April 16, 2026

Shenzhen Mindray Bio-medical Electronics Co., LTD.
Lei Li
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
China

Re: K253170
Trade/Device Name: uMEC 60/ uMEC 70/ uMEC 80/uMEC 100/uMEC 120/uMEC 150 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, CCK, DXG, DSJ
Dated: September 20, 2025
Received: September 26, 2025

Dear Lei Li:

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,

KIMBERLY N. CROWLEY -S Digitally signed by KIMBERLY N. CROWLEY -S

For: Jennifer Kozen
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

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.	K253170

Please provide the device trade name(s).

uMEC 60/ uMEC 70/ uMEC 80/uMEC 100/uMEC 120/uMEC 150 Patient Monitors

Please provide your Indications for Use below.

The uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 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.) and Carbon Dioxide (CO2).
All the parameters can be monitored on single adult, pediatric, and neonatal patients except for the following:
• The 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 uMEC 60/uMEC 70/ uMEC 80/uMEC 100/uMEC 120/uMEC 150 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 (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Mindray uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 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:	Li Lei Title: Manager Regulatory Affairs Phone: +86 755 81885953 Fax: +86 755 26582680 E-mail: lilei.js@mindray.com
Date Prepared:	September 25, 2025

2. DEVICE

Device Trade Name:	uMEC 60/ uMEC 70/ uMEC 80/uMEC 100/uMEC 120/uMEC 150 Patient Monitors
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:	II
Primary Product Code:	MHX
Subsequent Product Codes	Refer to Tabel 1
Panel:	Cardiovascular

Table 1: Secondary Product Codes

Regulation Number/Class	Product Codes	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
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

3. PREDICATE DEVICES

Primary predicate device:

- K200015- ePM Series Patient monitors, ShenZhen Mindray Bio-Medical Electronics CO., LTD.

4. DEVICE DESCRIPTION

The subject uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 Patient Monitors includes six monitors:

- uMEC 60 Patient Monitor
- uMEC 70 Patient Monitor
- uMEC 80 Patient Monitor
- uMEC 100 Patient Monitor
- uMEC 120 Patient Monitor
- uMEC 150 Patient Monitor

The above mentioned 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 uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 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.) and Carbon Dioxide (CO_2).

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

- The 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 uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 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. Comparing with the the primary predicate ePM Series Patient Monitors (K200015), the indications for use for the subject device uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 Patient Monitors are equivalent.

The subject and Primary predicate devices have the same use environment (healthcare facilities), and patient population (adult, pediatric, and neonatal patients).

In conclusion, the intended use of the subject device uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 Patient Monitors is substantially equivalent to that of the primary predicate ePM Series Patient Monitors (K200015).

Comparison of Technological Characteristics

The table below compare the key technological features of the subject devices to the primary predicate devices (K200015, ePM Series Patient Monitors). The features in grey are features which are different between the predicate devices and the subject devices. Where appropriate, the specific differences of the features are bolded.

Feature	**ePM 10**	**ePM 12**	**ePM 15**	**ePM 10M**	**ePM 12M**	**ePM 15M**	**uMEC 100**	**uMEC 60**	**uMEC 120**	**uMEC 70**	**uMEC 150**	**uMEC 80**
	Cleared in K200015						**Subject Device**					
Primary display and touch screen	10.1” **1024 ×800 pixels**	12.1” 1280* 800 pixels	15.6 1366 ×768 pixels	10.1” **1024 ×800 pixels**	12.1” 1280* 800pixels	15.6 1366 ×768 pixels	10.1” **1024×600 pixels**		12.1” 1280×800 pixels		15.6 1366×768 pixels	
Secondary display	Mirrored display						Mirrored display					
Power supply	Battery or AC power						Battery or AC power					
Battery	Rechargeable Lithium-Ion, 10.8VDC, 5600 mAh. Rechargeable Lithium-Ion, 10.95 VDC, 4500 mAh. Rechargeable Lithium-Ion, 10.95 VDC, 2600 mA						**Rechargeable Lithium-Ion,10.95V, 5200mAh**					
Data storage	Embedded Multi Media Card(eMMC)						Embedded Multi Media Card(eMMC)					
Data recorder	Supports internal thermal recorder						Supports internal thermal recorder					
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation						Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation					
Alarm system	The alarm lamp is **cyan**, yellow, or red depending on alarm type						The alarm lamp is yellow, or red depending on alarm type					
ECG	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 and neonate. 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, J-point Auto detection, Dual Channel Pace detection, adjustable QRS threshold and heart rate (HR). Arrhythmia detection is intended for adult, pediatric and neonate. Supports intelligent arrhythmia alarm. ST segment analysis is intended for adult, pediatric and neonate. **The measurement module has circuit board layout differences.**					
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,						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,					

Feature	**ePM 10**	**ePM 12**	**ePM 15**	**ePM 10M**	**ePM 12M**	**ePM 15M**	**uMEC 100**	**uMEC 60**	**uMEC 120**	**uMEC 70**	**uMEC 150**	**uMEC 80**
	Cleared in K200015						**Subject Device**					
	Nonsus.Vtac, Pause, Vent.Rhythm, Afib, Pauses/min, Pauses/min						Nonsus.Vtac, Pause, Vent.Rhythm, Afib, Pauses/min, Pauses/min					
Respiration rate (Resp)	Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm. Accuracy: 7 to 150 rpm: ±2 rpm or ±2%, whichever is greater; 0 to 6 rpm: Not specified						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 **The measurement module has circuit board layout differences.**					
Temperature (Temp)	Measurement range: 0 to 50°C (32 to 122°F) Accuracy: ±0.1°C or ±0.2°F (without probe).						Measurement range: 0 to 50°C (32 to 122°F) Accuracy: ±0.1°C or ±0.2°F (without probe). **The measurement module has circuit board layout differences.**					
Pulse oxygen saturation (SpO_2)	Supports Mindray SpO2 function, Masimo SpO2 function and Nellcor SpO2 function from multi parameter module. Mindray SpO2 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 SpO2 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 SpO2 function						Only support Mindray SpO2 function from multi parameter module. Measurement range: 0 to 100%; Accuracy: 70 to 100%: ±2% (adult/pediatric mode); 70 to 100%: ±3% (neonate mode); 0% to 69%: Not specified. **The measurement module has circuit board layout differences.**					

<table>
<tr><th rowspan="2">Feature</th><th>ePM 10</th><th>ePM 12</th><th>ePM 15</th><th>ePM 10M</th><th>ePM 12M</th><th>ePM 15M</th><th>uMEC 100</th><th>uMEC 60</th><th>uMEC 120</th><th>uMEC 70</th><th>uMEC 150</th><th>uMEC 80</th></tr>
<tr><td colspan="6">Cleared in K200015</td><td colspan="6">Subject Device</td></tr>
<tr><td></td><td colspan="6">Measurement range: 0 to 100%;
Accuracy:
70 to 100%: ±2% (adult/pediatric);
70 to 100%: ±3% (neonate);
0% to 69%: Not specified.</td><td colspan="6"></td></tr>
<tr><td>Pulse rate (PR)</td><td colspan="3">PR from built-in Mindray SpO2 Module
Measurement range: 20 to 254 bpm;
Accuracy: ±3 bpm.
PR from built-in Masimo SpO2 Module
Measurement range: 25 to 240 bpm;
Accuracy:
±3 bpm (measured without motion);
±5 bpm (measured with motion).
PR from built-in Nellcor SpO2 Module
Measurement range: 20 to 300 bpm;
Accuracy:
20 to 250 bpm: ±3 bpm;
251 to 300 bpm, not specified</td><td colspan="3">PR from built-in Mindray SpO2 Module
Measurement range: 20 to 254 bpm;
Accuracy: ±3 bpm.
PR from built-in Masimo SpO2 Module
Measurement range: 25 to 240 bpm;
Accuracy:
±3 bpm (measured without motion);
±5 bpm (measured with motion).
PR from built-in Nellcor SpO2 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="6">PR from built-in Mindray SpO2 Module
Measurement range:20 to 254 bpm;
Accuracy: ±3 bpm.

PR from IBP Module
Measurement range: 25 to 350 bpm;
Accuracy: ±1 bpm or ±1%, whichever is greater.</td></tr>
<tr><td>Non-invasive blood pressure (NIBP)</td><td colspan="6">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></td><td colspan="6">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></table></td></tr>
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<tr><th colspan="6">Cleared in K200015</th><th colspan="6">Subject Device</th></tr>
<tr><td></td><td colspan="6">Accuracy:
Max mean error: ±5 mmHg;
Max standard deviation: 8 mmHg.</td><td colspan="6"><table><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.
The measurement module has circuit board layout differences.</td></tr>
<tr><td>Invasive blood pressure (IBP)</td><td colspan="2">Uses an internal IBP module to measure invasive blood pressure. The monitor can monitor 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).</td><td colspan="2">Uses an internal IBP module or stand-alone IBP Module to measure invasive blood pressure.
The monitor can monitor 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).</td><td colspan="2">Not support</td><td colspan="4">Uses an internal IBP module to measure invasive blood pressure. The monitor can monitor 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).</td></tr>
<tr><td>Cardiac output (C.O.)</td><td colspan="2">Use internal 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</td><td colspan="2">Use internal or external C.O. module.
The cardiac output (C.O.)
measurement invasively measures
cardiac output and other hemodynamic parameters
using the right heart (atria) thermodilution</td><td colspan="2">Not support</td><td colspan="4">Use internal C.O. module.
The cardiac output (C.O.)
measurement invasively measures
cardiac output and other hemodynamic parameters using the right heart</td></tr>
</table>

Feature	ePM 10	ePM 12	ePM 15	ePM 10M	ePM 12M	ePM 15M	uMEC 100	uMEC 60	uMEC 120	uMEC 70	uMEC 150	uMEC 80
	Cleared in K200015						**Subject Device**					
	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).			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).						(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).		
Carbon dioxide (CO_2)	Compatible with **3 internal CO2 modules:** Sidestream CO2 2.0 module Mainstream CO2 Module MicroStream CO2 module			Compatible with 4 internal or external CO2 modules: Sidestream CO2 1.0 Module Sidestream CO2 2.0 module Mainstream CO2 module MicroStream CO2 module *10M does not support external CO2 modules			Not support			Compatible with **1 internal CO2 modules:** Sidestream CO2 2.0 module		

Feature	**ePM 10**	**ePM 12**	**ePM 15**	**ePM 10M**	**ePM 12M**	**ePM 15M**	**uMEC 100**	**uMEC 60**	**uMEC 120**	**uMEC 70**	**uMEC 150**	**uMEC 80**
	Cleared in K200015						**Subject Device**					
	Type: Sidestream CO2 Module (CO2 2.0): 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						Not support			Type: Sidestream CO2 Module (CO2 2.0): 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		
	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						Not support					

Feature	ePM 10	ePM 12	ePM 15	ePM 10M	ePM 12M	ePM 15M	uMEC 100	uMEC 60	uMEC 120	uMEC 70	uMEC 150	uMEC 80
	Cleared in K200015						**Subject Device**					
	reading-38). awRR: 0~70rpm: ±1rpm, 71~120rpm: ±2rpm,121~150rpm: ±3rpm											
	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.						Not support					

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 uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 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 specifications and is substantially equivalent to the predicate device.

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

Biocompatibility Testing

The uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 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 uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 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 uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 Patient Monitors were assessed for conformity with the relevant requirements of the following standards and found to comply:

- IEC 60601-1:2005/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]
- IEC 60601-1-2 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION 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

Bench Testing

To establish the substantial equivalence of the uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 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.

- ANSI AAMI IEC 60601-2-27:2011(R)2016 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- ANSI AAMI 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 Edition 3.0 2011-05 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 Second edition 2018-02 [Including AMD1:2023] Medical electrical equipment--Part2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56 Second edition 2017-03 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 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021] 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 [Including Amendment 2 (2021)]

8. CONCLUSION

Based on the detailed comparison of specifications for each of the characteristics to the predicate devices, the performance testing and conformance with applicable standards, the uMEC 60/uMEC 70/uMEC 80/uMEC 100/uMEC 120/uMEC 150 Patient Monitors can be found substantially equivalent to the predicate device.