K031481
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**510(k) Summary** MAY 2 9 2003

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:

Hauke Schik
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This summary was prepared on May 05, 2003.

2. The names of the devices are the Philips MP60, MP70, and MP90 IntelliVue Patient Monitor. Classification names are as follows:

| Device Panel | Classification | ProCode | Description |
|---|---|---|---|
| Circulatory System Devices (12625) | §870.1025, III | DSI | Detector and alarm, arrhythmia |
| | §870.1025, III | MLD | Monitor, ST Segment with Alarm |
| | §870.1025, III | MHX | Monotor, 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 |
| | §870.2450, 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 |

| | | | |
|---|---|---|---|
| | - | MSX | System, Network and Communication, Physiological Monitors |
| 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 |
| | §868.2375, 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 new devices are substantially equivalent to previously cleared Philips devices marketed pursuant to K001664, K021778 and 030038.

4. The modification is updated software of the Philips Medical System MP60, MP70 and MP90 IntelliVue patient monitor devices.

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

6. The new 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 new 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 Component Compact 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

MAY 2 9 2003

Philips Medizin Systeme Boeblingen GmbH
c/o Mr. Hauke Schik
Sr. Regulatory Affairs Engineer
Cardiac and Monitoring Systems
Hewlett-Packard Str. 2
Boeblingen
Germany D-71034

Re: K031481
Trade Name: The Philips MP60, MP70 and MP90 IntelliVue Patient Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: May 5, 2003
Received: May 12, 2003

Dear Mr. Schik:

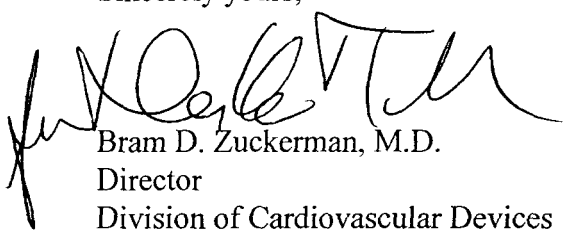
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031481

Device Name: The Philips IntelliVue MP60, MP70, and MP90 Patient Monitors, Release A.20.

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 hospital environments.

EASI 12-lead ECG is only for use on adult and pediatric patients.

ST Segment monitoring is restricted to adult patients only.

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

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** X **OR** **Over-The-Counter**
(Per 21 CFR 801.109)

**(Optional Format 1-2-96)**

**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K03148