October 5, 2021

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, Guangdong 518057
China

Re: K211475
Trade/Device Name: Vital Signs Monitors
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, CCK, DQA, DXN, FLL
Dated: September 2, 2021
Received: September 3, 2021

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211475

Device Name
Vital Signs Monitors

Indications for Use *(Describe)*
The VS 9/VS 8/VS 8A Vital Signs Monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including Temperature (Temp), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon Dioxide (CO2). All the parameters can be monitored on single adult, pediatric, and neonatal patients.
The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use. The VS 9/VS 8/VS 8A Vital Signs 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 VS series Patient Monitors is provided below.

1. SUBMITTER

Applicant: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Date Prepared: August 1, 2021

2. DEVICE

Device Trade Name:	Vital Signs Monitors
Device Common Name:	VS series Vital Signs Monitors (Including VS 9, VS 8, VS 8A)
Classification Name and Regulation	21 CFR 870.2300, Cardiac monitor (including cardiotachometer and rate alarm)
Primary Product Code:	MWI - Monitor, physiological, patient (without arrhythmia detection or alarms)
Regulatory Class	Class II
Panel	Cardiovascular

Table 1: Secondary Product Codes

Product Code	Regulation Number	Panel	Regulation description	Device Common Name
CCK	21 CFR 868.1400	Anesthesiology	Carbon dioxide gas analyzer	analyzer, gas, carbon-dioxide, gaseous-phase
DQA	21 CFR 870.2700	Cardiovascular	Oximeter	oximeter
DXN	21 CFR 870.1130	Cardiovascular	Noninvasive blood pressure measurement system	system, measurement, blood-pressure, non-invasive
FLL	21 CFR 880.2910	Cardiovascular	Clinical electronic thermometer	thermometer, electronic, clinical

3. PREDICATE DEVICE

Predicate Device: 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)

Reference Device: K182821 - Accutorr 7/VS-900 Vital Signs Monitor (SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD)

K193391 - TM80 telemetry module component of the BeneVision Central Monitoring System (SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD)

4. DEVICE DESCRIPTION

The subject VS series Vital Signs Monitors includes three monitors:

- VS 9 Vital Signs Monitor
- VS 8 Vital Signs Monitor
- VS 8A Vital Signs Monitor

The VS series Vital Signs Monitors are for use for adult, pediatric, and neonatal patients. The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. The monitors should only be used by persons who have received adequate training in their use.

5. INTENDED USE/INDICATIONS FOR USE

The VS 9/VS 8/VS 8A Vital Signs Monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including Temperature (Temp), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure

(NIBP), Carbon Dioxide (CO2). All the parameters can be monitored on single adult, pediatric, and neonatal patients.

The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use. The VS 9/VS 8/VS 8A Vital Signs Monitor 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 monitors intended to be used under the direction of clinical professionals. The monitoring parameters supported by the VS series are a subset of those supported by the predicate ePM series monitors (K191769).

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

Technological Comparisons

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 device and the subject devices.

Note: In order to maintain readability, Table 2 only compares the subject device to the predicate ePM 10 model from K191769.

Table 2: Technological Comparison

Feature	Predicate Devices (K191769)	Subject VS Devices		
	ePM 10	VS 9	VS 8	VS 8A
Display and touchscreen	10.1” 1280*800 pixels	10.1” 1280*800 pixels	**8” 1024*768 pixels**	
Wireless	Wifi: The ePM series patient monitors support the laird MSD45N WiFi module.	Wifi: VS series monitors support the silex SX-SDMAC-2832S+ WiFi module. Bluetooth: VS series monitors support Bluetooth.		
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	Only support Rechargeable Lithium-Ion, 10.8VDC, 5600 mAhwhich is as same as ePM 10.	Support soft package Rechargeable Lithium-Ion, 10.95VDC, 5000 mAh Rechargeable Lithium-Ion, 10.95VDC, 2500 mAh.	
Data storage	Embedded Multi Media Card(eMMC)	same		
Data Recorder	Supports internal thermal recorder	same		
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support	same		

<table>
<tr><th rowspan="2">Feature</th><th>Predicate Devices (K191769)</th><th colspan="3">Subject VS Devices</th></tr>
<tr><th>ePM 10</th><th>VS 9</th><th>VS 8</th><th>VS 8A</th></tr>
<tr><td></td><td>PITCH TONE and multi-level tone modulation.</td><td colspan="3"></td></tr>
<tr><td>Alarm system</td><td>The alarm lamp is cyan, yellow, or red depending on alarm type.
Supports Alarm Volume Escalation</td><td colspan="3">same</td></tr>
<tr><td>Temperature (Temp)</td><td>Use internal 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).</td><td colspan="3">Different. Supports 2 types of temperature module, but only one module can be integrated at one time.

Mindray Temp Module:
Technique: Thermal resistance
Measurement range:
Monitor mode:25 to 44 °C (77 to 111.2 °F)
Predictive mode: 34 to 43°C (93.2 to 109.4 °F)

Accuracy (Monitor mode):
25 to 32°C (not include 32°C): ± 0.2 °C
32 to 44°C (include 32°C): ±0.1 °C(± 0.2 °F)
or
77 to 89.6 °F (not include 89.6°F): ± 0.4 °F
89.6 to 111.2 °F (include 89.6°F): ± 0.2 °F
Statistical Results of Clinical Investigation Data (Predictive mode)
<table>
<tr><th></th><th>Clinical BIAS (Δcb)</th><th>Limits of Agreement (LA)</th><th>Clinical Repeatability (σr)</th></tr>
<tr><td>Oral</td><td>0.02°C</td><td>0.33°C</td><td>0.1°C</td></tr>
<tr><td>Axilla</td><td>0.06°C</td><td>0.38°C</td><td>0.13°C</td></tr>
<tr><td>Rectum</td><td>-0.05°C</td><td>0.48°C</td><td>0.14°C</td></tr>
</table>
Integrated an optional OEM temp module (the Exergen Temporal Scanner Thermometer, cleared in K011291)
Measurement range:
16.0°C to 43.0°C（61°F~110°F)
Measurement accuracy: ± 0.2°C</td></tr>
</table>

Feature	Predicate Devices (K191769)	Subject VS Devices		
	ePM 10	VS 9	VS 8	VS 8A
Pulse oxygen saturation (SpO2)	Supports Mindray SpO2 function, Masimo SpO2 function and Nellcor SpO2 function from multi parameter module. The specifications for various SpO2 functions are the same. 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 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 SpO2 function, Masimo SpO2 function and Nellcor SpO2 function from multi parameter module. The specifications for various SpO2 functions are the same. The Masimo SpO2 module and the Nellcor SpO2 module are identical to the Masimo SpO2 module and the Nellcor SpO2 module in K191769. **The internal Mindray SpO2 minor circuit board layout is different compared to the Mindray SpO2 module in** K191769.		
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	Same		

Feature	Predicate Devices (K191769)	Subject VS Devices		
	ePM 10	VS 9	VS 8	VS 8A
	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.			
Non- invasive blood pressure(NIBP)	Measurement range: Adult Pediatric Neonate Systolic 25~290 25~240 25~140 Diastolic 10~250 10~200 10~115 Mean 15~260 15~215 15~125 Accuracy: Max mean error: ±5 mmHg; Max standard deviation: 8 mmHg. Measure in deflation phase Supports NIBP Venipuncture	The specifications are same as ePM10. Neonate is measured in the deflation phase, such as in the predicate device, **Adult and Pediatric is measured in the inflation phase (inflation measuring mode) If the measurement fails in the inflation phase, the blood pressure will be measured in deflation phase as the predicate device.** **The ink used on the cuffs accessories has been modified.** VS9 and VS8 support NIBP Venipuncture, but VS 8A doesn't support the feature.		
Carbon dioxide(CO2)	Compatible with 3 internal CO2 modules: Sidestream CO2 2.0 module Mainstream CO2 module MicroStream CO2 module The internal CO2 modules are identical to the external CO2 module in K182075 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,	Compatible with 1 internal CO2 modules: Sidestream CO2 2.0 module 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	Not supported	

Feature	Predicate Devices (K191769)	Subject VS Devices		
	ePM 10	**VS 9**	**VS 8**	**VS 8A**
	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.	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. **Some electronic components have been replaced because they are nearing end of life or Mindray has changed suppliers.**		
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 four types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), National Early Warning Score2 (NEWS2) and user configurable Custom Score.	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 four types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), National Early Warning Score2 (NEWS2) and user configurable Custom Score. **The VS series monitors remove the History total scores and Operator ID function from the EWS Scores**.		
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.	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 **The VS series monitors have a modify interface and does not include the Review and Interval Function.**		
Pain Score	Not support	Support	Support	Support
Vitalslink	Not support	Support	Support	Support
Rolling Stand	without Worktop and Power Supply	**with Worktop and Power Supply**		

6.1. Substantial Equivalence Conclusion

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

To establish the substantial equivalence of the VS Series Vital Signs 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.

7. PERFORMANCE DATA

Biocompatibility Testing

The VS Series Vital Signs Monitors are not patient contacting. The only change to patient contacting devices is an ink change to the NIBP cuffs. Therefore, in accordance with FDA guidance, “Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" dated September 4, 2020, cytotoxicity, sensitization and irritation testing were performed.

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 VS Series Vital Signs Monitors was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

Electrical safety and electromagnetic compatibility (EMC)

The VS Series Vital Signs 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 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.
- IEC 62133-2:2017 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 - Part 2: Lithium systems.

Bench Testing

To establish the substantial equivalence of the VS Series Vital Signs 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 60601-1-6:2010, AMD1:2013 Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability (Edition 3.1)
- IEC 60601-1-8:2006+Am1:2012 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 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 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, AMD1:2018 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, COR1:2018 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

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

To meet the requirements for the validity and accuracy of the NIBP measurement of automated measurement type, Mindray conducted clinical investigation with Reference Invasive Blood Pressure Monitoring Equipment and Auscultation reference sphygmomanometer according to the

requirements of the standard ISO 81060-2:2018 Non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type. Study results demonstrated that the VS Series Vital Signs Monitors comply with the requirements of the standard in the neonate, infant, child and adult populations.

8. CONCLUSION

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