July 10, 2019

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park, Nanshan
Shenzhen, 518057, P.R. China

Re: K190011
Trade/Device Name: Passport Series Patient Monitors (including Passport 17m, Passport 12m 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, DQA, DRT, DSI, DSK, DXN, FLL, MLD, DPZ, CCK, CBQ, CBS, CBR, CCL, DSB, DXG, OLW, DSJ, KOI, GXY
Dated: June 6, 2019
Received: June 10, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Nicole Goodsell
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190011

Device Name
Passport Series Patient Monitors (including 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), respiration mechanics (RM), and neuromuscular transmission monitoring (NMT). 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, PAWP monitoring and NMT 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.

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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 12m, Passport 17m and T1)

Submitter

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Date Prepared

December 31, 2018

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	Anesthesiology	Enflurane gas analyzer	analyzer, gas, enflurane,

	868.1500			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
DSJ	21 CFR 870.1100	Cardiovascular	Blood pressure alarm	alarm, blood-pressure
KOI	21 CFR 868.2775	Anesthesiology	Electrical peripheral nerve stimulator	stimulator, nerve, peripheral, electric
GXY	21 CFR 870.1320	Neurology	Cutaneous electrode.	electrode, cutaneous

Primary Predicate Device:

K152902 - Passport Series Patient Monitors (Passport 12m, Passport 17m, and T1)
Shenzhen Mindray Bio-Medical Electronics Co., Ltd

K170876 - Passport Series Patient Monitors (Passport 12m and Passport 17m)
Shenzhen Mindray Bio-Medical Electronics Co., Ltd

Secondary Predicate Device:

K182075 -BeneVision N Series Patient Monitors
Shenzhen Mindray Bio-Medical Electronics Co., Ltd

K171292 - A7 Anesthesia System
Shenzhen Mindray Bio-Medical Electronics Co., Ltd

Indications for Use:

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), respiration mechanics (RM), and neuromuscular transmission monitoring (NMT). 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, PAWP monitoring and NMT 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 (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), pulmonary artery wedge pressure (PAWP), and carbon dioxide (CO_2). 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.

Substantial Equivalence:

Comparison of Indications

The indications for use of the subject devices have not changed in this 510(K).
Indications of the predicate device (Passport 12m and 17m Patient Monitors K170876,T1 Patient Monitor K152902) and the subject device (Passport 12m,Passport 17m and T1)) are the same.

Comparison of Technological Characteristics

The table below compares the key technological feature of the subject devices to the primary predicate device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902). 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 (Compare with Passport 12m and 17m Patient Monitors K170876,T1 Patient Monitor K152902)

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 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		
Wireless module	The ASUS module is used for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS).	The ASUS, Silex and Laird modules are used for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS).	The Cyberlink modules is used for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS).	Same	Same	Laird (2.4GHz/5GHz) wireless module is added

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Module rack	Independent of the patient monitor, provides 8 standard module slots to extend the measurement capabilities of the system		Not supported	Same		Same
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
External memory card	Compact Flash		Secure Digital	Same		Same
Data Recorder	The thermal recorder records patient information, measurement numerics, up to three waveforms, etc.		Not supported	Same		Same
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation			Same		
Supports T1 as a module	Supported		/	Same		Same
Supports N1 as a module	Not supported		Not supported	Supported		Same

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
MPM module	MPM 2.0 module, it support: 3/5/12 lead ECG, NIBP, dual channel Temp, SpO2, dual channel IBP measurement		/	MPM 3.0 module is added, it support: 3/5/12 lead ECG, NIBP, dual channel Temp, SpO2, dual channel IBP measurement When MPM 3.0 module is used with Passport 12m and 17m, the functionality and performance is same with MPM 2.0 module.		/
ECG	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, heart rate (HR), an interpretation of resting 12-lead ECG, J-point Auto detection, Dual Channel Pace detection and Adjustable QRS Detection Threshold			Same		
Arrhythmia Analysis (Mindray Algorithm)	Asystole, VFib/VTac, Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVCs, Tachy, Brady, Missed Beats, Vent. Rhythm, PNP, PNC, Multif. PVC, Nonsus. Vtac, Pause, Irr. Rhythm, AFib			Same		
Arrhythmia Analysis (Mortara Algorithm)	Asystole, Vfib, Vtac, Vent. Rhythm, Couplet, Run PVCs, Bigeminy, Trigeminy, R on T, Multif. PVC, Irr. Rhythm, Tachy, Brady, Missed Beats, PNP, PNC, PVCs			Same		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Respiration rate (Resp)	Uses the MPM (Multi Parameter Module) to measure the change in impedance measured across the thorax to determine the respiration rate.			Same		
Temperature (Temp)	Uses the MPM (Multi Parameter Module) to measure core and skin temperature. The patient monitor can monitor two temperatures simultaneously using thermally sensitive resistors (thermistors).			Same		
Pulse oxygen saturation (SpO_2)	Uses the MPM (Multi Parameter Module) or the SpO2 module to measure the amount of oxygenated haemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. Is compatible with the following 3 modules to measure oxygen saturation: • Mindray SpO_2 Module • Masimo SpO_2 Module • Nellcor SpO_2 Module			Same		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Pulse rate (PR)	PR from Mindray SpO2 Measurement range: 20 to 254 bpm Accuracy:±3 bpm PR from Masimo SpO2 Measurement range: 25 to 240 bpm Accuracy:±3 bpm (measured without motion) ±5 bpm (measured with motion) PR from Nellcor SpO2 Measurement range: 20 to 300 bpm Accuracy:20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified PR from IBP Measurement range: 25 to 350 bpm Accuracy:±1 bpm or ±1%, whichever is greater PR from NIBP Measurement range: 40 to 240 bpm Accuracy: ±3 bpm or ±3%, whichever is greater			PR from Mindray SpO2 Same PR from Masimo SpO2 Same PR from Nellcor SpO2 Same PR from IBP Same PR from NIBP Measurement range: 30 to 300 bpm Accuracy: Same		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Non-invasive blood pressure (NIBP)	Measurement range: Adult: Systolic: 40-270 mmHg Diastolic: 10-210 mmHg Mean:20-230 mmHg Pediatric: Systolic:40-200mmHg Diastolic:10-150mmHg Mean:20-165mmHg Neonate: Systolic:40-135 mmHg Diastolic:10-100mmHg Mean:20-110 mmHg Accuracy: Max mean error: ±5 mmHg Max standard deviation: 8 mmHg			Measurement range: Adult: Systolic: 25-290 mmHg Diastolic: 10-250 mmHg Mean:15-260 mmHg Pediatric: Systolic:25-240mmHg Diastolic:10-200mmHg Mean:15-215mmHg Neonate: Systolic:25-140 mmHg Diastolic:10-115 mmHg Mean:15-125 mmHg Accuracy: Same		
Invasive blood pressure (IBP)	Uses the MPM (Multi Parameter Module) or the IBP Module to measure invasive blood pressure. The monitor can monitor up to 8 invasive blood pressures and displays systolic, diastolic and mean pressures and a waveform for each pressure. Supports the PPV function.			Same		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Pulse Pressure Variation (PPV)	Supported feature of IBP			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
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), mixed venous oxygen saturation (SvO_2) and central venous oxygen saturation ($ScvO_2$).		Not supported	Same		Same
Central venous oxygen saturation ($ScvO_2$)	ScvO2 module is used to measure central venous oxygen saturation ($ScvO_2$).		Not supported	Same		Same

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
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 2.0 module is added, the functionality and performance is same with Sidestream CO2 1.0 module. The other modules and specifications remains the same.		Same
Anesthetic gas (AG)	Is compatible with the following 2 modules to measure Anesthetic gas: • 3-slot AG Module • 2-slot AG Module The AG module analyzes gas samples from the patient and calculates CO2, O2, N2O and AA waves and related numerics, airway respiratory rate, and MAC (minimum alveolar concentration). Supports the 3-slot AG module.		Not supported	Support Sample Gas Recycling feature for AG module		Same

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Impedance cardiograph (ICG)	Uses the ICG Module to measure a patient's hemodynamic status using a non-invasive method based on thoracic electrical bioimpedance (TEB) technology.		Not supported	Same		Same
Bispectral index (BIS)	Measured parameters: EEG, BIS, BIS L, BIS R		Not supported	Same		Same
Respiration mechanics (RM)	Measures respiration mechanics for adults, pediatrics and infants.		Not supported	Same		Same

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
NMT	Uses the NMT module to monitor objective neuromuscular transmission. It evaluates muscle relaxation of patients under neuromuscular block by measuring the strength of muscle reaction after electrically stimulating the dedicated motor nerve.		Not supported	Same		Same

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
cleaning and disinfecting agents	List of agents: Sodium hypochlorite bleach Hydrogen peroxide Isopropanol Rely+On TMVirkon® 1-Propanol Perform®			More agents are added: Metrex CaviCide1™ Virex® II 256 Virex® TB Alpet® D2 Surface Sanitizing Wipes Clorox Dispatch ® Hospital Cleaner Disinfectant Towels with Bleach Clorox Healthcare® Bleach Germicidal Wipes Clorox Healthcare ® Hydrogen Peroxide Cleaner Disinfectant Wipes Diversey Oxivir® TB Wipes Metrex CaviWipes™ PDI Sani-Cloth® AF3 Germicidal Disposable Wipe PDI Sani-Cloth® Bleach Germicidal Disposable Wipe PDI Sani-Cloth® HB Germicidal Disposable Wipe PDI Sani-Cloth® Plus Germicidal Disposable Cloth PDI Super Sani-Cloth® Germicidal Disposable Wipe VIRAGUARD Hospital Surface Disinfectants		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Support new Masimo SpO2 accessories	Not supported			Added: 040-003378-00 RD SET MD 14-05, PC 5 ft 040-003379-00 RD SET MD 14-12, Patient Cable 12 ft 040-003310-00 8pin masimo Cable（RD SET） 040-003426-00 LNCS to RD Adapter 040-003381-00 RD to LNC Adapter Cable 040-003376-00 RD SET DCI, Adult Reusable Sensor 040-003377-00 RD SET DCI, Pediatric Reusable Sensor 040-003380-00 RD Set TC-I SpO2 Reusable Tip-Clip Ear Sensor, 3ft 040-003382-00 RD SET Adhesive Sensor 040-003383-00 RD SET PDT Adhesive Sensor 040-003384-00 RD Set Infant Adhesive Sensor 040-003385-00 RD Set Neo Adhesive Sensor 040-003386-00 RD Set NeoPt Adhesive Sensor 040-003387-00 RD Set NeoPt-500 Non-adhesive sensor		
Support new ECG accessories	Not supported			Added： 040-003528-00 ECG cable, 12-lead, defibrillation-proof, AHA		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Support new CO2 accessories	Not supported			Added: 100-000138-00 DRYLINE PRIME Gas Sampling Line With Airway Adapter, Adult/Pediatric 100-000139-00 DRYLINE PRIME Gas Sampling Line With Airway Adapter, Neonate 100-000140-00 RYLINE PRIME+ Gas Sampling Line With Airway Adapter, Adult/Pediatric 100-000141-00 DRYLINE PRIME+ Gas Sampling Line With Airway Adapter, Neonate 100-000142-00 DRYLINE PRIME Nasal Gas Sampling Line, Adult 100-000143-00 DRYLINE PRIME Nasal Gas Sampling Line, Pediatric 100-000144-00 DRYLINE PRIME Nasal Gas Sampling Line, Neonate 100-000145-00 DRYLINE PRIME+ Nasal Gas Sampling Line, Adult 100-000146-00 DRYLINE PRIME+ Nasal Gas Sampling Line, Pediatric 100-000147-00 DRYLINE PRIME+ Nasal Gas Sampling Line, Neonate 100-000151-00 DRYLINE PRIME Water Trap Mini		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Improve the SpO2/CO2/BIS signal cord resistance to damage	Not supported			Supported Note: T1 doesn't support BIS module		
Corrected an issues where NIBP misreported "NIBP Excessive Motion" after 49 days of running	Not supported			Supported		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
The End tidal (Et) and Fraction of inspired (Fi) numerics for anesthetic agent (AA) physiological alarms are trigged only when the monitored parameter value is higher than the high alarm limit or is lower than the low alarm limit	Not supported			Supported		Same
Extend the setting range of low alarm limit of EtO_2	Not supported			Supported		Same

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Support the non-overlapping relationships of alarm limit setting of physiological alarms	Not supported			Supported		
Support re-alarming after a physiological alarm is reset	Not supported			Supported		
Support password protection for accessing the Alarm Setup menu	Not supported			Supported		
Support authorization of the user via the LDAP	Not supported			Supported		
Support the Facility information of patient monitor	Not supported			Supported		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Support the Room No. information of patient monitor	Not supported			Supported		
Support the Visit Number in the patient demographics	Not supported			Supported		
Support printing of the arrhythima settings in reports	Not supported			Supported		
Change the factory default setting of printer paper size	Not supported			Supported		
Support to display the MAC address of patient monitor	Not supported			Supported		
Support the display mode of ST values in the parameter tile	Not supported			Supported		

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Support encryption of patient private information sent to the network	Not supported			Supported		
Support Laird 2.4GHz/5GHz Wifi module	Supported		Not supported	Same		Supported
Support adjustment of the ST point on multiple displayed leads	Supported		Not supported	Same		Supported
Support QT report printing	Supported		Not supported	Same		Supported
Support NIBP measurement on clock	Supported		Not supported	Same		Supported
Support network application transmission priority setting	Supported		Not supported	Same		Supported
Support ECG beat annotation	Supported		Not supported	Same		Supported

	Predicate Device (Passport 12m and 17m Patient Monitors K170876, T1 Patient Monitor K152902)			Subject Devices		
Feature	**Passport 17m**	**Passport 12m**	**T1**	**Passport 17m**	**Passport 12m**	**T1**
Support DNS for ADT and LDAP server address	Not supported			Same		Supported
Corrected an issues where the Bed No. of the Passport 12m/17m is changed after T1 is pulled out of the monitors	Not supported			Same		Supported

Performance Data

- To establish the substantial equivalence of the Passport Series Patient Monitors (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.

  ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance

  IEC 60601-1-2 :2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests

  IEC 60601-2-25: 2011 (2nd edition) Particular requirements for the basic safety and essential performance of electrocardiographs

  IEC 60601-2-27:2011 (3rd edition) Particular requirements for the safety, including essential performance of electrocardiographic monitoring equipment

  ISO 80601-2-61:2011 Particular requirements for the basic safety and essential performance of pulse oximeter equipment

  IEC 80601-2-30:2009/AMD1:2013 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

  ISO 80601-2-56:2009 (First edition) Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement

  IEC 60601-2-34 (Third Edition): 2011 Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

  IEC 60601-2-49:2011 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

  ISO 80601-2-55 First edition 2011-12-15 Medical electrical equipment - Part

2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications for each of the modifications to the previously cleared Passport Series devices, Passport 12m and Passport 17m (K170876) and relevant reference predicates, T1 (K152902) and relevant reference predicates, the performance testing results and conformance with applicable standards show that the Passport Series Patient Monitors (including Passport 12m, Passport 17m and T1) can be found substantially equivalent to the predicate devices.