patient Monitors MP2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX400, MX450, MX500, MX550, MX600, MX700, MX800 and IntelliVue X1(M3001AL) and X2 Multi-Measurement Module that consist of display units including built-in or separate flat panel displays and central processing units (CPU) and physiological measurement modules.

The monitors acquire multiple physiological patient signals (via connected external measurement modules), display measurement values, waves and trends, generate physiological and technical alarms, provide data recording and support patient data management.

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. The monitors can also be used mobile, during patient transport in a hospital setting.

The measurement sensors of the connected external measurement modules are applied at diverse bodily locations, depending on the actual physiological parameters monitored, e.g. on a patient's finger for the pulse oximetry or on a patient's upper arm for the non-invasive blood pressure.

The monitors have a color display with touch-screen as a primary input device. They also support a specialized remote control, keyboard and pointing devices such as a mouse. One external display, which provides an adaptive duplicate image of the primary display, can be connected to a built-in video port.

The monitors interact with the connected external measurement devices locally at the bedside or in transport situations and with the Central Station via LAN or wireless link.

The subject modification introduces the Masimo rainbow SET® technology as a further SpO2 option for the Philips IntelliVue MP2 and MP5/MP5SC Patient Monitor and for the Philips IntelliVue X1(M3001AL) and X2 Multi-Measurement Modules.

Additionally the software revision L.02 is made available for the entire IntelliVue Patient Monitors family.

Intended Use

The Intended Use and Indications for Use of the subject Philips IntelliVue MP2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX400, MX450, MX500, MX550, MX600, MX700 and MX800 patient monitors and the Philips IntelliVue X1(M3001AL) and X2 Multi-Measurement Module have not changed as a result of the device modification. The devices have the following detailed Indications for Use Statements in their Instructions for Use:

Philips 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.

Philips 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 IntelliVue MP5 and MP5SC Patient Monitor:

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 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 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.

Philips IntelliVue MX 400/450/500/550 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 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) is restricted to neonatal patients only.
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.

Philips IntelliVue MX 600/700/800 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 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 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 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.

Philips IntelliVue MP20-90 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.

The addendum to the instructions for use for the devices contains the following statement:

Indications for Use Addendum for Masimo rainbow SET ® Measurement in IntelliVue

The Masimo rainbow SET measurement is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), 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 with patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

5.) Technological Characteristics:
The modified devices have the same technological characteristics as the legally marketed predicate devices.

6.) Summary of Verification & Validation Activities and Conclusion:
Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate. Testing involved system level and as well as testing from the hazard analysis.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Testing as required by the hazard analysis was conducted and all specified pass/fail criteria have been met. The test results confirmed the effectiveness of the implemented design risk mitigation measures.

Verification according to the applicable EMC, safety, and performance standards was conducted as described below:

Standard	**Type**
AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Basic Safety and Essential Performance
IEC 60601-1-2:2007	Electromagnetic Compatibility
IEC 60601-2-49:2011	Multiparameter Patient Monitoring
ISO 80601-2-61:2011	SpO_2 Monitoring
IEC 62304:2006	Software Life Cycle Processes

Pass/Fail criteria were based on the specifications cleared for the predicate devices and all test results showed substantial equivalence. The results demonstrate that the Philips IntelliVue patient monitors and IntelliVue Multi-Measurement Modules meet all safety and reliability requirements and performance claims.