



Food and Drug Administration
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July 17, 2015

Philips Medizin Systeme Boeblingen Gmbh
Johannes Schmid
Regulatory Affairs Engineer
Hewlett-packard Str. 2
Boeblingen, 71034 DE

Re: K151681

Trade/Device Name: Philips IntelliVue MP40, MP50, MP60, MP70, MP80, MP90, MX500, MX550, MX600, MX700 and MX800 patient monitors with software revision L.03

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, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWR, GWS, FLL

Dated: June 18, 2015

Received: June 22, 2015

Dear Mr. Johannes Schmid,

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,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over a large, light gray watermark of the FDA logo.

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 Name: **IntelliVue Patient Monitors MP40, MP50, MP60, MP70, MP80 and MP90**

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 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.

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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)

Indications for Use (continued)

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.

Indications for Use

510(k) Number (if known): _____

Device Name: **IntelliVue Patient Monitors MX500, MX550, MX600, MX700, and MX800**

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

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

The 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.

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)

Indications for Use (continued)

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.

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 18, 2015

2. The name and classification of the devices:

Trade name:

IntelliVue Patient Monitors MP40, MP50, MP60, MP70, MP80, MP90 and MX500, MX550, MX600, MX700, MX800.

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. Cardiometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment

Device Panel	Classification	ProCode	Description
	§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
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	ORT	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 devices Philips IntelliVue Patient Monitors MP40, MP50, MP60, MP70, MP80, MP90 and MX500, MX550, MX600, MX700, MX800 software Rev. L.03 are substantially equivalent to the previously cleared IntelliVue Patient Monitors MX500, and

MX550 software Rev. K.20 marketed pursuant to K141015, K130849 and K131872 and the IntelliVue Patient Monitors MP40, MP50, MP60, MP70, MP80, MP90 and MX600, MX700, MX800 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.

The new G7m Gas Analyzer Module (866173) is substantially equivalent to the legally marketed predicate Philips G5 Gas Analyzer Module (M1019A) marketed pursuant to K141015, K131872, K130849, K122439, K120366, K113657, K113441, K110622, K102562, K101449, K100939, K093268, K091927, K083517, K082633, K081793, K072020, K071426, K063315, K063725, K062283, K062392, K061610, K061052, K060541.

4. Description of the device

The subject devices Philips IntelliVue Patient Monitor family comprises the multi-parameter patient monitor models: IntelliVue Patient Monitors MP40, MP50, MP60, MP70, MP80, MP90 and MX500, MX550, MX600, MX700, MX800 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 extends the capability of IntelliVue Patient Monitors MP40, MP50, MP60, MP70, MP80, MP90 and MX500, MX550, MX600, MX700, MX800 by:

- G7m Gas Analyzer (866173)

The legally marketed G5 Gas Analyzer Module (M1019A) used together with the IntelliVue Patient Monitors MP40 - MP90 and MX500-MX800 has been re-designed to create the new G7m Gas Analyzer Module (866173) intended for use with the IntelliVue Patient Monitors MP40 - MP90 and MX500-MX800.

When connected to a patient monitor, the G7m Gas Analyzer Module (866173) acquires airway gases of intubated patients and measures continuously carbon dioxide (CO₂), oxygen (O₂), nitrous oxide (N₂O), and up to two of the automatically identified anesthetic agents Enflurane (ENF), Halothane (HAL), Isoflurane (ISO), Sevoflurane (SEV) or Desflurane (DES), and calculates the respiration rate.

The IntelliVue Patient Monitors MP40 - MP90 and MX500-MX800 have additionally been modified to support the new G7m Gas Analyzer Module (866173). The modification for this purpose is limited to a minor software changes in the AGM/EGM Application Software Module (ASW).

Additionally the software revision L.03 is made available for the entire IntelliVue Patient Monitors family.

5. Intended Use

The intended use of the modified devices, as described in the labeling, has not changed from that of the predicate devices as a result of the modification.

Philips IntelliVue MX 500/550/600/700/800 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 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.

Philips IntelliVue MP40-90 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 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.

6. Technological Characteristics

The modification to the IntelliVue Patient Monitors MP40, MP50, MP60, MP70, MP80, MP90 and MX500, MX550, MX600, MX700, MX800 is limited to some minor software and hardware changes that do not affect fundamental scientific technology of the devices.

The hardware of the legally marketed G5 Gas Analyzer Module (M1019A) has been re-designed to create the new G7m Gas Analyzer Module (866173). Standard electronic components of the G5 have been replaced by the state-of-the-art components and packed in a new housing. The new G7m uses the same common interface as all IntelliVue measurement modules.

Design, materials, energy source, portability, user interface, radio technology, measurement principle, and all performance specifications of the modified IntelliVue Patient Monitors remain all unchanged.

7. Summary of V&V activities

The modified IntelliVue Patient Monitors MP40, MP50, MP60, MP70, MP80, MP90 and MX500, MX550, MX600, MX700, MX800 have been subject to the following V&V activities:

- EMC testing of the new G7m Gas Analyzer Module (866173) with host devices IntelliVue Patient Monitors MP40 to MP90, and MX500 to MX800 according to the recognized consensus standard IEC 60601-1-2:2007 Ed.3
- Safety and performance testing of the new G7m Gas Analyzer Module (866173) with host devices IntelliVue Patient Monitors according to the recognized consensus standards:
 - o ANSI/AAMI ES60601:2005 +A1:2012, Ed. 3 (IEC 60601:2005 +A1:2012 MOD, Ed. 3),
 - o ISO 80601-2-55 First Edition 2011-12-15,

- Mechanical Testing of the new G7m Gas Analyzer Module (866173): Shock and vibration to simulate the environment of use during stationary use and rough handling in hospitals, according to the IEC TR60721-4-7 Class 7M1 and IEC 60068-2-xx standard series
- Temperature and humidity testing of the new G7m Gas Analyzer Module (866173) to simulate the climatic conditions during device operation in hospital environments and during storage
- Ensuring Compliance to Software Life cycle requirements as required by the recognized consensus standard IEC 62304 'Medical devices software-software life cycle processes', 2006
- 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 and performance tests of the modified patient monitors with the G7m Gas Analyzer Module (866173) in order to verify support of the new features. The conducted tests demonstrate that the new features, provided by the modified patient monitors are correctly implemented on the subject devices.

8. Conclusion

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

V&V testing comprised functionality, safety, EMC, mechanical, and environmental tests. 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 MP40, MP50, MP60, MP70, MP80, MP90 and MX500, MX550, MX600, MX700, MX800 meet all defined reliability requirements and performance claims.