



Food and Drug Administration
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February 18, 2016

Shenzhen Mindray Bio-medical Electronics Co., Ltd
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan
Shenzhen, 518057 CN

Re: K152902

Trade/Device Name: Passport Series Patient Monitors (Passport 12m, Passport 17m and T1)

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, DSI, MLD, DRT, DXN, DSK, FLL, DQA, DPZ, CCK, CBQ, CBS, CBR, CCL, DSB, DXG, OLW

Dated: February 4, 2016

Received: February 5, 2016

Dear Yanhong Bai:

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,

Kenneth J. Cavanaugh -S

for

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)
K152902

Device Name
Passport Series Patient Monitors (Passport 12m, Passport 17m and T1)

Indications for Use (Describe)

Passport 12m and 17m Patient Monitors:

The Passport 17m and Passport 12m patient monitors are intended 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, QT analysis, and heart rate (HR)), respiration rate (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), pulmonary artery wedge pressure (PAWP), 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). The equipment also provides an interpretation of resting 12-lead ECG.

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

- The arrhythmia detection, ST Segment analysis of Mortara algorithm, BIS, RM, CCO, SvO₂/ScvO₂, and PAWP monitoring are intended for adult and pediatric patients only;
- ST Segment analysis of Mindray algorithm is intended for adult patients only;
- C.O. monitoring is restricted to adult patients only;
- ICG monitoring is only for use on adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 155kg.

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should 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.

T1 Patient Monitor:

The T1 Patient Monitor is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable, arrhythmia detection, ST Segment analysis, QT analysis, and heart rate (HR)), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), pulmonary artery wedge pressure (PAWP), and carbon dioxide (CO₂). The equipment also provides an interpretation of resting 12-lead ECG.

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

- The arrhythmia detection, ST Segment analysis of Mortara algorithm, and PAWP monitoring are intended for adult and pediatric patients;
- ST Segment analysis of Mindray ECG algorithm is intended for adult patients only.

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should 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.

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.

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 (including Passport 17m, Passport 12m and T1)

Submitter: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Date Prepared: September 30, 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 cardiometer and rate alarm)	monitor, cardiac (incl. cardiometer & 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
DSB	21 CFR 870.2770	Cardiovascular	Impedance plethysmograph	plethysmograph, impedance
DXG	21 CFR 870.1435	Cardiovascular	Single-function, preprogrammed diagnostic computer	computer, diagnostic, pre-programmed, single-function
OLW	21 CFR 882.1400	Neurology	Electroencephalograph	index-generating electroencephalograph software

Primary Predicate Device: K143195 - Passport Series Patient Monitors (Including Passport 17M, Passport 12m, and T1); Shenzhen Mindray Bio-Medical Electronics Co., Ltd

Reference Predicates:

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:

Passport 12m and 17m Patient Monitors:

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The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should 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.

T1 Patient Monitor:

The T1 Patient Monitor is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, or 5-lead, or 12-lead selectable, arrhythmia detection, ST Segment analysis, QT analysis, and heart rate (HR)), respiration (Resp), temperature (Temp), pulse oxygen saturation (SpO₂), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), pulmonary artery

wedge pressure (PAWP), and carbon dioxide (CO₂). The equipment also provides an interpretation of resting 12-lead ECG.

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

- The arrhythmia detection, ST Segment analysis of Mortara algorithm, and PAWP monitoring are intended for adult and pediatric patients;
- ST Segment analysis of Mindray ECG algorithm is intended for adult patients only.

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should 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.

Device Description:

The subject Passport Series Patient Monitors includes three monitors:

- Passport 12m Patient Monitor
- Passport 17m Patient Monitor
- T1 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 12m and 17m Patient monitors provide patient monitoring capabilities based on the user selected modules that are plugged into the main monitor. The T1 patient monitor is one of the available modules that can be plugged into the Passport 17m or 12m monitor. The T1 can also be used as a standalone monitor and when used as a standalone monitor, it provides a subset of the functions that are provided by Passport 17m and 12m.

Performance Data:

- To establish the substantial equivalence of the Passport Series Patient Monitors (including Passport 12m, Passport 17m and T1), 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 12m, Passport 17m and T1 devices 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 12m, Passport 17m and T1 as multiparameter monitors.

Comparison of Technological Characteristics - The table below compares the key technological feature of the subject devices to the primary predicate device (the Mindray Passport Series Patient Monitors K143195). 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

Feature	Predicate Device (K143195)			Subject Devices		
	17m	12m	T1	17m	12m	T1
Integrated display and touchscreen	17" 1280*1024 pixels	12" 800*600 pixels	5", 480*272 pixels	Same	Same	Same
Secondary display	Independent control and display	Display is linked to integrated display	Independent display and control via a VGA port in the T1 docking station	Same	Same	Same
Additional display features	The minitrends diagram, OxyCRG diagram, other monitor view, and calculation can be viewed when using an external LCD screen			Same	Same	Same
Wireless module	The ASUS module is used for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS).	Support wireless function using the ASUS and Silex wireless module.	Support wireless function using the Cyberlink wireless module	Same	Same	Same
Module rack	Independent of the patient monitor, provides 8 standard module slots to extend the measurement capabilities of the system		Not supported	Same	Same	Same

Feature	Predicate Device (K143195)			Subject Devices		
	17m	12m	T1	17m	12m	T1
Power supply	Two rechargeable Lithium-ion battery or AC power supply	One rechargeable Lithium-ion battery or AC power supply	One rechargeable Lithium-ion battery or DC power supply or AC power supply	Same	Same	Same
Battery	Chargeable Lithium-Ion, 11.1 VDC, 4500 mAh, 350 g		Chargeable Lithium-Ion, 7.4 VDC, 2500 mAh	Same	Same	Same
External memory card	Compact Flash		Secure Digital	Same	Same	Same
Data Recorder	The thermal recorder records patient information, measurement numerics, up to three waveforms, etc.		Not supported	Same	Same	Same
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation			Same	Same	Same
Supports T1 as a module	Supported		/	Same	Same	/
ECG (Mindray Algorithm)	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, an interpretation of resting 12-lead ECG, J-point Auto detection, Dual channel Pace detection and heart rate (HR)			Added QT analysis		
ECG (Mortara Algorithm)	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, J-point Auto detection, 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		
Adjustable QRS Detection Threshold (Mindray Algorithm)	Not supported			Added		
Respiration rate (Resp)	Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm. Accuracy: 7 to 150 rpm: ± 2 rpm or $\pm 2\%$, whichever is greater; 0 to 6 rpm: Not specified.			Same	Same	Same

Feature	Predicate Device (K143195)			Subject Devices														
	17m	12m	T1	17m	12m	T1												
Temperature (Temp)	Measurement range: 0 to 50°C (32 to 122°F) Accuracy: $\pm 0.1^{\circ}\text{C}$ or $\pm 0.2^{\circ}\text{F}$ (without probe)			Same	Same	Same												
Pulse oxygen saturation (SpO ₂)	<p>Mindray SpO₂ Module Measurement range: 0 to 100% Accuracy: 70 to 100%: $\pm 2\%$ (adult/pediatric mode) 70 to 100%: $\pm 3\%$ (neonate mode) 0% to 69%: Not specified.</p> <p>Masimo SpO₂ Module Measurement range: 1 to 100% Accuracy: 70 to 100%: $\pm 2\%$ (measured without motion in adult/pediatric mode) 70 to 100%: $\pm 3\%$ (measured without motion in neonate mode) 70 to 100%: $\pm 3\%$ (measured with motion) 1% to 69%: Not specified.</p> <p>Nellcor SpO₂ Module Measurement range: 0 to 100% Accuracy: 70 to 100%: $\pm 2\%$ (adult/pediatric) 70 to 100%: $\pm 3\%$ (neonate) 0% to 69%: Not specified.</p>			Same	Same	Same												
Pulse rate (PR)	<p>PR from Mindray SpO₂ Module Measurement range: 20 to 254 bpm Accuracy: ± 3 bpm</p> <p>PR from Masimo SpO₂ Module Measurement range: 25 to 240 bpm Accuracy: ± 3 bpm (measured without motion) ± 5 bpm (measured with motion)</p> <p>PR from Nellcor SpO₂ Module Measurement range: 20 to 300 bpm Accuracy: 20 to 250 bpm: ± 3 bpm 251 to 300 bpm, not specified</p> <p>PR from IBP Module Measurement range: 25 to 350 bpm Accuracy: ± 1 bpm or $\pm 1\%$, whichever is greater"</p>			Same	Same	Same												
Non-invasive blood pressure (NIBP)	<p>Measurement range:</p> <table border="0"> <tr> <td>Adult</td> <td>Pediatric</td> <td>Neonate</td> </tr> <tr> <td>Systolic: 40 to 270</td> <td>40 to 200</td> <td>40 to 135</td> </tr> <tr> <td>Diastolic: 10 to 210</td> <td>10 to 150</td> <td>10 to 100</td> </tr> <tr> <td>Mean: 20 to 230</td> <td>20 to 165</td> <td>20 to 110</td> </tr> </table> <p>Accuracy: Max mean error: ± 5 mmHg Max standard deviation: 8 mmHg</p>			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	Same	Same	Same
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																

Feature	Predicate Device (K143195)			Subject Devices		
	17m	12m	T1	17m	12m	T1
Invasive blood pressure (IBP)	Measurement range: -50 to 300 mmHg Accuracy: $\pm 2\%$ or ± 1 mmHg, whichever is greater (without sensor)			Same	Same	Same
Pulse Pressure Variation (PPV)	Supported feature of IBP			Same	Same	Same
Cardiac output (C.O.)	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. The monitor is capable of storing 6 measurements.	Not supported		Same	Same	Same
Continuous cardiac output (CCO)	CCO/SvO ₂ interface module is used to interface with Edwards Vigilance II monitor / Vigileo Monitor which measures continuous cardiac output (CCO) and mixed venous oxygen saturation (SvO ₂).	Not supported		Same	Same	Same
Mixed/central venous oxygen saturation (SvO ₂ /ScvO ₂)	CCO/SvO ₂ interface module is used to interface with Edwards Vigilance II monitor / Vigileo Monitor which measures mixed venous oxygen saturation (SvO ₂) and central venous oxygen saturation (ScvO ₂).	Not supported		Same	Same	Same
Carbon dioxide (CO ₂)	<p>Sidestream CO₂ Module: Measurement range: 0 to 99 mmHg Accuracy: 0 to 40 mmHg: ± 2 mmHg 41 to 76 mmHg: $\pm 5\%$ of the reading 77 to 99 mmHg: $\pm 10\%$ of the reading</p> <p>Microstream CO₂ Module: Measurement range: 0 to 99 mmHg Accuracy: 0 to 38 mmHg: ± 2 mmHg 39 to 99 mmHg: $\pm 5\%$ of the reading $\pm 5\%$ of the reading + 0.08% of (the reading - 38)</p> <p>Mainstream CO₂ Module: Measurement range: 0 to 150 mmHg Accuracy: 0 to 40 mmHg: ± 2 mmHg 41 to 70 mmHg: $\pm 5\%$ of the reading 71 to 100 mmHg: $\pm 8\%$ of the reading 101 to 150 mmHg: $\pm 10\%$ of the reading</p>			Same	Same	Same

Feature	Predicate Device (K143195)			Subject Devices		
	17m	12m	T1	17m	12m	T1
Oxygen (O ₂)	Oxygen values are calculated based on user input and not directly measured.		Not supported	Same	Same	Same
Anesthetic gas (AG)	The AG module can identify two anesthetic gases in a mixture automatically and distinguish between them according to their contributions to the MAC value for display as the primary and secondary anesthetic agents.		Not supported	Same	Same	Same
Impedance cardiograph (ICG)	Measurement range: SV: 5 to 250 ml HR: 44 to 2m C.O. 1.4 to 15 L/min Accuracy: SV: Not specified. HR: ±2 bpm C.O. Not specified.		Not supported	Same	Same	Same
Bispectral index (BIS)	Measured parameters: EEG, BIS, BIS L, BIS R		Not supported	Same	Same	Same
Respiration mechanics (RM)	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."		Not supported	Same	Same	Same
2 New neonatal pre-wired electrode	Not supported			Added		

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications for each of the modifications to the previously cleared Passport Series devices (K143195), the performance testing and conformance with applicable standards, the Passport Series Patient Monitors (including Passport 12m, Passport 17m and T1) can be found substantially equivalent to the predicate devices.