8.0 510(k) Summary

MAR 2 4 2006

K060541

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:

Herbert van Dyk
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany
Tel: ++49 7031 463-1734 Fax: ++49 7031 463-2442
e-mail: herbert.van_dyk@philips.com

This summary was prepared on February 24, 2006.

2. The names of the devices are the Philips MP20, MP30, MP40, MP50, MP60, MP70, MP80 and MP90 IntelliVue Patient Monitors. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Circulatory System Devices (12625)	§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)
	§870.2300, II	MSX	System, Network and Communication, Physiological Monitors
	§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
	§870.2450, II	DXJ	Display, Cathode-Ray Tube, Medical
	§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
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
Anesthesiology and Respiratory Therapy (12624)	§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 (12520)	§880.2910, II	FLL	Thermometer, Electronic, Clinical
Neurological (12513)	§882.1400, II	GWR	Electroencephalograph
	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The modified devices are substantially equivalent to previously cleared Philips devices marketed pursuant to K014159, K021778, K030038, K032858, K040304, K040183 and K040357, K041235, K41741, K042845, K050141, 050762 and K051106, K052801 , K053522, K060221, and K053204 to Dräger Medical M1019A IntelliVue G5 Anesthesia Gas Monitor

4. The modification is the introduction of Release D.03 software for the IntelliVue patient monitor devices, MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90

5. The modified devices have the same intended use as the legally marketed predicate devices. They are intended for the monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in hospital

environment and during transport within hospital environments.

6. The modified devices have 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, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the Philips 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

MAR 2 4 2006

Philips Medizin Systeme Boeblingen GmbH
c/o Herbert van Dyk
Sr. Regulatory Affairs Engineer
Hewlett-Packard-Str. 2
D-71034 Boeblingen
GERMANY

Re: K060541
Trade Name: Philips MP20, MP30, MP40, MP50, MP60, MP70. MP80, and MP90 IntelliVue Patient Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor w/ Arrhythmia Detection or Alarms
Regulatory Class: Class II (two)
Product Code: MHX, CCK, CCL, CBQ, NHO, NHP, NHQ, CBS, CBR, BZQ
Dated: February 24, 2006
Received: March 1, 2006

Dear Mr. van Dyk:

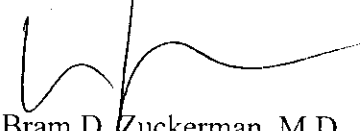
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 443-6597 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): K060541

Device Name: The Philips MP20, MP30, MP40, MP50, MP60, MP70, MP80 and MP90 IntelliVue Patient Monitors, Release D.03

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, recording and alarming of multiple physiological parameters of adults, pediatrics and neonates in healthcare facilities. The MP20, MP30, MP40 and MP50 are additionally intended for use in transport situations within healthcare facilities.

ST Segment monitoring is restricted to adult patients only.

The transcutaneous gas measurement ($tcpO_2$ / $tcpCO_2$) is restricted to neonatal patients only.

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 K060541