DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 3, 2016

Shenzhen Mindray Bio-medical Electronics Co., Ltd
Bai Yanhong
Product Approval Engineer, Technical Regulation Department
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park, Nanshan
Nanshan, 518057 CN

Re: K153448
Trade/Device Name: Passport Series Patient Monitors (Passport 8 and Passport 12)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: February 4, 2016
Received: February 8, 2016

Dear Bai Yanhong:

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 Industry and Consumer Education 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153448

Device Name

Passport Series Patient Monitors (Passport 8 and Passport 12)

Indications for Use *(Describe)*

The Passport Series Patient Monitors(Passport 8 and Passport 12), are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable), arrhythmia detection and ST Segment analysis, QT analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO2), and anesthetic gas (AG).

All the parameters can be applied to single adult, pediatric and neonatal patients with the exception of the following:

- C.O. monitoring is restricted to adult patients only;
- PAWP monitoring is not intended for neonatal patients;
- The Mortara ECG Algorithm arrhythmia detection and ST Segment analysis is intended for adult and pediatric patients. The Mindray ECG Algorithm arrhythmia detection is intended for adult and pediatric patients, and the Mindray ECG Algorithm ST Segment analysis is intended for adult patients only.
- 12-lead monitoring and AG monitoring are available for Passport 12 Patient Monitor only.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Passport Series Patient Monitors is provided below.

Device Common Name: Patient Monitor

Device Proprietary Name: Passport Series Patient Monitors (Passport 8 and Passport 12)

Submitter: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Date Prepared: November 18, 2015

Classification Regulation: 21 CFR 870.1025, Class II, Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Panel: Cardiovascular

Classification Regulation, Classification Name and Product Codes:

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
Primary				
MHX	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, physiological, patient (with arrhythmia detection or alarms)
Secondary				
Product Code	**Regulation Number**	**Panel**	**Regulation Description**	**Device Common Name**
DSI	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	detector and alarm, arrhythmia
MLD	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, st segment with alarm
DRT	21 CFR 870.2300	Cardiovascular	Cardiac Monitor (including cardiotachometer and rate alarm)	monitor, cardiac (incl. cardiotachometer & rate alarm)

DXN	21 CFR 870.1130	Cardiovascular	Noninvasive blood pressure measurement system	system, measurement, blood-pressure, non-invasive
DSK	21 CFR 870.1110	Cardiovascular	Blood pressure computer	computer, blood-pressure
FLL	21 CFR 880.2910	Cardiovascular	Clinical electronic thermometer	thermometer, electronic, clinical
DQA	21 CFR 870.2700	Cardiovascular	Oximeter	Oximeter
DPZ	21 CFR 870.2710	Cardiovascular	Ear oximeter	oximeter, ear
CCK	21 CFR 868.1400	Anesthesiology	Carbon dioxide gas analyzer	analyzer, gas, carbon-dioxide, gaseous-phase
CBQ	21 CFR 868.1500	Anesthesiology	Enflurane gas analyzer	analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)
CBS	21 CFR 868.1620	Anesthesiology	Halothane gas analyzer	analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
CBR	21 CFR 868.1700	Anesthesiology	Nitrous oxide gas analyzer	analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
CCL	21 CFR 868.1720	Anesthesiology	Oxygen gas analyzer	analyzer, gas, oxygen, gaseous-phase
DXG	21 CFR 870.1435	Cardiovascular	Single-function, preprogrammed diagnostic computer	computer, diagnostic, pre-programmed, single-function

Primary Predicate Device: K132662 - Passport Series Patient Monitors (Including Passport 8, Passport 12); Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Reference Predicates:
K132075 - Passport Series Patient Monitors (Including Passport 12M, Passport 17M,T1); Shenzhen Mindray Bio-Medical Electronics Co., Ltd
K101521 - Philips ST/AR ST and Arrhythmia Software Model; Philips Medical Systems
K150352 - V Series Monitoring System; Shenzhen Mindray Bio-Medical Electronics Co., Ltd
K150632 - Hypervisor IX Monitoring System; Shenzhen Mindray Bio-Medical Electronics Co., Ltd

Indications for Use:

The Passport Series Patient Monitors(Passport 8 and Passport 12), are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable), arrhythmia detection and ST Segment analysis, QT analysis, heart rate (HR), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO2), and anesthetic gas (AG).

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- 12-lead monitoring and AG monitoring are available for Passport 12 Patient Monitor only.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

Device Description:

The subject Passport Series Patient Monitors includes two monitors:

- Passport 8 Patient Monitor
- Passport 12 Patient Monitor

All of the devices in the family are multiparameter monitors indicated for monitoring, displaying, reviewing, alarming, and transferring multiple physiological parameters. The Passport 8 and Passport 12 Patient monitors provide patient monitoring capabilities based on the user selected modules that are plugged into the main monitor.

Performance Data:

• To establish the substantial equivalence of the Passport Series Patient Monitors (including Passport 8, Passport 12), Mindray conducted functional and system level testing on the subject devices. The testing provided an evaluation of the performance of the device relevant to each of the modifications to the subject devices since their previous clearance. The functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.

• In addition, Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.

• Mindray has also followed the FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm issues on October 28, 2003.

Substantial Equivalence:

Comparison of Indications - Both the predicate device and the subject Passport 8 and Passport 12 monitors are multiparameter patient monitors intended to be used in healthcare facilities under the direction of clinical professionals. The indications for use of the subject devices have been modified to include the new feature of QT analysis. Although this feature is not present in the predicate device, it is present in the cleared Philips ST/AR ST and Arrhythmia software (K101521), and thus does not constitute a new intended use for a multi-parameter monitor.

In conclusion, the minor changes to the indications for use do not change the fundamental intended use of the Passport 8 and Passport 12 as multiparameter monitors.

Comparison of Technological Characteristics - The table below compares the key technological feature of the subject devices to the primary predicate device (Passport Series Patient Monitors K132662). The features in grey are the features that have been modified since their previous clearances and that are the subject of this 510(k).

Device Comparison Table

	Predicate Device (K132662)		**Subject Devices**	
Feature	**Passport 8**	**Passport 12**	**Passport 8**	**Passport 12**
Integrated display and touchscreen	8.4" 800*600 pixels	12.1" 800*600 pixels	Same	Same
Secondary display	Display is linked to integrated display		Same	
Power supply	One rechargeable Lithium-ion batteries or AC power supply	Two rechargeable Lithium-ion battery or AC power supply	Same	Same
Battery	Chargeable Lithium-Ion, 11.1 VDC, 4500 mAh		Same	
Data Recorder	The thermal recorder can be used to print patient information, measurement numerics, and waveforms.		Same	
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation		Same	
ECG (Mindray Algorithm)	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, Pace detection and heart rate (HR)		Added QT analysis , Added an additional Pace detection channel to enhance the Pace detection function, added ECG J-point auto detection , added adjustable QRS Detection Threshold	
ECG (Mortara Algorithm)	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, , and heart rate (HR)		Same	
Arrhythmia Analysis (Mindray Algorithm)	Asystole, VFib/VTac, Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, R on T, VT>2, PVCs, Tachy, Brady, Missed Beats, Vent. Rhythm, PNP, PNC, Multif. PVC, Nonsus. Vtac, Pause, Irr. Rhythm		Added AFib	
Arrhythmia Analysis (Mortara Algorithm)	Asystole, Vfib, Vtac, Vent. Rhythm, Couplet, VT>2, Bigeminy, Trigeminy, R on T, Multif. PVC, Irr. Rhythm, Tachy, Brady, Missed Beats, PNP, PNC		Same	
Respiration rate (Resp)	Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm. Accuracy: 7 to 150 rpm:±2 rpm or ±2%, whichever is greater; 0 to 6 rpm: Not specified.		Same	

	Predicate Device (K132662)		**Subject Devices**	
Feature	**Passport 8**	**Passport 12**	**Passport 8**	**Passport 12**
Temperature (Temp)	Measurement range: 0 to 50°C (32 to 122°F) Accuracy: ±0.1°C (without probe)		Same	
Pulse oxygen saturation (SpO_2)	Is compatible with the following 3 modules to measure oxygen saturation: • Mindray SpO_2 Module • Masimo SpO_2 Module • Nellcor SpO_2 Module Mindray SpO_2 Module Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (in adult/pediatric mode) 70 to 100%: ±3% (in neonate mode) 0% to 69%: Not specified Masimo SpO2 Module Measurement range: 1 to 100% Accuracy:70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified. Nellcor SpO2 Module Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified.		Same	

	Predicate Device (K132662)		**Subject Devices**	
Feature	**Passport 8**	**Passport 12**	**Passport 8**	**Passport 12**
Pulse rate (PR)	Pulse rate may be obtained from the SpO_2 module, NIBP module or the IBP module. PR from Mindray SpO2 Module Measurement range: 20 to 254 bpm Accuracy:±3 bpm PR from Masimo SpO2 Module Measurement range: 25 to 240 bpm Accuracy:±3 bpm (measured without motion) ±5 bpm (measured with motion) PR from Nellcor SpO2 Module Measurement range: 20 to 300 bpm Accuracy:20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified PR from NIBP Module Measurement range: 40 to 240 bpm Accuracy: ±3bpm or ±3%, whichever is greater PR from IBP Module Measurement range: 25 to 350 bpm Accuracy:±1 bpm or ±1%, whichever is greater"		Same	
Non-invasive blood pressure (NIBP)	Uses the oscillometric method for measuring non-invasive blood pressure (NIBP). This measurement can be used for adults, pediatrics and neonates. Measurement range: Adult / Pediatric / Neonate Systolic: 40 to 270 / 40 to 200 / 40 to 135 Diastolic: 10 to 210 / 10 to 150 / 10 to 100 Mean: 20 to 230 / 20 to 165 / 20 to 110 Accuracy: Max mean error: ±5 mmHg Max standard deviation: 8 mmHg		Same	
Invasive blood pressure (IBP)	The monitor can measure invasive blood pressures and displays systolic, diastolic and mean pressures and a waveform for each pressure. Measurement range: -50 to 300 mmHg Accuracy:±2% or ±1 mmHg, whichever is greater (without sensor)		Same	
Pulse Pressure Variation (PPV)	Not supported		Added.	

	Predicate Device (K132662)		**Subject Devices**	
Feature	**Passport 8**	**Passport 12**	**Passport 8**	**Passport 12**
Cardiac output (C.O.)	The cardiac output (C.O.) measurement invasively measures cardiac output and other hemodynamic parameters using the right heart (atria) thermodilution method. The temperature change is displayed as a curve in the C.O. split screen, and the monitor calculates the C.O. value from this curve.		Same	
Carbon dioxide (CO_2)	Is compatible with the following 3 modules to measure carbon dioxide: • Sidestream CO_2 Module • Microstream CO_2 Module • Mainstream CO_2 Module CO_2 monitoring is based on calculations from measuring the absorption of infrared (IR) light of specific wavelengths using a photodetector. Sidestream CO2 Module: Measurement range: 0 to 99 mmHg Accuracy: 0 to 40 mmHg: ±2 mmHg 41 to 76 mmHg: ±5% of the reading 77 to 99 mmHg: ±10% of the reading Microstream CO2 Module: Measurement range: 0 to 99 mmHg Accuracy: 0 to 38 mmHg: ±2 mmHg 39 to 99 mmHg: ±5% of the reading +0.08% of (the reading-38) Mainstream CO_2 Module Measurement range: 0 to150 mmHg Accuracy: 0 to 40 mmHg: ±2 mmHg 41 to 70 mmHg: ±5% of the reading 71 to 100 mmHg: ±8% of the reading 101 to 150 mmHg: ±10% of the reading		Same	
Anesthetic gas (AG)	Not supported	The AG module analyzes gas samples from the patient and calculates CO_2, O_2, N_2O and AA waves and related numerics, airway respiratory rate, and MAC (minimum alveolar concentration).	Same	Same

	Predicate Device (K132662)		Subject Devices	
Feature	**Passport 8**	**Passport 12**	**Passport 8**	**Passport 12**
2 New neonatal pre-wired electrodes	Not supported		Added	
DIAP output	Not supported.		Added. Output the measuring value and alarm limits of all the parameters by RS232 port.	

Substantial Equivalence Conclusion:
Based on the detailed comparison of specifications for each of the modifications to the previously cleared Passport Series devices (K132662) and relevant reference predicates, the performance testing and conformance with applicable standards, the Passport Series Patient Monitors (Passport 8 and Passport 12) can be found substantially equivalent to the predicate devices.