October 31, 2019

Shenzhen Mindray Bio-medical Electronics Co., LTD.
Yanhong Bai
Manager Regulatory Affairs, Technical Regulation Department
Mindray Building, Keji 12th Road South,
Hi-tech Industrial Park, Nanshan
Shenzhen, 518057 Cn

Re: K191769
Trade/Device Name: ePM Series Patient monitors
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
Dated: September 30, 2019
Received: October 1, 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 Jennifer Shih
Acting 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)*
K191769

Device Name
ePM Series Patient Monitors

Indications for Use *(Describe)*
The ePM 10/ePM 12/ePM 15/ePM 10M/ePM 12M/ePM 15M 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). 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:
• The arrhythmia detection and PAWP monitoring is intended for adult and pediatric patients only;
• C.O. monitoring is intended for adult patients only;
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/ePM 12/ePM 15/ePM 10M/ePM 12M/ePM 15M monitors are 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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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the ePM Series Patient Monitors is provided below.

1. SUBMITTER

Applicant:	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. Mindray Building, Keji 12th Road South High-tech Industrial Park, Nanshan Shenzhen 518057, P.R. China Tel: +86 755 81888998 Fax: +86 755 26582680
Contact:	Contact Person: Yanhong Bai Title: Manager Regulatory Affairs Phone: +86 755 81885635 Fax: +86 755 26582680 E-mail: baiyanhong@mindray.com
Date Prepared:	October 23, 2019

2. DEVICE

Device Trade Name:	ePM Series Patient Monitors (Including ePM 10, ePM 12, ePM 15, ePM 10M, ePM 12M, ePM 15M)
Device Common Name:	Patient Monitor
Classification Name:	21 CFR 870.1025, Class II, Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class:	Class II
Panel:	Cardiovascular
Primary Product Code:	MHX - Monitor, Physiological, Patient (with arrhythmia detection or alarms)

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
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

3. PREDICATE DEVICES

- Predicate: K182075– BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19. BeneVision N22, BeneVision N1) (Shenzhen Minray Bio-Medical Electronics Co., LTD)

4. DEVICE DESCRIPTION

The subject ePM Series Patient Monitors includes six monitors:

- ePM 10 Patient Monitor
- ePM 12 Patient Monitor

- ePM 15 Patient Monitor
- ePM 10M Patient Monitor
- ePM 12M Patient Monitor
- ePM 15M Patient Monitor

The ePM Series Patient Monitors are Mindray's new generation monitoring product family with ergonomic and flexible design in platform of both software and hardware to meet the clinical needs of monitoring.

5. INTENDED USE/INDICATIONS FOR USE

The ePM 10/ePM 12/ePM 15/ePM 10M/ePM 12M/ePM 15M 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 (SpO_2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Pulmonary Artery Wedge Pressure (PAWP), Cardiac Output (C.O.), Carbon Dioxide (CO_2), Oxygen (O_2) and Anesthetic Gas (AG). 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:

- The arrhythmia detection and PAWP monitoring is intended for adult and pediatric patients only;
- C.O. monitoring is intended for adult patients only;

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/ePM 12/ePM 15/ePM 10M/ePM 12M/ePM 15M monitors are not intended for helicopter transport, hospital ambulance, or home use.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Both the predicate devices and the subject devices are multi parameter patient monitors intended to be used under the direction of clinical professionals. The monitoring parameters supported by the ePM series are a subset of those supported by the predicate BeneVision N series monitors (K182075).

In conclusion, the minor differences of the indications for use do not change the fundamental intended use of the ePM Series as a multiparameter monitor.

Technological Comparison

The table below compares the key technological feature of the subject devices to the predicate device (N series Patient Monitors, K182075). The features in gray are features which are different between the predicate devices and the subject devices.

Table 2: Device Comparison Table

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
Display and touchscreen	12.1" 1280*800 pixels.	**15.6" 1366* 768 pixels**.	12.1" 1280* 800 pixels	**10.1" 1280* 800 pixels.**	**15.6" 1366* 768 pixels**	12.1" 1280* 800 pixels.	**10.1" 1280* 800 pixels**
Secondary display	Mirrored display.	Mirrored display.					
Wireless	2.4GHz/5GHz dual band module.	2.4GHz/5GHz dual band module.					
Power supply	Battery or AC power.	Battery or AC power					
Battery	Rechargeable Lithium-Ion, 11.1 VDC, 4500 mAh.	**Rechargeable Lithium-Ion, 10.8VDC, 5600 mAh.** **Rechargeable Lithium-Ion, 10.95 VDC, 4500 mAh.** **Rechargeable Lithium-Ion, 10.95 VDC, 2600 mA**					
Data storage	Embedded Multi Media Card (eMMC).	Same					
Data Recorder	Supports internal thermal recorder.	Same					
Device integration	Use Benelink Module to integrate 3rd party devices. Allow parameter values 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	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation.	Same					
Alarm system	The alarm lamp is cyan, yellow, or red depending on alarm type. Supports Alarm Volume Escalation	Same					

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
ECG	Use ECG module of MPM3.0 3-lead, 5-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 and heart rate (HR); Arrhythmia detection is intended for adult and pediatric. Supports intelligent arrhythmia alarm. ST segment analysis is intended for adult, pediatric and neonate**.**	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 and heart rate (HR). Arrhythmia detection is intended for adult, pediatric**.** Supports intelligent arrhythmia alarm. ST segment analysis is intended for adult, pediatric and neonate.					
Arrhythmia Analysis	Asystole, VFib/Vtac, Vtac, Vent.Brady, Extreme Tachy, Extreme Brady, PVCs, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVCs/min, Tachy, Brady, Missed Beats, Vent Rhythm, Pacer Not Pacing, Pacer Not Capture, Multif.PVC, Nonsus.Vtac, Pause, Vent.Rhythm, Afib, Pauses/min, Pauses/min;	Same					
Respiration rate (Resp)	Use Respiration module of MPM 3.0 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.	Measurement specifications are the same. **The measurement module has minor circuit board layout differences.**					
Temperature (Temp)	Use temperature module of MPM 3.0 Measurement range: 0 to 50°C (32 to 122°F) Accuracy: ±0.1°C or ±0.2°F (without probe).	Measurement specifications are same. **The measurement module has minor circuit board layout differences.**					

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
Pulse oxygen saturation (SpO_2)	Supports Mindray SpO_2 function, Masimo SpO_2 function and Nellcor SpO_2 function from MPM 3.0 module. Mindray SpO_2 function Measurement range: 0 to 100%; Accuracy:70 to 100%: ±2% (adult/pediatric mode); 70 to 100%: ±3% (neonate mode); 0% to 69%: Not specified. Masimo SpO_2 function Measurement range: 1 to 100%; Accuracy:70 to 100%: ±2% (measured without motion in adult/pediatric mode); 70 to 100%: ±3% (measured without motion in neonate mode); 70 to 100%: ±3% (measured with motion); 1% to 69%: Not specified. Nellcor SpO_2 function Measurement range: 0 to 100%; Accuracy:70 to 100%: ±2% (adult/pediatric); 70 to 100%: ±3% (neonate); 0% to 69%: Not specified. Note: The specifictions of the various SpO2 functions provided by each manufacturer are the same across platforms.	Supports Mindray SpO_2 function, Masimo SpO_2 function and Nellcor SpO_2 function from multi parameter module. The specifications for various SpO2 functions are the same. The Masimo SpO2 module and the Nellcor SpO2 module in the internal MPM 3.0 module are identical to the Masimo SpO2 module and the Nellcor SpO2 module in K182075. **The internal Mindray SpO2 minor circuit board layout differences when compared to the Mindray SpO2 module in K182075**					

<table>
<tr><td></td><td>Predicate Devices (K182075)</td><td colspan="6">Subject ePM Devices</td></tr>
<tr><td>Feature</td><td>N12</td><td>ePM 15</td><td>ePM 12</td><td>ePM 10</td><td>ePM 15M</td><td>ePM 12M</td><td>ePM 10M</td></tr>
<tr><td>Pulse rate (PR)</td><td>PR from Mindray SpO_2 Module
Measurement range: 20 to 254 bpm;
Accuracy: ±3 bpm.

PR from Masimo SpO_2 Module
Measurement range: 25 to 240 bpm;
Accuracy: ±3 bpm (measured without motion);
±5 bpm (measured with motion).

PR from Nellcor SpO_2 Module
Measurement range: 20 to 300 bpm;
Accuracy:20 to 250 bpm: ±3 bpm;
251 to 300 bpm, not specified.

PR from IBP Module
Measurement range: 25 to 350 bpm;
Accuracy: ±1 bpm or ±1%, whichever is greater.</td><td colspan="3">PR from built-in Mindray SpO_2 Module
Measurement range: 20 to 254 bpm;
Accuracy: ±3 bpm.

PR from built-in Masimo SpO_2 Module
Measurement range: 25 to 240 bpm;
Accuracy: ±3 bpm (measured without motion);
±5 bpm (measured with motion).

PR from built-in Nellcor SpO_2 Module
Measurement range: 20 to 300 bpm;
Accuracy:20 to 250 bpm: ±3 bpm;
251 to 300 bpm, not specified.

Same</td><td colspan="3">PR from built-in Mindray SpO_2 Module
Measurement range: 20 to 254 bpm;
Accuracy: ±3 bpm.

PR from built-in Masimo SpO_2 Module
Measurement range: 25 to 240 bpm;
Accuracy: ±3 bpm (measured without motion);
±5 bpm (measured with motion).

PR from built-in Nellcor SpO_2 Module
Measurement range: 20 to 300 bpm;
Accuracy:20 to 250 bpm: ±3 bpm;
251 to 300 bpm, not specified.

PR from external IBP Module
Measurement range: 25 to 350 bpm;
Accuracy: ±1 bpm or ±1%, whichever is greater.

Same</td></tr>
<tr><td>Non-invasive blood pressure (NIBP)</td><td>Measurement range:
<table><tr><td></td><td>Adult</td><td>Pediatric</td><td>Neonate</td></tr><tr><td>Systolic</td><td>25-290</td><td>25-240</td><td>25-140</td></tr><tr><td>Diastolic</td><td>10-250</td><td>10-200</td><td>10-115</td></tr><tr><td>Mean</td><td>15-260</td><td>15-215</td><td>15-125</td></tr></table>
Accuracy:
Max mean error: ±5 mmHg;
Max standard deviation: 8 mmHg.</td><td colspan="6">Measurement specifications are the same.

The measurement module has minor differences related to the circuit board layout and over pressure protection channel.</td></tr>
</table>

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
Invasive blood pressure (IBP)	Uses the MPM3.0 or the external 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. Support PPV function. Measurement range: -50 to 300 mmHg; Accuracy: ±2% or ±1 mmHg, whichever is greater (without sensor).	Uses an internal IBP module **The circuit board layout has minor differences compared to the predicate**. Measurement specifications are the same			Uses an internal IBP module or stand-alone IBP Module **The circuit board layout of the internal IBP module has minor differences compared to the predicate.** The stand-alone IBP module is identical with the predicate device's Measurement specifications are the same.		
Cardiac output (C.O.)	Use external C.O. module The cardiac output (C.O.) measurement invasively measures cardiac output and other hemodynamic parameters using the right heart (atria) thermodilution method. The temperature change is displayed as a curve in the C.O. split screen, and the monitor calculates the C.O. value from this curve. The monitor is capable of storing 6 measurements. Measurement range: C.O: 0.1 to 20 L/min; TB: 23 to 43°C; TI: 0 to 27°C; Accuracy: C.O: ±5% or ±0.1 L /min, whichever is greater; TB, TI: ±0.1°C (without sensor).	Use internal C.O. module Internal C.O. module is identical to the external C.O. module in K182075			Use internal or external C.O. module The built-in C.O. module is identical with the external C.O. module in K182075. The only difference between the subject external C.O. module and the external C.O. module in K182075 is that the subject module includes **a pogo pin interface**		

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
Carbon dioxide (CO_2)	Compatible with the following 4 modules to measure carbon dioxide: • Sidestream CO_2 1.0 module • Sidestream CO_2 2.0 module • Mainstream CO_2 module • MicroStream CO_2 module	Compatible with 3 internal CO_2 modules: • Sidestream CO_2 2.0 module • Mainstream CO_2 module • MicroStream CO_2 module The internal CO_2 modules are identical to the external CO_2 module in K182075			Compatible with 4 internal or external CO_2 modules: • Sidestream CO_2 1.0 module • Sidestream CO_2 2.0 module • Mainstream CO_2 module • MicroStream CO_2 module *10M does not support external CO_2 modules The subject internal CO_2 modules are identical with predicate external CO2. The only difference between the subject external CO2 modules and the predicate external CO2 modules that the subject modules include **a pogo pin interface**		
	<u>Type: Sidestream CO2 Module (CO2 2.0):</u> Measurement range: 0~150mmHg Accuracy: 0~40 mmHg: ±2mmHg, 41~76 mmHg: ±5% of reading, 77~99 mmHg: ±10% of reading, **100~150mmHg: ±(3mmHg + 8% of reading),** ISO accuracy mode: Add ±2mmHg to the full accuracy mode AwRR measurement: awRR measurement range: 0 to 150rpm; **awRR: <60rpm, ±1rpm, 60~150rpm, ±2rpm.**	Same			Same		

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
	Type: Microstream CO2 Module Measurement range: CO2: 0~99mmHg; awRR: 0~150rpm; Accuracy: CO2: 0~38mmHg: ±2mmHg; 39~99mmHg: ±5% of the reading+0.08% of (the reading-38). awRR: 0~70rpm: ±1rpm, 71~120rpm: ±2rpm,121~150rpm: ±3rpm	Same			Same		
	Type: Mainstream CO2 Module Measurement range: CO2: 0~150mmHg; awRR: 0~150rpm; Accuracy: CO2: 0~40mmHg: ±2mmHg, 41~70mmHg: ±5% of the reading, 71~100mmHg: ±8% of the reading, 101~150mmHg: ±10% of the reading; awRR: ±1rpm.	Same			Same		

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
Oxygen (O_2)	Oxygen values are measured by the Sidestream CO_2 2.0 or the AG module using a paramagnetic method. Measurement range: 0~100% (CO_2 and AG), Accuracy: 0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3% (CO_2 and AG).	Not support			Same		

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
Anesthetic gas (AG)	The AG module analyzes gas samples from the patient and calculates CO_2, O_2, N_2O, and AA waveforms and related numerics that include airway respiratory rate and MAC (minimum alveolar concentration). Measurement range: CO_2, HAL, ENF, ISO, SEV, DES: 0~30 %; O_2, N_2O: 0~100 %; awRR: 2~100 rpm. Accuracy: Full accuracy mode: CO_2:0%≤CO_2≤1%, ±0.1%ABS, 1%< CO_2≤5%, ±0.2% ABS, 5%< CO_2≤7%, ±0.3% ABS, 7%< CO_2≤10%, ±0.5% ABS, 10%< CO_2 not specified; N_2O: 0~20%$_{REL}$: ±2% $_{ABS}$, 20~100%$_{REL}$: ±3% $_{ABS}$; O_2 0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3%; HAL, ENF, ISO: 0~1%$_{REL}$: ±0.15% $_{ABS}$, 1~5%$_{REL}$: ±0.2% $_{ABS}$, >5%$_{REL}$, not specified; SEV: 0~1%$_{REL}$: ±0.15% $_{ABS}$, 1~5%$_{REL}$: ±0.2% $_{ABS}$, 5~8%$_{REL}$: ±0.4% $_{ABS}$, >8%$_{REL}$, not specified; DES： 0~1%$_{REL}$: ±0.15% $_{ABS}$, 1~5%$_{REL}$: ±0.2% $_{ABS}$, 5~10%$_{REL}$: ±0.4% $_{ABS}$, 10~15%$_{REL}$: ±0.6% $_{ABS}$,15~18%$_{REL}$: ±1% $_{ABS}$,>18%$_{REL}$, not specified; awRR:2~60rpm, ±1rpm, >60rpm, not specified. This measurement can be used for adults, pediatrics and neonates.	Not support			Measurement specifications are the same. The only difference between the subject AG module the predicate AG module is that the subject module includes **a pogo pin interface**		
Wireless function	The Wireless radio module (Laird) is used for connecting to a wireless monitoring network with a central monitoring system (CMS).	same					

	Predicate Devices (K182075)	**Subject ePM Devices**					
Feature	**N12**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
ECG 24h Summary	Provides the function to statistical results of heart rate changes and cardiac arrhythmia of patients within 24 hours, including HR statistics, ARR statistics, ST statistics, QT/QTc statistics and Pace statistics.	Same					
EWS	The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS) and user configurable Custom Score.	MEWS and NEWS are same. **Added NEWS 2.0.** **Custom Score added NIBP-D and NIBP-M options.** **Updated the user interface.**					
Glasgow Coma Scale (GCS)	The GCS a well-established scoring system used to assess the state of consciousness based three sub-components: eye-opening response, verbal response, and limb movement	Same					

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness.

7. PERFORMANCE DATA

To establish the substantial equivalence of the ePM Series Patient Monitors, Mindray conducted functional and system level testing to validate the performance of the devices. The testing provided an evaluation of the performance of the device relevant to each of the differences between the subject device and the predicate device. The results of the functional and system level testing show that the subject device meets its specifications and is substantially equivalent to the predicate device.

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

Mindray complies with the FDA Special Controls Document relevant to this device “Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm Guidance for Industry and FDA (10/28/2003)”.

Biocompatibility Testing

The ePM Series Patient Monitors are not patient contacting. There are no new patient contacting accessories or components. There have been no material changes to the previously cleared patient contacting devices, therefore biocompatibility testing is not required.

Software Verification and Validation Testing

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.

Electromagnetic Compatibility and Electrical Safety

The ePM Series Patient Monitors were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, 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 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.
- UL 62133:2017 (Second Edition) Secondary cell and batteries containing alkaline or other non-acid electrolytes

Bench Testing

To establish the substantial equivalence of the ePM Series Patient Monitors, Mindray conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification, and is substantially equivalent to the predicate device.

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

- IEC 60601-1-6: 2013 Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance- collateral standard: usability
- IEC 60601-1-8: 2012 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 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

- IEC 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 80601-2-30:2018 Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34:2011 Medical electrical equipment - part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
- IEC 80601-2-49:2018 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55: 2018 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56: 2017 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 80601-2-61: 2017 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- AAMI / ANSI EC57:2012 Testing and reporting performance results of cardiac rhythm and st-segment measurement algorithms

8. CONCLUSION

Based on the detailed comparison of specifications for each of the modifications to the previously cleared BeneVision N Series Patient Monitors (K182075), the performance testing and conformance with applicable standards, the ePM Series Patient Monitors (including ePM 10, ePM, 12, ePM 15, ePM 10M, ePM 12M, ePM 15M) can be found substantially equivalent to the predicate device.