K132075

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K132075

Submitter:

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- **Date Prepared:**

March 21, 2014

Name of the devices:

- **Trade/Proprietary Name:**
  Passport M Series Patient Monitors (including models Passport 17M and Passport 12M)

- **Common Name:** Patient Monitor

- **Classification**

21 CFR 870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Class II
21 CFR 870.1025	Detector and Alarm, Arrhythmia	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm	Class II
21 CFR 870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	Class II
21 CFR 870.1130	Non-Invasive blood pressure measurement System	Class II
21 CFR 870.1110	Blood pressure computer	Class II
21 CFR 880.2910	Clinical Electronic Thermometers –Temperature Monitor with Probe	Class II
21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 870.2710	Ear Oximeter, Pulse	Class II
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	Class II
21 CFR 868.1500	Enflurane gas analyzer	Class II
21 CFR 868.1620	Halothane gas analyzer	Class II
21 CFR 868.1700	Nitrous Oxide gas analyzer	Class II
21 CFR 868.1720	Oxygen gas analyzer	Class II
21 CFR 882.1400	Electroencephalograph	Class II
21 CFR 870.2770	Impedance plethysmograph	Class II
21 CFR 870.1435	Single-function, preprogrammed diagnostic computer	Class II

Legally Marketed Predicate Devices:

K092449, BENEVIEW T SERIES PATIENT MONITORS, MODELS BENEVIEW T8, T6 AND T5, Shenzhen Mindray Bio-medical Electronics Co., LTD.

K102562, INTELLIVUE PATIENT MONITOR, MODELS MP2, X2, MP5, MP5T, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, & MX800, PHILIPS MEDIZINSYSTEME BOBLINGEN GMBH.

K091786, PULSION CEVOX OPTICAL MODULE (PC3015), CEVOX DISPOSABLE PROBES (PV2022-30 THRU -38, PV2022-46 THRU -48), PULSION MEDICAL SYSTEMS AG

K071073, Solar 8000 and Transport Pro with Patient Data Module, GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES

Device Description:

The Passport M Series Patient Monitors (including models Passport 17M and Passport 12M) are the developed new series based on the technical platform of the BeneView T Series patient monitors. The new series, much more compact and flexible with the appearance changes, are the sub-configuration models of the BeneView T Series patient monitors by adding some parameters monitoring functions, such as continuous cardiac output (CCO) and mixed /central venous oxygen saturation (SvO2/ScvO2) monitoring.
And comparing with the cleared BeneView T Series Patient Monitors using Mortara ECG algorithm, the subject patient monitors adopt Mindray Monitoring ECG Algorithm as an optional ECG algorithm to implement ECG monitoring, arrhythmia detection, and ST Segment Analysis.

Statement of intended Use:

The Passport M Series Patient Monitors including models Passport 17M and Passport 12M are intended to be used for monitoring, displaying, reviewing, alarming and transferring of multiple physiological parameters including ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis), heart rate(HR)), respiration rate(RESP), temperature (TEMP), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure(IBP), cardiac output (C.O.), continuous cardiac output (CCO), mixed /central venous oxygen saturation (SvO2/ScvO2), carbon dioxide (CO2), Oxygen(O2), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS) and respiration mechanics (RM).

All the parameters can be applied for single adult, pediatric and neonatal patients with the exception of the follows: the arrhythmia detection, ST Segment analysis (Mortara algorithm), BIS, RM, CCO, SvO2/ScvO2 and PAWP monitoring are intended for adult and pediatric patients only. ST Segment analysis (Mindray algorithm) is intended for adult patients only. C.O. is only for use on adult patients. The ICG is only for use on adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 155kg.

The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. It is not intended for helicopter transport, hospital ambulance, or home use.

Technology:

Based on the technical platform of the BeneView T Series patient monitors, which were previously cleared by FDA under K092449, on AUG 31, 2010, we developed the Passport M Series Patient Monitors including models Passport 17M and Passport 12M.

Test Summary:

The Passport M Series Patient Monitors (including models Passport 17M and Passport 12M) comply with the recognized safety, performance and electromagnetic compatibility standards. A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. Mindray's product development process required that the following activities be completed during the development of those patient monitors:

Requirements specification review
Hardware and Software testing
Code design and code reviews
Environmental EMC testing
Safety testing
Performance testing
Hardware and Software validation

Conclusion:

The results of all testing demonstrate that the Passport M Series Patient Monitors (including models Passport 17M and Passport 12M) are as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

April 18, 2014

Mindray North America
c/o Mr. Russell Olsen
VP Quality & Regulatory Affairs
800 Macarthur Blvd
Mahwah, NJ 07430 US

Re: K132075
Trade/Device Name: Passport M Series Patient Monitoring (including models Passport 17M and Passport 12M)
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Secondary Product Codes: DSI, MLD, DRT, DXN, DSK, FLL, DQA, DPZ, CCK, CBQ, CBS, CBR, CCL, DSB, DXG, OLW
Dated: March 13, 2014
Received: March 14, 2014

Dear Mr. Russell Olsen:

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

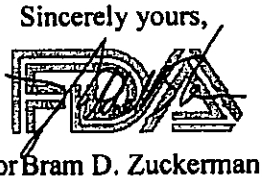
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132075

Indications for Use

510(k) Number (if known): _____

Device Name: Passport M Series patient monitors

Indications for Use:

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Prescription Use X _____ **(Part 21 CFR 801 Subpart D)** **AND/OR** **Over-The-Counter Use** _____ **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.04.18 13:29:08 -04'00'