

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 Sep 8, 2008.

2. The names of the devices are the Philips MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors and IntelliVue XDS. 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 |   |

| Device Panel                              | Classification | ProCode | Description  |
|---|----------------|---------|--|
|   | -              | 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        |
| 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 devices are substantially equivalent to previously cleared Philips IntelliVue Patient Monitors marketed pursuant to K021778, K030038, K032858, K033444, K033513, K040304, K040357, K041235, K042845, K050762, K051106, K052801, K053522, K060221, K060541, K061052, K061610, K062283, K063315, K062392, K063725, K71426, K72020.
4. The modification is the introduction of software release G.02 for the entire IntelliVue Patient Monitors family, models MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 and the introduction of the IntelliVue XDS application.
5. The modified devices have the same intended use as the legally marketed predicate devices. The Philips MP2, X2, MP5, MP20,

MP30, MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors are intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP2, X2, MP5, MP20, MP30, MP40, and MP50 are additionally intended for use in transport situations within hospital environments. The MP5 is also intended for use during patient transport outside of a hospital environment. The monitors are not intended for home use. They are intended for use by health care professionals.

6. The modified devices have the same technological characteristics as the legally marketed predicate device.
7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate. Testing involved system level and regression tests as well as testing from the 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 Philips IntelliVue Patient Monitors meet all reliability requirements and performance claims.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**OCT - 3 2008**

Philips Medizin Systeme Böblingen GmbH  
c/o Mr. Andreas Suchi  
Senior Regulatory Affairs Engineer,  
Hewlett-Packard-Str. 2  
Boeblingen, 71034  
GERMANY

Re: K082633  
Philips MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80 and MP90  
IntelliVue Patient Monitors, Software Revision G.02.  
Regulation Number: 21 CFR 870.1025  
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement  
and alarm)  
Regulatory Class: Class II (two)  
Product Code: DSI  
Dated: September 8, 2008  
Received: September 10, 2008

Dear Mr. Suchi:

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.

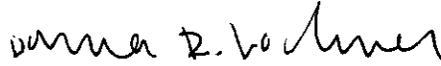
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K082633

Device Name: Philips MP2, X2, MP5, MP20, MP30, MP40, MP50, MP60, MP70, MP80, and MP90 IntelliVue Patient Monitors, Software Revision G.02.

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, X2, MP5, 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.

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

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K082633