November 15, 2017

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

Re: K171901
Trade/Device Name: uMEC Series Patient Monitors (including uMEC6, uMEC7, uMEC10, uMEC12, uMEC15, uMEC15S)
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, DRS
Dated: October 11, 2017
Received: October 16, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171901

Device Name
uMEC Series Patient Monitors (including uMEC6, uMEC7, uMEC10, uMEC12, uMEC15, uMEC15S)

Indications for Use *(Describe)*
The uMEC Series Patient Monitor family consists of the uMEC6, uMEC7, uMEC10, uMEC12, uMEC15 and uMEC15S patient monitors. All of the devices in the family are multiparameter monitors indicated for monitoring, displaying, reviewing, and transferring multiple physiological parameters. The specific indications for use are provided below.

The uMEC series patient monitors are intended for monitoring, displaying, reviewing, and transferring of multiple physiological parameters including ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, and heart rate (HR)), respiration rate (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure(IBP), cardiac output (C.O.), carbon dioxide (CO2).

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:
The arrhythmia detection and SpO2 are intended for adult and pediatric patients only;
ST Segment analysis is intended for adult patients only; and
C.O. monitoring is restricted to adult patients only.

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the uMEC series patient monitors is provided below.

Device Common Name:	Patient Monitor
Device Trade Name:	uMEC Series Patient Monitors(including uMEC6, uMEC7, uMEC10, uMEC12, uMEC15, uMEC15S)
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:	Yanhong Bai Manager Regulatory Affairs SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. Mindray Building, Keji 12th Road South High-tech Industrial Park, Nanshan 518057, P.R. China Tel: +86 755 81885635 Fax: +86 755 26582680 E-mail: baiyanhong@mindray.com
Date Prepared:	**June 23, 2017**
Classification Regulation:	870.1025 – Arrhythmia detector and alarm (including ST-segment measurement and alarm) Class II
Panel:	Cardiovascular
Product Code:	MHX - monitor, physiological, patient (with arrhythmia detection or alarms)

Subsequent Product Codes:

Product Code	Regulation Number	Panel	Regulation description	Device Common Name
DSI	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	detector and alarm, arrhythmia
MLD	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, st segment with alarm
DRT	21 CFR 870.2300	Cardiovascular	Cardiac Monitor (including cardiotachometer and rate alarm)	monitor, cardiac (incl. cardiotachometer & rate alarm)
DXN	21 CFR 870.1130	Cardiovascular	Noninvasive blood pressure measurement system	system, measurement , blood-pressure,
DSK	21 CFR 870.1110	Cardiovascular	Blood pressure computer	computer, blood-pressure
FLL	21 CFR 880.2910	Cardiovascular	Clinical electronic thermometer	thermometer, electronic, clinical
DQA	21 CFR 870.2700	Cardiovascular	Oximeter	oximeter
CCK	21 CFR 868.1400	Anesthesiology	Carbon dioxide gas analyzer	analyzer, gas, carbon-dioxide,
DXG	21 CFR 870.1435	Cardiovascular	Single-function, preprogrammed diagnostic	computer, diagnostic, pre-programmed,
DSJ	21 CFR 870.1100	Cardiovascular	Blood pressure alarm	alarm, blood-pressure
DRS	21 CFR 870.2850	Cardiovascular	transducer, blood-pressure, extravascular	Extravascular blood pressure transducer.

Predicate Device: K152902 –Passport Series Patient Monitors

Indication for Use:

The uMEC Series Patient Monitor family consists of the uMEC6, uMEC7, uMEC10, uMEC12, uMEC15 and uMEC15S patient monitors. All of the devices in the family are multiparameter monitors indicated for monitoring, displaying, reviewing, and transferring multiple physiological parameters. The specific indications for use are provided below.

The uMEC series patient monitors are intended for monitoring, displaying, reviewing, and

transferring of multiple physiological parameters including ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, and heart rate (HR)), respiration rate (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure(IBP), cardiac output (C.O.), carbon dioxide (CO2).

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:

The arrhythmia detection and SpO2 are intended for adult and pediatric patients only;

ST Segment analysis is intended for adult patients only;

C.O. monitoring is restricted to adult patients only;

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance.

Device Description:

The subject uMEC Series Patient Monitors include six monitors:

- uMEC6 Patient Monitor
- uMEC7 Patient Monitor
- uMEC10 Patient Monitor
- uMEC12 Patient Monitor
- uMEC15 Patient Monitor
- uMEC15S Patient Monitor

The uMEC 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.

Performance Data:

- To establish the substantial equivalence of the uMEC Series Patient Monitors, Mindray conducted functional and system level testing on the subject device. 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 functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.

- Mindray has followed the following FDA Guidance Documents relevant to this device:
  - Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm Guidance for Industry and FDA (10/28/2003)
  - Cardiac Monitor Guidance (Including Cardiotachometer and Rate Alarm)
- Mindray has conducted testing to ensure the subject device meets relevant consensus standards.

ANSI/AAMI ES60601-1:2005/(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 60601-1-2:2007 Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance-- Collateral standard: Electromagnetic compatibility--Requirements and tests
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 60601-1-6: 2013 Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance--collateral standard: usability
IEC 60601-2-49:2011 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
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 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 80601-2-30:2013 Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 80601-2-56: 2009 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: 2011 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-55: 2011 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors
AAMI / ANSI EC57:2012 testing and reporting performance results of cardiac rhythm and st-segment measurement algorithms
IEC 62133 : 2012 secondary cells and batteries containing alkaline or other non-acid electrolytes - safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

Comparison of Indications:

Both the predicate device and the subject uMEC Series Patient Monitors are multiparameter patient monitors intended to be used in healthcare facilities under the direction of clinical professionals. Some features present in the cleared Passport Series Patient Monitors are not present in uMEC Series Patient Monitors. In conclusion, the minor differences to the indications

for use do not change the fundamental intended use of the uMEC series Patient Monitors as multiparameter monitors.

Comparison of Technological Characteristics:

The technological characteristics of the subject device are compared to the predicate device in the table below.

	Predicate Device (K152902)	**Subject Devices**					
Feature	**Passport 17m**	**uMEC6**	**uMEC10**	**uMEC7**	**uMEC12**	**uMEC15**	**uMEC15S**
Integrated display and touchscreen	17" 1280*1024 pixels	10.4" 800*600 pixels	10.4" 800*600 pixels	12.1" 800*600 pixels	12.1" 800*600 pixels	15" 1024*768 pixels	15" 1024*768 pixels
Power supply	Two rechargeable Lithium-ion battery or AC power supply	One standard Rechargeable Lithium-ion battery or One optional Rechargeable Lithium-ion battery or AC power supply					
Battery	Chargeable Lithium-Ion, 11.1 VDC, 4500 mAh	Chargeable Lithium-Ion, 11.1 VDC, 2500 mAh（Standard） Chargeable Lithium-Ion, 11.1 VDC, 5000 mAh（Optional）					
Data Recorder	The thermal recorder records patient information, measurement numerics, up to three waveforms, etc.	Same					
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation	Same					
ECG	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, and heart rate (HR); Support Mindray and Mortara algorithm.	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis andheart rate (HR); Only support Mindray algorithm and don't support interpretation of resting 12-lead ECG					
ECG measurement range and Accuracy	HR: Neonate: 15 to 350 bpm; Pediatric: 15 to 350 bpm; Adult: 15 to 300 bpm; ±1 bpm or ±1%, whichever is greater. ST: -2.0 to 2.0 mV RTI; -0.8 to 0.8 mV: ±0.02 mV or ±10%, whichever is greater. Beyond this range: Not specified. QT: [200，800]ms; ±30ms	Same					
Arrhythmia Analysis	Asystole, VFib/VTac, Vtac, Vent. Brady, ExtremeTechy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, R on T, RunPVCs,PVCs, Tachy, Brady, Missed Beats, Vent. Rhythm, PNP, PNC, Multif. PVC,Nonsus. Vtac, Pause, Irr. Rhythm, Afib	Same					

	Predicate Device (K152902)	**Subject Devices**					
Feature	**Passport 17m**	**uMEC6**	**uMEC10**	**uMEC7**	**uMEC12**	**uMEC15**	**uMEC15S**
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 (SpO_2)	MindraySpO2 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. MasimoSpO2 Module 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. NellcorSpO2 Module Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified.	MindraySpO2 Module Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric mode) 0% to 69%: Not specified. MindraySpO2 Module do not support neonate mode and the specifications for Adult/pediatric are same Not Support Masimo and NellcorSpO2 Module					
Pulse rate (PR)	PR from MindraySpO2 Module Measurement range: 20 to 254 bpm Accuracy: ±3 bpm PR from MasimoSpO2 Module Measurement range: 25 to 240 bpm Accuracy: ±3 bpm (measured without motion) ±5 bpm (measured with motion) PR from NellcorSpO2 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	PR from MindraySpO2 Module Measurement range: 20 to 254 bpm Accuracy: ±3 bpm PR specifications from MindraySpO2 module are same Not Support Masimo and NellcorSpO2 Module		PR from MindraySpO2 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 PR specifications from MindraySpO2 module and IBP Module are same Not Support Masimo and NellcorSpO2 Module			

<table>
<tr><td></td><td>Predicate Device (K152902)</td><td colspan="6">Subject Devices</td></tr>
<tr><td>Feature</td><td>Passport 17m</td><td>uMEC6</td><td>uMEC10</td><td>uMEC7</td><td>uMEC12</td><td>uMEC15</td><td>uMEC15S</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>40-270</td><td>40-200</td><td>40-135</td></tr><tr><td>Diastolic</td><td>10-210</td><td>10-150</td><td>10-100</td></tr><tr><td>Mean</td><td>20-230</td><td>20-165</td><td>20-110</td></tr></table>
Accuracy:
Max mean error: ±5 mmHg
Max standard deviation: 8 mmHg</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>
Accuracy:
Max mean error: ±5 mmHg
Max standard deviation: 8 mmHg
The measurement range of subject devices is wider than the predicate device</td></tr>
<tr><td>Invasive blood pressure (IBP)</td><td>Measurement range: -50 to 300 mmHg
Accuracy: ±2% or ±1 mmHg, whichever is greater (without sensor)</td><td colspan="2">Not Supported</td><td colspan="4">Same as the predicate device</td></tr>
<tr><td>Cardiac output (C.O.)</td><td>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)</td><td colspan="2">Not Supported</td><td colspan="4">Same as the predicate device</td></tr>
</table>

	Predicate Device (K152902)	**Subject Devices**					
Feature	**Passport 17m**	**uMEC6**	**uMEC10**	**uMEC7**	**uMEC12**	**uMEC15**	**uMEC15S**
Carbon dioxide (CO_2)	Sidestream CO2 Module: Measurement range0 – 13%Accuracy: 0-5%: ±0.26% abs 5-10%: ±5% of the reading 10-13%: ±10% of the reading ±0.3%ABS increase in error for ISO accuracy mode awRR measurement: awRR measurement range: 0 to 120rpm awRR measurement accuracy: ±2rpm	Not Supported		Sidestream CO2 Module: Measurement range:0 to 20% Accuracy: CO2 concentration<1%: ±0.1% 1%≤CO2 concentration<5%: ±0.2% 5%≤CO2 concentration<7%±0.3%7%≤CO2 concentration<12%±0.4% 12%≤CO2 concentration≤13%±0.5% 13%<CO2 concentration≤20%±(0.43%+8%rel) ±0.3%ABS increase in error for ISO accuracy mode awRR measurement: awRR measurement range: 0 to 150rpm awRR measurement accuracy: <60rpm: ±1rpm 60 to 150 rpm: ±2rpm The CO2 measurement range of subject devices is wider than thepredicate device The awRR measurement range of subject devices is wider than thepredicate device. The Accuracy of awRR is also improved			

Substantial Equivalence Conclusion:

Based on the detailed comparison between the previously cleared Passport Series devices (K152902) and the subject uMEC series devices, the performance testing and conformance with applicable standards, the uMEC Series Patient Monitors (including uMEC6, uMEC7, uMEC10, uMEC12, uMEC15, uMEC15S) can be found substantially equivalent to the predicate devices.