MAR 2 2 2012

8. 510(k) Summary K113441

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:

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This summary was prepared on November 17, 2011.

2. The names of the devices are:
Trade Name: Philips MP2, X2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue patient monitors

Common name: Multiparameter Patient Monitor

Classification names are as follows:

Device Panel	Classification	ProCode	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
	§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)

Device Panel	Classification	ProCode	Description
	§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
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 Philips MP2, X2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue Patient monitors are substantially equivalent to previously cleared Philips IntelliVue patient monitors marketed pursuant to: K110622, K110474, K102562, K101449, K100939, K093268, K091927, K083517, K082633, K081793, K072070, K071426, K063725, K063315, K062283, K062392, K061610, K061052, K060541, K060221, K053522, K052801, K051106, K050762, K050141, K042845, K041235, K040304, K033513, K033444, K032858, K031481, K030038, K023871, and K021778.

4. Description of the devices
   The Philips IntelliVue Patient Monitor family comprises the multi-parameter patient monitor models MP2, X2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue Patient Monitors which consist of display units including build-in or separate flat panel displays and central processing units as well as physiological measurement modules.
   All monitors share the same system architecture and exactly the same software is executed on each.
   The Patient Monitor family is a flexible and modular monitoring solution optimized for the surgical, cardiac, general medical and neonatal care environments. The monitors can be connected to the Philips Multi-Measurement Module (MMS) family with its extensions and to the IntelliVue family plug-in measurement modules. The monitors can also be connected to the IntelliVue anesthetic gas modules and to the IntelliVue TcG10 Measurement Module.

The subject modification is the introduction of the Integrated Pulmonary Index (IPI) software module as an extension to the legally marketed Microstream CO2 measurement module as integrated or interfaced to the Patient Monitor family.
The IPI is a numerical integer value ranging from 1 to 10. It is calculated based on the four major parameters from the monitoring of the physiological parameters CO2 and SpO2 in order to provide a simple and clear single parameter indication of the patient's ventilation status. These four major parameters are etCO2 and Respiration Rate (RR) which are received from the Microstream CO2 measurement module, as well as SpO2 and Pulse Rate (PR) which are received from the pulse oximetry module of the host system.
The IPI is available for all three groups of pediatric patients (1 - 3 years, 3 - 6 years, and 6 - 12 years) and for adult patients. It is not available for Neonatal/ Infant patients (patients up to the age of one year).

5. Indications for Use
Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of and to generate alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP2, MP5, MP5T, MP5SC, X2, MP20, MP30, MP40, and MP50 are additionally intended for use in transport situations within hospital environments. The MP2, X2 and MP5 are also intended for use during patient transport outside of a hospital environment.

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

6. Technological characteristics
The modified devices have the same substantial technological characteristics, such as fundamental design, user interface, materials, energy source, and measurement technology, as the legally marketed predicate devices.

7. Summary and conclusion

Verification and validation testing activities were conducted to establish the safety, performance, functionality, and reliability characteristics of the modified devices with respect to the predicate devices.

V&V testing were executed including, safety, functionality and regression testing and testing from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices.

The results demonstrate that the modified Philips MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue Patient Monitors are as safe and as effective and perform as the predicate devices.

The modified devices are substantially equivalent in intended use and fundamental technological characteristics compared to the appropriate predicate devices. The modified devices introduce no new questions concerning the safety or effectiveness and are, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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MAR 2 2 2012

Re: K113441
Trade/Device Name: Philips MP2, X2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue Patient Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-segment measurement and alarm).
Regulatory Class: II
Product Code: MHX
Dated: February 28, 2012
Received: March 5, 2012

Dear Dr. Seher:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Philips MP2, X2, MP5, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue patient monitors, software revision J.01.

Indications for Use:
Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of and to generate alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP2, MP5, MP5T, MP5SC, X2, MP20, MP30, MP40, and MP50 are additionally intended for use in transport situations within hospital environments. The MP2, X2 and MP5 are also intended for use during patient transport outside of a hospital environment.

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) __X__ AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) ____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k113441