K063725

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:

Markus Stacha
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany
Tel: ++49 7031 463-2840 Fax: ++49 7031 463-2442
e-mail: markus.stacha@philips.com

FEB 8 2007

This summary was prepared on December 13, 2006.

2. The names of the device is the Philips MP5 IntelliVue 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

Device Panel	Classification	ProCode	Description
	§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
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 MP5 IntelliVue Patient Monitor is substantially equivalent to previously cleared Philips MP5 IntelliVue Patient Monitor marketed pursuant to K062392, the M3/M3046A Compact Portable Patient Monitor marketed pursuant to K971910, K992273, K030973, and the Welch Allyn SureTemp® Plus thermometer module marketed pursuant to K031740.

4. The modification adds the capability to the MP5 patient monitor to interface to the legally marketed Welch Allyn SureTemp® Plus thermometer module. The modification also adds the capability to the MP5 patient monitor to function in a transport environment outside of hospitals, such as a road ambulance, airplane or helicopter.

5. The modified Philips MP5 IntelliVue Patient Monitor is intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults, pediatrics and

neonates in a hospital environment and during patient transport inside and outside of hospital environment. It is not intended for home use. The monitor is intended for use by health care professionals.
The MP5 monitor with interfaced Welch Allyn SureTemp® Plus thermometer module is intended for use with adult and pediatric patients in a hospital environment.

6. The modified device has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicate. Testing involved system level tests, performance tests, EMC, safety and environmental testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the modified Philips MP5 IntelliVue Patient Monitor meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2007

Philips Medizin Systeme Boeblingen GmbH
Cardiac and Monitoring Systems
c/o Markus Stacha
Hewlett-Packard-Str. 2
D-71034 Boeblingen,
GERMANY

Re: K063725
Trade Name: Philips MP5 IntelliVue Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class II
Product Code: MHX
Dated: December 13, 2006
Received: December 15, 2006

Dear Mr. Stacha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K063725

Device Name: Philips MP5 IntelliVue Patient Monitor.

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring and recording of and to generate alarms for multiple physiological parameters of adults, pediatrics and neonates in a hospital environment and during transport situations within and outside of hospital environment.

Prescription Use (Part 21 CFR 801 Subpart D) yes AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) No

(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 Cardiovascular Devices
510(k) Number K063725