June 8, 2020

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 China

Re: K200015
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, DPZ, CCK, DXG, DSJ, CBQ, CBS, CBR, CCL
Dated: May 9, 2020
Received: May 12, 2020

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,

Jennifer Shih
Assistant Director (Acting)
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

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)*
K200015

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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

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: December 28, 2019

2. DEVICE

Device Trade Name: ePM Series 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： 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

K191769 - ePM Series Patient Monitors (Including ePM 10/ePM 12/ePM 15/ePM 10M/ePM 12M/ePM 15M) (SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD)

4. REFERENCE DEVICE

K103142 – The spacelabs Multi-parameter Module (SPACELABS HEALTHCARE, INC.)

5. 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.

6. INDICATIONS FOR USE

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

7. 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 subject ePM series are identical with those supported by the predicate ePM series monitors (K191769).

The indications for use statement of the subject devices include Arrhythmia Detection used on neonatal patients. Although this feature is not present in the primary predicate devices, it is present in the cleared spacelabs Multi-parameter Module (K103142) and does not constitute a new intended use.

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

Comparison of Technological Characteristics

The table below compares the key technological feature of the subject device to the primary predicate device (ePM series Patient Monitors, K191769). The features in gray are features which are different between the predicate devices and the subject devices.

Table 2: Device Comparison Table

	Predicate Devices (K191769)						**Subject ePM Devices**					
Feature	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**	**ePM 15**	**ePM 12**	**ePM 10**	**ePM 15M**	**ePM 12M**	**ePM 10M**
Display and touchscreen	15.6” 1366*768 pixels	12.1” 1280*800pixels	10.1” 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*800pixels	15.6” 1366*768 pixels	12.1” 1280*800 pixels	10.1” 1280*800 pixels
Secon	Mirrored display						Same					

dary display		
Wireless	2.4GHz/5GHz dual band module	Same
Power supply	Battery or AC power	Same
Battery	Rechargeable Lithium-Ion, 10.8VDC, 5600 mAh. Rechargeable Lithium-Ion, 10.95 VDC, 4500 mAh. Rechargeable Lithium-Ion, 10.95 VDC, 2600 mA	Same
Data storage	Embedded Multi Media Card(eMMC)	Same
Data Recorder	Supports internal thermal recorder	Same
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.	Same
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	Same
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).	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 and pediatric. Supports intelligent arrhythmia alarm. ST segment analysis is intended for adult, pediatric and neonate.	Arrhythmia detection is intended for adult, pediatric and **neonate**. Supports intelligent arrhythmia alarm. ST segment analysis is intended for adult, pediatric and neonate. Refer to Section 12.3.
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)	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.	Same
Temperature (Temp)	Measurement range: 0 to 50 ℃ (32 to 122 ℉) Accuracy: ±0.1 ℃ or ±0.2 ℉ (without probe).	Same
Pulse oxygen saturation (SpO2)	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);	Same

	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 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.			
Pulse rate (PR)	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 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 external IBP Module Measurement	Same	Same

<table>
<tr><td></td><td></td><td>range:
25 to 350 bpm;
Accuracy:
±1 bpm or ±1%, whichever is greater.</td><td></td><td></td></tr>
<tr><td>Non-invasive blood pressure (NIBP)</td><td colspan="2">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="2">Same</td></tr>
<tr><td>Invasive blood pressure (IBP)</td><td>Uses an internal 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).</td><td>Uses an internal IBP module or stand-alone 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).</td><td>Same</td><td>Same</td></tr>
<tr><td>Cardiac output</td><td>Use internal C.O. module. The cardiac output (C.O.) measurement invasively</td><td>Use internal or external C.O. module.</td><td>Same</td><td>Same</td></tr>
</table>

(C.O.)	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 ℃; TI: 0 to 27 ℃; Accuracy: C.O: ±5% or ±0.1 L /min, whichever is greater; TB, TI: ±0.1 ℃ (without sensor).	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 ℃; TI: 0 to 27 ℃; Accuracy: C.O: ±5% or ±0.1 L /min, whichever is greater; TB, TI: ±0.1 ℃ (without sensor).		
Carbon dioxide(CO2)	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	Same	Same

		module MicroStream CO2 module *10M does not support external CO2 modules		
	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.	Same		
	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		
	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,	Same		

	101~150mmHg: ±10% of the reading; awRR: ±1rpm.			
Oxygen (O2)	Not support	Oxygen values are measured by the Sidestream CO2 2.0 or the AG module using a paramagnetic method. Measurement range: 0~100% (CO2 and AG), Accuracy: 0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3% (CO2 and AG).	Same	Same
Anesthetic gas (AG)	Not support	The AG module analyzes gas samples from the patient and calculates CO2, O2, N2O, and AA waveforms and related numerics that include airway respiratory rate and MAC (minimum alveolar concentration). Measurement range: CO2, HAL, ENF, ISO, SEV, DES: 0~30 %; O2, N2O: 0~100 %; awRR: 2~100 rpm. Accuracy: Full accuracy	Same	Same

		mode: CO2:0%≤CO2≤1%, ±0.1%ABS, 1%< CO2≤5%, ±0.2% ABS, 5%< CO2≤7%, ±0.3% ABS, 7%< CO2≤10%, ±0.5% ABS, 10%< CO2 not specified; N2O: 0~20%REL: ±2% ABS, 20~100%REL: ±3% ABS; O2 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.		
Wireless function	The Wireless radio module (Laird) is used for connecting to a wireless monitoring network with a central monitoring system (CMS).		Same	
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 NEWS2) and user configurable Custom Score.		Same	
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	

Substantial Equivalence Conclusion

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

8. 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 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 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

There have been no changes to the hardware and mechanical construction of the ePM Series Monitors since their previous clearance. Therefore additional Electromagnetic Compatibility and Electrical Safety testing is not required to demonstrate substantial equivalence.

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 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- AAMI / ANSI EC57:2012 Testing and reporting performance results of cardiac rhythm and st-segment measurement algorithms

9. CONCLUSION

Based on the detailed comparison between the predicate devices and the subject devices, the performance testing and conformance with applicable standards, the ePM Series Patient Monitors can be found substantially equivalent to the predicate devices.