May 20, 2026

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Li Lei
Technical Regulation Manager
Mindray Bldg., Keji 12th Rd. S.
Hi-Tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
China

Re: K260098
Trade/Device Name: ePM Series Patient Monitor (ePM 10/ePM 10A/ePM 10C/Guardian plus/ ePM 12/ePM 12A/ePM 12C / ePM 15/ePM 15A/ePM 15C /ePM 10M/ ePM 10MA/ ePM 10MC/ePM 12M/ ePM 12MA/ ePM 12MC/ePM 15M/ ePM 15MA/ ePM 15MC)
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, DXG, DSJ, CBQ, CBS, CBR, CCL, KOI, OLW, OLT, OMC, ORT, GXY
Dated: April 22, 2026
Received: April 22, 2026

Dear Li Lei:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260098

Please provide the device trade name(s).

ePM Series Patient Monitor (ePM 10/ePM 10A/ePM 10C/Guardian plus/ ePM 12/ePM 12A/ePM 12C / ePM 15/ePM 15A/ePM 15C /ePM 10M/ ePM 10MA/ ePM 10MC/ePM 12M/ ePM 12MA/ ePM 12MC/ePM 15M/ ePM 15MA/ ePM 15MC)

Please provide your Indications for Use below.

The ePM 10/ePM 10A/ePM 10C/Guardian plus/ ePM 12/ePM 12A/ePM 12C / ePM 15/ePM 15A/ePM 15C / ePM 10M/ ePM 10MA/ ePM 10MC/ePM 12M/ ePM 12MA/ ePM 12MC/ePM 15M/ ePM 15MA/ ePM 15MC patient monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, 6-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.), Carbon Dioxide (CO2), Oxygen (O2) and Anesthetic Gas (AG), Bispectral Index (BIS), Neuromuscular Transmission Monitoring (NMT). The system also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients except for the following:

- NMT, the PAWP monitoring is intended for adult and pediatric patients only;
- BIS monitoring is only intended for patients aged 4 years and above;
- C.O. monitoring is intended for adult and pediatric patients.

The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use. The ePM 10/10A/10C/ Guardian plus/ ePM 12/ePM 12A/ePM 12C / ePM 15/ePM 15A/ePM 15C /ePM 10M/ ePM 10MA/ ePM 10MC/ePM 12M/ ePM 12MA/ ePM 12MC/ePM 15M/ ePM 15MA/ ePM 15MC monitors are not intended for helicopter transport, hospital ambulance, or home use.

Please select the types of uses (select one or both, as applicable).

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

1. SUBMITTER INFORMATION

Applicant:	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Contact:	Li Lei
Phone:	+86 755 81885953
Email:	lilei.js@mindray.com
Address	Mindray Building, Keji 12th Road South Hi-tech Industrial Park, Nanshan Shenzhen Guangdong 518057, China

2. CORRESPONDENT INFORMATION

Contact:	Li Lei
Title:	Manager, Technical Regulations Department
Firm:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Phone:	+86 755 81885953
Email:	lilei.js@mindray.com

3. DATE PREPARED: APRIL 14, 2026

4. DEVICE INFORMATION

Device Name:	ePM Series Patient Monitor
Common Name:	Patient Monitor
Regulation Number:	21 CFR 870.1025
Regulation Name:	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Product Code:	MHX
Regulatory Class:	2

Table 1: Secondary Product Codes

Regulation Number/Class	Product Code	Regulation description	Device Common Name
870.1025, II	DSI	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Detector and alarm, arrhythmia

Regulation Number/Class	Product Code	Regulation description	Device Common Name
870.1025, II	MLD	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Monitor, st segment with alarm
870.2300, II	DRT	Cardiac Monitor (including cardiotachometer and rate alarm)	Monitor, cardiac (incl. cardiotachometer & rate alarm)
870.1130, II	DXN	Noninvasive blood pressure measurement system	System, measurement, blood-pressure, non-invasive
870.1110, II	DSK	Blood pressure computer	Computer, blood-pressure
880.2910, II	FLL	Clinical electronic thermometer	Thermometer, electronic, clinical
870.2700, II	DQA	Oximeter	Oximeter
870.2710, II	DPZ	Ear oximeter	Oximeter, ear
868.1400, II	CCK	Carbon dioxide gas analyzer	Analyzer, gas, carbon-dioxide, gaseous-phase
870.1435, II	DXG	Single-function, preprogrammed diagnostic computer	Computer, diagnostic, pre-programmed, single-function
870.1100, II	DSJ	Blood pressure alarm	Alarm, blood-pressure
868.1500, II	CBQ	Enflurane gas analyzer	Analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)
868.1620, II	CBS	Halothane gas analyzer	Analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
868.1700, II	CBR	Nitrous oxide gas analyzer	Analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
868.1720, II	CCL	Oxygen gas analyzer	Analyzer, gas, oxygen, gaseous-phase
868.2775, II	KOI	Electrical peripheral nerve stimulator.	Stimulator, nerve, peripheral, electric
882.1400, II	OLW	Electroencephalograph.	Index-generating electroencephalograph software
882.1400, II	OLT	Electroencephalograph	Non-normalizing quantitative electroencephalograph software

Regulation Number/Class	Product Code	Regulation description	Device Common Name
882.1400, II	OMC	Electroencephalograph.	Reduced- montage standard electroencephalograph
882.1400, II	ORT	Electroencephalograph	Burst suppression detection software for electroencephalograph
882.1320, II	GXY	Cutaneous electrode.	Electrode, cutaneous

5. PREDICATE DEVICE INFORMATION

Primary Predicate Device Name: ePM Series Patient Monitor

510(k) Number: K200015

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

6. DEVICE DESCRIPTION

The subject devices are the ePM Series Patient Monitors family, which consists of the 19 monitors identified in **Table 2**.

Table 2 Overview of ePM-series monitors

ePM-Series Patient Monitor Model	Description
ePM 10M/10MA/10MC ePM 12M/12MA/12MC ePM 15M/15MA/15MC	ePM 10M / 10MA / 10MC / 12M / 12MA / 12MC / 15M / 15MA / 15MC consist of the main unit, internal modules, external modules, input devices, output devices, an internal rack, a Satellite Module Rack.
ePM 10/10A/10C/Guardian plus ePM 12/12A/12C ePM 15/15A/15C	ePM 10/10A/10C/Guardian plus/12/12A/12C/15/15A/15C consist of the main unit, internal modules, input devices, and output devices.

The differences between the ePM 10M/10MA/10MC, ePM 12M/12MA/12MC, and ePM 15M/15MA/15MC include the display size and resolution, the configuration of built-in CO2 module, the number of batteries, and the AC-power module.

The differences between the xxM/xxMA/xxMC models include the base, rear cover color and the work mode.

The differences between the ePM 10/10A/10C/Guardian plus, ePM 12/12A/12C and ePM 15/15A/15C consist of the display size and the number of batteries.

The differences between the xx/xxA/xxC/Guardian plus models include the base, rear cover color and the work mode.

All the other hardware and software is the same.

7. INDICATIONS FOR USE

The indications for use statement for the ePM Series Patient Monitors is provided below.

The ePM 10/ePM 10A/ePM 10C/Guardian plus/ ePM 12/ePM 12A/ePM 12C / ePM 15/ePM 15A/ePM 15C /ePM 10M/ ePM 10MA/ ePM 10MC/ePM 12M/ ePM 12MA/ ePM 12MC/ePM 15M/ ePM 15MA/ ePM 15MC patient monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, 6-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.), Carbon Dioxide (CO2), Oxygen (O2) and Anesthetic Gas (AG), Bispectral Index (BIS), Neuromuscular Transmission Monitoring (NMT). The system also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients except for the following:

- NMT, the PAWP monitoring is intended for adult and pediatric patients only;
- BIS monitoring is only intended for patients aged 4 years and above;
- C.O. monitoring is intended for adult and pediatric patients.

The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use. The ePM 10/10A/10C/ /Guardian plus/ ePM 12/ePM 12A/ePM 12C / ePM 15/ePM 15A/ePM 15C /ePM 10M/ ePM 10MA/ ePM 10MC/ePM 12M/ ePM 12MA/ ePM 12MC/ePM 15M/ ePM 15MA/ ePM 15MC monitors are not intended for helicopter transport, hospital ambulance, or home use.

8. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 3 provides a comparison of the technological features of system compared to the predicate system in K200015.

Table 3: Device Comparison Table

Feature	ePM 10	ePM 12	ePM 15	ePM 10M	ePM 12M	ePM 15M	ePM 10 / 10A / 10C / Guardian plus	ePM 12 / 12A / 12C	ePM 15 / 15A / 15C	ePM 10M / 10MA / 10MC	ePM 12M / 12MA / 12MC	ePM 15M / 15MA / 15MC
	Cleared in K200015						**Subject Device**					
Base and rear cover colors	Dark blue						ePM 10/Guardian plus: Dark blue ePM 10A/10C: Medium blue-gray	ePM 12: Dark blue ePM 12A/12C: Medium blue-gray	ePM 15: Dark blue ePM 15A/15C: Medium blue-gray	ePM 10M: Dark blue ePM 10MA / 10MC: Medium blue-gray	ePM 12M: Dark blue ePM 12MA/12MC: Medium blue-gray	ePM 15M: Dark blue ePM 15MA/15MC: Medium blue-gray
Work Mode	Support standby mode, privacy mode, night mode and intubation mode.			Support CPB mode, standby mode, privacy mode, night mode and intubation mode.			ePM 10/10A/ Guardian plus support standby mode, privacy mode, night mode and intubation mode. ePM 10C supports standby mode, night mode and intubation mode, and optional privacy mode.	ePM 12/12A support standby mode, privacy mode, night mode and intubation mode. ePM 12C supports standby mode, night mode and intubation mode, and optional privacy mode.	ePM 15/15A support standby mode, privacy mode, night mode and intubation mode. ePM 15C supports standby mode, night mode and intubation mode, and optional privacy mode.	ePM 10M/10MA support CPB mode, standby mode, privacy mode, night mode and intubation mode. ePM 10MC supports CPB mode, standby mode, night mode and intubation mode, and optional privacy mode	ePM 12M/12MA support CPB mode, standby mode, privacy mode, night mode and intubation mode. ePM 12MC supports CPB mode, standby mode, night mode and intubation mode, and optional privacy mode.	ePM 15M/15MA support CPB mode, standby mode, privacy mode, night mode and intubation mode. ePM 15MC supports CPB mode, standby mode, night mode and intubation mode, and optional privacy mode.
Primary Display	10.1”	12.1”	15.6”	10.1”	12.1”	15.6”	10.1”	12.1”	15.6”	10.1”	12.1”	15.6”
Display and touch screen resolution	1280*800 pixels	1280*800 pixels	1366*768 pixels	1280*800 pixels	1280*800 pixels	1366*768 pixels	1280*800 pixels	1280*800 pixels	1366*768 pixels	1280*800 pixels	1280*800 pixels	1366*768 pixels
Secondary display	Mirrored display VGA display output						Mirrored display TMDS display output					
Wireless module	Supports Laird Wireless Module 2.4G/5G module for connecting to a network wirelessly to construct a monitoring network with a central monitoring system (CMS).						Supports Silex Wireless Module 2.4G/5G module for connecting to a network wirelessly to construct a monitoring network with a central monitoring system (CMS).					
Internal Module rack	Not supported	Not supported	Not supported	Supported pogo pin-based and infrared-based communication	Supported pogo pin-based and infrared-based communication	Supported pogo pin-based and infrared-based communication	Not supported	Not supported	Not supported	Supported pogo pin-based communication	Supported pogo pin-based communication	Supported pogo pin-based communication
Satellite Module Rack	Not supported	Not supported	Not supported	Not supported	Not supported	Not supported	Not supported	Not supported	Not supported	Supported	Supported	Supported
Main Control Hardware Platform	AM335x，DDR3 (standard configuration: 512 MB; full configuration: 1 GB)						AM62X, 1GB DDR4					
Power supply	One rechargeable Lithium ion battery or 40WAC power supply	One or two rechargeable Lithium- ion batteries or 40W AC power supply.		One rechargeable Lithium ion battery or 40W AC power supply	One or two rechargeable Lithium ion batteries or 40W AC power supply.	One or two rechargeable Lithium ion batteries or 63W AC power supply	One rechargeable Lithium ion battery or 40WAC power supply	One or two rechargeable Lithium ion batteries or 40W AC power supply.		One rechargeable Lithium ion battery or 65W AC power supply	One or two rechargeable Lithium ion batteries or 65W AC power supply.	One or two rechargeable Lithium ion batteries or 63W AC power supply
External battery box	Not supported	Supported	Not supported	Not supported	Supported	Not supported	Not supported	Supported	Not supported	Not supported	Supported	Not supported
Battery	Chargeable Lithium-Ion, 10.8VDC, 5600 mAh. Chargeable Lithium-Ion, 10.95 VDC, 4500 mAh. Chargeable Lithium-Ion, 10.95 VDC, 2600 mAh						Chargeable Lithium-Ion, 10.8VDC, 5600 mAh. Chargeable Lithium-Ion, 10.95 VDC, 5200 mAh. Chargeable Lithium-Ion, 10.95 VDC, 2600 mAh					
Data storage	Embedded Multi Media Card (eMMC)： Two 4GB eMMC or one 8GB eMMC.						Embedded Multi Media Card (eMMC)： One 8 GB eMMC					
Data Recorder	Supports a built-in thermal recorder						Supports a built-in thermal recorder					
Device Integration	Use the RS-232 interface to integrate 3rd party devices. Allow parameter values, waveforms and alarms from 3rd party devices to be displayed, stored and printed.						Use the RS-232 interface to integrate 3rd party devices. Allow parameter values, waveforms and alarms from 3rd party devices to be displayed, stored and printed.					
Speaker	Provides audible alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multilevel tone modulation.						Provides audible alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multilevel tone modulation.					
Alarm System	Supports alarm volume escalation. The alarm lamp will light cyan, yellow, or red depending on the alarm type. Supports ISO, mode 1, and mode 2 auditory alarm signals.						Supports alarm volume escalation. The alarm lamp will light cyan, yellow, or red depending on the alarm type. Supports ISO, mode 1, mode 2 and ISO3 auditory alarm signals.					
ECG	Uses the multi- parameter module integrated on the main control board to measure the ECG signal and support 3-lead, 5-lead, 6-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, J-point Auto detection, Dual Channel Pace detection, adjustable QRS threshold, Multi-lead ECG synchronization analysis and heart rate (HR). Supports intelligent arrhythmia alarm. HR Measurement range:15~350bpm (neonate, pediatric), 15~300bpm(adult); Accuracy: ±1 bpm or ±1%, whichever is greater. ST Measurement range: -2.0mV~+2.0mV; Accuracy: -0.8mV~+0.8mV, Accuracy: ±0.02mV or ±10%, whichever is greater, other range: not specified. QT Measurement range: 200~800ms; Accuracy: ±30ms. Supports two-channel ECG analysis algorithm						Uses the multi- parameter module integrated on the main control board to measure the ECG signal and support 3-lead, 5-lead, 6-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, J-point Auto detection, Dual Channel Pace detection, adjustable QRS threshold, Multi-lead ECG synchronization analysis and heart rate (HR). Supports intelligent arrhythmia alarm. HR Measurement range:15~350bpm (neonate, pediatric), 15~300bpm(adult); Accuracy: ±1 bpm or ±1%, whichever is greater. ST Measurement range: -2.0mV~+2.0mV; Accuracy: -0.8mV~+0.8mV, Accuracy: ±0.02mV or ±10%, whichever is greater, other range: not specified. QT Measurement range: 200~800ms; Accuracy: ±30ms. Supports four-channel ECG analysis algorithm					

Feature	ePM 10	ePM 12	ePM 15	ePM 10M	ePM 12M	ePM 15M	ePM 10 / 10A / 10C / Guardian plus	ePM 12 / 12A / 12C	ePM 15 / 15A / 15C	ePM 10M / 10MA / 10MC	ePM 12M / 12MA / 12MC	ePM 15M / 15MA / 15MC
	Cleared in K200015						**Subject Device**					
Respiration rate (Resp)	Uses the multi- parameter module integrated on the main control board to measure the respiration waveforms and respiratory rate through trans-thoracic impedance method. 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.						Uses the multi- parameter module integrated on the main control board to measure the respiration waveforms and respiratory rate through trans-thoracic impedance method. 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.					
Temperature (Temp)	Uses the multi- parameter module integrated on the main control board to measure temperature using the thermal resistance method. Measurement range: 0 to 50°C (32 to 122°F). Accuracy: ±0.1°C or ±0.2°F (without probe).						Uses the multi- parameter module integrated on the main control board to measure temperature using the thermal resistance method. Measurement range: 0 to 50°C (32 to 122°F). Accuracy: ±0.1°C or ±0.2°F (without probe).					
Pulse oxygen saturation (SpO2)	Uses the built-in multi parameter module integrated on the main control board or built-in third part SpO2 Module installed on the main control board to measure Pulse oxygen saturation. ePM series patient monitors are compatible with the following 3 types of modules to measure oxygen saturation: Built-in Mindray SpO2 module is integrated on the main control board Measurement range:0~100% Accuracy:70%~100%: ±2%ABS (Adult/Pediatric); 70%~100%: ±3%ABS (Neotate); 0~69%: not specified. Built-in Masimo SpO2 module is installed on the main control board Measurement range:1~100%, Accuracy: without motion 70%~100%: ±2%ABS (Adult/Pediatric), 70%~100%: ±3%ABS (Neotate), 1~69%: not specified; With motion 70%~100%: ±3%ABS, 1~69%: not specified. Nellcor SpO2 module is installed on the main control board Measurement range:0~100 %, Accuracy: 70%~100%: ±2%ABS (Adult/Pediatric); 70%~100%:±3%ABS (Neotate); 0~69%: not specified.						The external SpO_2 module can be used on ePM 10M/10MA/10MC/12M/12MA/12MC/15M/15MA/15MC The built- in SpO2 module can be used on ePM 10/10A/10C/Guardian plus/12/12A/12C/15/15A/15C /10M/10MA/10MC/12M/12MA/12MC/15M/15MA/15MC. Uses the built-in multi parameter module integrated on the main control board， built-in third part SpO2 Module installed on the main control board or external SpO2 module to measure Pulse oxygen saturation ．ePM series patient monitors are compatible with the following 3 types of modules to measure oxygen saturation: Built-in Mindray SpO2 module is integrated on the main control board Measurement range:0~100% Accuracy:70%~100%: ±2%ABS (Adult/Pediatric); 70%~100%: ±3%ABS (Neotate); 0~69%: not specified. Built-in Masimo SpO2 module (MSX2040) is installed on the main control board Measurement range:1~100%, Accuracy: without motion 70%~100%: ±2%ABS (Adult/Pediatric), 70%~100%: ±3%ABS (Neotate), 1~69%: not specified; With motion 70%~100%: ±3%ABS, 1~69%: not specified. Nellcor SpO2 module is installed on the main control board Measurement range:0~100 %, Accuracy: 70%~100%: ±2%ABS (Adult/Pediatric); 70%~100%:±3%ABS (Neotate); 0~69%: not specified.					
Pulse rate (PR)	Pulse rate may be obtained from the SpO2 measurement or the IBP measurement. Measurement range: 20~254bpm (Mindry SpO2), 25~240bpm (Masimo SpO2), 20~300bpm (Nellcor SpO2), 25~350bpm (IBP). Accuracy: ±3 bpm (Mindray SpO2), ±3 bpm without motion, ±5 bpm with motion (Masimo); 20~250bpm ±3 bpm; 251~300bpm, not specified (Nellcor SpO2); ±1 bpm or ±1%, whichever is greater (IBP).						Pulse rate may be obtained from the SpO2 measurement or the IBP measurement. Measurement range: 20~254bpm (Mindry SpO2), 25~240bpm (Masimo SpO2) (MSX2040) , 20~300bpm (Nellcor SpO2), 25~350bpm (IBP). Accuracy: ±3 bpm (Mindray SpO2), ±3 bpm without motion, ±5 bpm with motion (Masimo); 20~250bpm ±3 bpm; 251~300bpm, not specified (Nellcor SpO2); ±1 bpm or ±1%, whichever is greater (IBP).					
Non-invasive blood pressure (NIBP)	Uses the multi- parameter module integrated on the main control board to measure NIBP. It uses the oscillometric method for measuring non-invasive blood pressure (NIBP). Measurement range: Systolic: 25~290mmHg (Adult), 25~240mmHg (Pediatric), 25~140mmHg (Neonate). Diastolic: 10~250mmHg (Adult), 10~200mmHg (Pediatric), 10~115mmHg (Neonate). Mean: 15~260mmHg (Adult), 15~215mmHg (Pediatric), 15~125mmHg (Neonate). PR:30~300bpm. Accuracy: NIBP: Max mean error: ±5mmHg; Max standard deviation: 8mmHg. PR: ±3 bpm or ±3%, whichever is greater.						Uses the multi- parameter module integrated on the main control board to measure NIBP. It uses the oscillometric method (deflation measurement method and inflation measurement method) for measuring non-invasive blood pressure (NIBP). Measurement range: Systolic: 25~290mmHg (Adult), 25~240mmHg (Pediatric), 25~140mmHg (Neonate). Diastolic: 10~250mmHg (Adult), 10~200mmHg (Pediatric), 10~115mmHg (Neonate). Mean: 15~260mmHg (Adult), 15~215mmHg (Pediatric), 15~125mmHg (Neonate). PR:30~300bpm. Accuracy: NIBP: Max mean error: ±5mmHg; Max standard deviation: 8mmHg. PR: ±3 bpm or ±3%, whichever is greater. Default value of Pediatric Initial Pressure for NIBP Module: 120 mmHg The NIBP measurement interval can be set. The options include manual, sequence, 24h, 12h, 8h，4h, 3h, 2h, 1.5h, 1h, 30min, 20min, 15min, 10min, 5min, 3min, 2.5min, 2 min, 1min					
Invasive blood pressure (IBP)	Uses the multi- parameter module integrated on the main control board or the external IBP Module (only used in ePM 10M/12M/15M) 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. Support Pulse Pressure Variation (PPV)and Pulmonary Artery Wedge Pressure (PAWP)function. Measurement range: -50~300mmHg, Accuracy of module: ±2% or ±1mmHg, whichever is greater This measurement can be used for adults, pediatrics and neonates except that PAWP is not for neonates.						Uses the multi- parameter module integrated on the main control board or the external IBP Module (only used in ePM 10M/12M/15M) to measure invasive blood pressure. The monitor can monitor up to 6 invasive blood pressures and displays systolic, diastolic and mean pressures and a waveform for each pressure. Support Pulse Pressure Variation (PPV)and Pulmonary Artery Wedge Pressure (PAWP)function, Systolic Pressure Variation (SPV) , Intra-abdominal pressure (IAP) and abdominal perfusion pressure(APP). Measurement range: -50~300mmHg, Accuracy of module: ±2% or ±1mmHg, whichever is greater This measurement can be used for adults, pediatrics and neonates except that PAWP is not for neonates.					
Cardiac output (C.O.)	The built-in cardiac output (C.O.) module or external cardiac output (C.O.) (only can be used in ePM 10M/12M/15M) module 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. The monitor can store up to 6 measurements. Measurement range: C.O.: 0.1~20 L/min. TB: 23~43℃ , TI: 0~27℃ . Accuracy: C.O.: ±5% or±0.1L/min, whichever is greater. TB,TI: ±0.1℃ (without sensor). This measurement can be used for adults.						The built-in cardiac output (C.O.) module or external cardiac output (C.O.) (only can be used in ePM 10M/10MA/10MC/12M/12MA/12MC/15M/15MA/15MC) module 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. The monitor can store up to 6 measurements. Measurement range: C.O.: 0.1~20 L/min. TB: 23~43℃ , TI: 0~27℃ . Accuracy: C.O.: ±5% or±0.1L/min, whichever is greater. TB,TI: ±0.1℃ (without sensor). This measurement can be used for adults and pediatrics.					

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

Not applicable. The ePM Patient Monitor Series is not patient contacting.

Electrical Safety

The following electrical safety testing was conducted:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI C63.27-2021, American National Standard for Evaluation of Wireless Coexistance
- AAMI TIR69:2017 (R2020), Risk management of radio-frequency wireless coexistence for medical devices and systems

Electromagnetic Compatibility (EMC)

The following electromagnetic compatibility testing was conducted:

- IEC 60601-1-2 Ed. 4.1 en:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Verification of the ePM Series Patient Monitors was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

Performance Testing

The following performance testing was completed:

- IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- IEC 60601-2-25 Edition 2.0 2011-10Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of electrocardiographs

- IEC 60601-2-27 Edition 3.0 2011-03Medical electrical equipment - Part 2: Particular Requirements for the Safety, Including Essential Performance of Electrocardiographic Monitoring Equipment
- IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34 Edition 3.0 2011-05 Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
- EN IEC 80601-2-49:2019 Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors
- ISO 80601-2-55 Second edition 2018-02 [Including AMD1:2023] Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors [Including Amendment 1 (2023)]
- ISO 80601-2-56 Second edition 2017-03 [Including AMD1:2018]Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement[Including: Amendment 1 (2018)]
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 60601-2-10 Edition 2.2 2023-01 CONSOLIDATED VERSION Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

10. CONCLUSION

The results of the performance testing described above demonstrate that the subject device ePM Series Patient Monitor Series is substantially equivalent to the predicate device.