September 11, 2020

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

Re: K192137
Trade/Device Name: IntelliVue Patient Monitor MX500, IntelliVue Patient Monitor MX550
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, MUD, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWR, GWS, FLL
Dated: August 12, 2020
Received: August 13, 2020

Dear Stefan Breuer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jennifer Shih Kozen
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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)* K192137

Device Name
IntelliVue Patient Monitor MX500, IntelliVue Patient Monitor MX550

Indications for Use *(Describe)*

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.
The monitors are 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 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.

(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 (continued)

The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.

The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

The IntelliVue NMT Module is intended to be used as an objective neuromuscular transmission monitor, using accelerometry for measuring the muscle contraction following an electrical stimulation of a peripheral nerve. The NMT Module is intended to be used with adult and pediatric patients.

The Masimo rainbow SET measurement is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRac). The Masimo rainbow SET measurement is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused.

The noninvasive Masimo O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥40 kg and on pediatrics ≥5 kg and <40 kg, in healthcare environments.

5 510(k) Summary

510(k) Summary

SUBMITTER

5.1 Date Prepared	August 12, 2020
5.2 Submitter/Owner	**Philips Medizin Systeme Boeblingen GmbH** FDA Establishment Registration Number 9610816 Hewlett-Packard-Str. 2 71034 Boeblingen Germany Phone: +49 151 1961 5514 Fax: +49 7031 463 2202
5.3 Key Contact	Stefan Breuer Senior Regulatory Affairs Engineer Stefan.Breuer@philips.com
5.4 510(k) Submission Type	Abbreviated 510(k)

DEVICE

5.5 Trade Name	IntelliVue Patient Monitors MX500 and MX550
5.6 Common Name	Multiparameter Patient Monitor

5.7 Classification Name

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
			§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
			§870.2700, II	MUD	Oximeter, Tissue Saturation
		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

PREDICATE DEVICE

5.8 Predicate Devices		***510(k) No.***	***Company Name Device Name***	***Product Code***
	Primary Predicate	K161531	Philips IntelliVue Patient Monitors MX500 and MX550	See **Section 5.7**
Reference Devices	Reference Device	K162603	Masimo O3 Regional Oximeter System	MUD
	Reference Device	K123043	Masimo Infrared Mainstream Gas Analyzer CO2	CCK, CBQ, CBR, CBS, NHO, NHP, NHQ
	Reference Device	K171121	Masimo Infrared Sidestream Gas Analyzer CO2	MWI, BZQ, CAT, CBQ, CBR, CBS, CCK, CCL, DPZ, DQA, DXN, FLL, GWQ, GXY, NHO, NHP, NHQ, OLT, OLW, OMC, ORT

The Philips IntelliVue Patient Monitor MX500 is substantially equivalent to the legally marketed Philips IntelliVue Patient Monitor MX500 (K161531).
The Philips IntelliVue Patient Monitor MX559 is substantially equivalent to the legally marketed Philips IntelliVue Patient Monitor MX550 (K161531).

DEVICE DESCRIPTION

5.9 Philips IntelliVue Patient Monitors MX500 and MX550 – description of the device per 21 CFR 807.92(a)(4)

The IntelliVue Patient Monitors MX500 and MX550 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 noninvasive blood pressure, temperature, CO2, tcpO2/ tcpCO2, C.O., CCO, intravascular SO2, SvO2, 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 at the patient bedside vicinity and can also be used during patient transport inside hospitals.
The monitors have a color display with touchscreen 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.

INDICATIONS FOR USE

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

Name	Indications for Use/Intended Use
Philips IntelliVue Patient Monitors MX500 and MX550 Subject Device	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 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) 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. The Masimo rainbow SET measurement is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRac). The Masimo rainbow SET measurement is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused. The noninvasive Masimo O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥40 kg and on pediatrics ≥5 kg and <40 kg, in healthcare environments.

Philips IntelliVue Patient Monitors MX500 and MX550 Primary Predicate	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 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) 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. 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PRIMARY PREDICATE DEVICE

5.11 Predicate Device Comparison Table

Similarities	
Feature of Comparison	**Description of Feature**
Indications for use	Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
Users	Healthcare professionals
Target patient population	Adult, pediatric, neonatal
Environment of use	In hospital environments
Monitor mechanical and electrical/electronic hardware, including dimensions and weight	The proposed changes do not cause any changes to the monitors' electrical or mechanical hardware.
Human, device and system interfaces	The human, device and system interfaces of the monitors are not altered by the proposed changes.
Electrical safety	ANSI/AAMI ES60601-1:2005/(R)2012, Ed.3 (cons.), IEC 60601-1, Ed.3.1:2012-08 (cons.)
Temperature/humidity specifications	Temperature and humidity specifications are not affected by the proposed changes.
Biocompatibility	The devices do not have patient contact, therefore biocompatibility aspects are not applicable.

Differences	
Feature of Comparison	**Description of Feature**
Intended use	The intended use has been extended by the intended use of the added Masimo O3 Regional Oximeter System: The noninvasive Masimo O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥40 kg and on pediatrics ≥5 kg and <40 kg in healthcare environments. This added statement is unchanged from the reference device and does not alter the substantial equivalence of the devices.
Supported physiological measurements, including all specifications and accessories	Masimo O3, IRMA CO2 and ISA CO2 have been added to the otherwise unchanged physiological measurements that the devices support. The added measurements do not alter the substantial equivalence of the devices.
Electromagnetic compatibility	Subject devices conform to IEC 60601-1-2:2014 (Ed. 4); predicate devices have conformed to IEC 60601-1-2:2007 (Ed. 3). This change is due to updated recognized consensus standards and does not alter the substantial equivalence of the devices.
Plug-in modules	Two plug-in modules are added:

Differences	
Feature of Comparison	**Description of Feature**
	• O3 plug-in module (867184) digital interface and isolating power supply to external Masimo O3 measurement device • CO2 plug-in module (867185) digital interface and isolating power supply to external Masimo IRMA CO2 or ISA CO2 measurement devices The added plug-in modules do not alter the substantial equivalence of the devices.
Monitor software	Two software modules have been added: • "Masimo O3" and • "Masimo CO2" The added software modules communicate with external Masimo measurement device via O3/CO2 plug-in module 867184/867185. The added software modules receive physiological data from external Masimo measurement device and forward it into existing, unchanged SW infrastructure for presentation, data storage, user interface and alarming. This does not alter the substantial equivalence of the devices.

5.12 Substantial Equivalence Summary

The technological characteristics of the subject of this 510(k), the IntelliVue Patient Monitors MX500/MX550 with Masimo O3, IRMA CO2 and ISA CO2, are equivalent to the predicate devices IntelliVue Patient Monitors MX500/MX550.

Philips has additionally identified three reference devices for comparison in order to demonstrate substantial equivalence of the modified IntelliVue Patient Monitors. The tables in this summary identify the predicate and reference devices and highlight a comparison between the IntelliVue Patient Monitors MX500/MX550 (K161531, cleared July 1, 2016), Masimo O3 Regional Oximeter System (K162603, cleared May 26, 2017), Masimo Infrared Mainstream Gas Analyzer CO2 (K123043, cleared October 25, 2012), Masimo Infrared Sidestream Gas Analyzer CO2 (K171121, cleared November 17, 2017) and the proposed modifications to the IntelliVue Patient Monitors MX500/MX550.

The changes described within this 510(k) do not raise different question of safety or effectiveness, or affect the safety or effectiveness of the devices. The risks associated with the use of the device are well characterized and do not raise different questions of safety or effectiveness. Risk analysis was performed and no new questions that could affect safety or effectiveness have been identified. Therefore, the modified devices incorporating the Masimo O3, IRMA CO2 and ISA CO2 measurements are substantially equivalent to the predicate devices.

PERFORMANCE DATA

5.13 Non-Clinical Tests – Harmonized Standards

The IntelliVue Patient Monitors MX500 and MX550 has passed all safety tests for demonstrated compliance with the harmonized standards below.

Standard	FDA Recognition #	Title #
IEC 62304:2015 Edition 1.1 (consolidated version)	13-79	Medical device software – software life cycle processes
AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012 (Ed. 3.1)	19-4	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2014 (Ed. 4.0)	19-8	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-1-8:2012 (Ed. 2.1)	5-76	Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 80601-2-55:2011 (Ed. 1)	1-96	Medical Electrical Equipment - Part 2-55: Particular Requirements For The Basic Safety And Essential Performance Of Respiratory Gas Monitors

5.14 Non-clinical Bench Tests

Bench Testing and Shelf life

Bench testing was performed to verify system level device specifications, mechanical and electrical specifications, and packaging integrity.

The subject devices do not contain any aging components, thus, the likelihood of time-dependent product degradation is low. For this reason, a shelf life for these devices is not needed and, therefore, not specified.

Consequently, performance data is not needed to establish that device performance is maintained for the entirety of the shelf life.

The devices are not sterile, are not re-processed single use devices, and are not intended for sterilization. Therefore sterilization is not evaluated for the proposed changes.

Biocompatibility

The subject devices do not have any contact with patients. Therefore, biocompatibility requirements are not applicable.

This is unchanged from the legally marketed predicate devices.

The legally marketed medical accessories intended for use with the subject devices, as listed in Annex E of the original 510(k), remain all unchanged. Therefore, biocompatibility aspects are not affected.

Software Verification and Validation

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 (2005). The Philips IntelliVue Patient Monitors MX500/MX550 Software Level of Concern was determined to be Major, since a failure or latent flaw could indirectly result in death or serious injury of the patient or operator through incorrect or delayed information or through the action of a care provider.

Electromagnetic Compatibility and Electrical Safety

Electrical safety and electromagnetic compatibility (EMC) testing was conducted on the Philips IntelliVue Patient Monitors MX500/MX550. The device complies with the applicable requirements within the ANSI AAMI ES60601-1 / IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

No new issues of safety or effectiveness are introduced as a result of using this device.

5.15 Clinical Studies

The IntelliVue Patient Monitors MX500 and MX550, like the predicate device, did not require clinical trials.

FDA recognized standards, FDA guidance documents, harmonized standards, verification and validation, software validation, usability validation, and risk management activities have taken place for the IntelliVue Patient Monitors MX500 and MX550.

Based upon the design, intended use, indications for use, classification, usability and safety testing the IntelliVue Patient Monitors MX500 and MX550 is substantially equivalent to the listed predicate device.

No new issues of safety or effectiveness are introduced as a result of using this device.

CONCLUSIONS

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety and electromagnetic compatibility, software verification and validation demonstrate that the IntelliVue Patient Monitors MX500 and MX550 do not raise different questions of safety and effectiveness when compared to the predicate, performs as intended, and has performance characteristics that are substantially equivalent to the IntelliVue Patient Monitors MX500 and MX550 predicate device.