December 15, 2022

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

Re: K221267
Trade/Device Name: VS 8 Vital Signs Monitor, VS 8A Vital Signs Monitor, VS 9 Vital Signs Monitor
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: April 19, 2022
Received: May 2, 2022

Dear Li Lei:

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,

Robert T. Kazmierski -S

for

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)*
K221267

Device Name
VS Series 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 Monitor 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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E-mail: lilei.js@mindray.com

Date Prepared: April 19, 2022

2. DEVICE

Device Trade Name:	VS Series Vital Signs Monitors (Including VS 9/VS 8/VS 8A)
Device Common Name:	Vital Signs Monitor
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: K211475 - VS Series Vital Signs Monitor (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

Indications of the predicate device and the subject device are the same.

Technological Comparisons

Table 2 compares the key technological feature of the subject device to the predicate device (VS series Vital Signs Monitor, K211475). The features in gray are features that have been modified since their previous clearances and that are the subject of this 510(k).

Table 2: Technological Comparison

Feature	**Predicate Devices (K211475)**			**Subject Devices**		
	VS 9	**VS 8**	**VS 8A**	**VS 9**	**VS 8**	**VS 8A**
Integrated display and touchscreen	10.1" 1280*800 pixels	8" 1024*768 pixels		Same	Same	
Touch screen	Capacitive touch screen			Same		
Function Button And Rotary Encoder	Not supported	Support		Same	Same	
Power supply	One or two rechargeable Lithium-ion battery or AC power supply			Same		
Battery	Chargeable Smart Lithium-Ion, 10.8 VDC, 5600 mAh	Chargeable non-Smart Lithium-Ion, 10.95 VDC, 2500 mAh or Chargeable non-Smart Lithium-Ion, 10.95 VDC, 5000 mAh		Same	Same	
Data Recorder	The thermal recorder can be used to print patient information, measurement numerics, and waveforms.			Same		
Speaker	Provide alarm tones (45 to 85 dB), key tones; support PITCH TONE and multi-level tone modulation			Same		
WiFi	2.4G/5G dual band WiFi, compatible with IEEE 802.11 a/b/g/n/ac			Same		
Bluetooth	Bluetooth 5			Same		

<table>
<tr><th>Feature</th><th colspan="3">Predicate Devices (K211475)</th><th colspan="3">Subject Devices</th></tr>
<tr><td></td><td>VS 9</td><td>VS 8</td><td>VS 8A</td><td>VS 9</td><td>VS 8</td><td>VS 8A</td></tr>
<tr><td>Mindray Temperature Module</td><td colspan="3">Mindray Temp Module (SmarTemp):
Technique: Thermal resistance

Measurement range:
Monitor mode:25 to 44 ℃ (77 to 111.2 ℉)
Predictive mode: 34 to 43 ℃ (93.2 to 109.4 ℉)

Accuracy (Monitor mode):
25 to 32℃(not include 32℃): ± 0.2 ℃
32 to 44℃(include 32℃): ±0.1 ℃(± 0.2 ℉)
or
77 to 89.6 ℉ (not include 89.6℉): ± 0.4 ℉
89.6 to 111.2 ℉ (include 89.6℉): ± 0.2 ℉

Statistical Results of Clinical Investigation Data(Predictive mode)
<table>
<tr><td></td><td>Clinical BIAS (Δcb)</td><td>Limits of Agreement (LA)</td><td>Clinical Repeatability (σr)</td></tr>
<tr><td>Oral</td><td>0.02℃</td><td>0.33℃</td><td>0.1℃</td></tr>
<tr><td>Axilla</td><td>0.06℃</td><td>0.38℃</td><td>0.13℃</td></tr>
<tr><td>Rectum</td><td>-0.05℃</td><td>0.48℃</td><td>0.14℃</td></tr>
</table></td><td colspan="3">Similar.
The performance of the module is validated by the clinical trial.

New Mindray Temp Module (TrueTemp):

Technique: Thermal resistance

Monitor mode:25 to 44 ℃ (77 to 111.2 ℉)
Predictive mode: 34 to 42 ℃ (93.2 to 107.6 ℉)

Accuracy (Monitor mode):
25 to 44℃: ±0.1 ℃(± 0.2 ℉)
Or 77 to 111.2 ℉: ± 0.2 ℉

Statistical Results of Clinical Investigation Data(Predictive mode)
<table>
<tr><td></td><td>Clinical BIAS (Δcb)</td><td>Limits of Agreement (LA)</td><td>Clinical Repeatability (σr)</td></tr>
<tr><td>Oral</td><td>0.03°C</td><td>0.37°C</td><td>0.14°C</td></tr>
<tr><td>Axilla</td><td>0.03°C</td><td>0.32°C</td><td>0.12°C</td></tr>
<tr><td>Rectum</td><td>-0.06°C</td><td>0.38°C</td><td>0.14°C</td></tr>
</table></td></tr>
<tr><td>Exergen Temperature (Temp) Module</td><td colspan="3">Integrated an optional OEM temp module (the Exergen Temporal Scanner Thermometer, cleared in K011291)
Measurement range: 15.5℃ to 42℃（60°F~107.6°F)
Measurement accuracy: ± 0.2°C or ± 0.4°F</td><td colspan="3">Same</td></tr>
</table>

Feature	Predicate Devices (K211475)			Subject Devices		
	VS 9	**VS 8**	**VS 8A**	**VS 9**	**VS 8**	**VS 8A**
Pulse oxygen saturation (SpO2)	Is compatible with the following 3 modules to measure oxygen saturation: • Mindray SpO2 Module • Masimo SpO2 Module • Nellcor SpO2 Module **Mindray SpO2 Module:** Measurement range: 0 to 100% Accuracy: 70 to 100%: ±2% ABS (adult/pediatric mode) 70 to 100%: ±3% ABS (neonate mode) 0% to 69%: Not specified. **Masimo SpO2 Module:** Measurement range: 1 to 100% Accuracy: 70 to 100%: ±2% ABS (without motion in adult/pediatric mode) 70 to 100%: ±3% ABS (without motion in neonate mode) 70 to 100%: ±3% ABS (with motion) 1% to 69%: Not specified. **Nellcor SpO2 Module:** Measurement range: 0 to 100% Accuracy: 70 to 100%: ±2%ABS (adult/pediatric mode) 70 to 100%: ±3% ABS(neonate mode) 0% to 69%: Not specified.			Same		
Non-invasive blood pressure (NIBP)	Uses the oscillometric method for measuring non-invasive blood pressure (NIBP), support inflation measuring mode. This measurement can be used for adults, pediatrics and neonates. Measurement range: Adult Pediatric Neonate Systolic: 25 to 290 25 to 240 25 to 140 Diastolic: 10 to 250 10 to 200 10 to 115 Mean: 15 to 260 15 to 215 15 to 125 Accuracy: Maximum average error: ±5 mmHg Maximum standard deviation: 8mmHg			Same		
NIBP Venipuncture	Uses the NIBP cuff to cause sub-diastolic pressure to block the venous blood vessel and therefore help venous puncture			Same		

Feature	Predicate Devices (K211475)			Subject Devices		
	VS 9	**VS 8**	**VS 8A**	**VS 9**	**VS 8**	**VS 8A**
Pulse rate (PR)	Pulse rate may be obtained from the SpO2 module or the NIBP module. **PR from Mindray SpO2 Module** Measurement range: 20 to 254 bpm Resolution: 1bpm Accuracy: ±3 bpm **PR from Masimo SpO2 Module** Measurement range: 25 to 240 bpm Resolution: 1bpm Accuracy: ±3 bpm (without motion) ±5 bpm (with motion) **PR from Nellcor SpO2 Module** Measurement range: 20 to 300 bpm Resolution: 1bpm Accuracy: 20 to 250 bpm: ±3 bpm 251 to 300 bpm: not specified **PR from NIBP Module** Measurement range: 30 to 300 bpm Resolution: 1bpm Accuracy: ±3bpm or ±3%, whichever is greater			Same		
Carbon dioxide (CO2)	CO2 parameter measuring. CO2 measurement range: 0-150mmHg Resolution: 1mmHg CO2 Accuracy： Full accuracy mode: 0~40 mmHg: ±2mmHg 41~76 mmHg: ±5% of reading 77~99 mmHg: ±10% of reading 100~150mmHg: ±(3mmHg + 8% of reading) ＞ 150mmHg CO2: unspecified ISO accuracy mode: Add ±2mmHg to the full accuracy mode	Not supported		Same	Same	

Feature	Predicate Devices (K211475)			Subject Devices		
	VS 9	**VS 8**	**VS 8A**	**VS 9**	**VS 8**	**VS 8A**
NIBP VeniPuncture	Support		Not supported	Same		Same

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 subject VS Series Vital Signs Monitors, Mindray conducted functional and system level testing to validate the performance of the devices. The results of the software and 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 subject VS Series Vital Signs Monitors are not patient contacting.

The subject VS Series Vital Signs Monitors have a new Mindray Temperature Module (TrueTemp) and TrueTemp temperature probe. The Mindray Temperature Module is non-patient contacting. The only component TrueTemp temperature probe that is patient contacting is the probe cover. Cytotoxicity, Sensitization, and Intracutaneous Reactivity testing was completed and passed.

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 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.
- AIM Standard 7351731 Rev. 2.00 2017-02-23 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard

Bench Testing

Mindray has conducted testing in accordance with the following standards to establish substantial equivalence, ensure the subject devices meet relevant consensus standards, and the device performs as intended.

- ISO 80601-2-56 Second edition 2017-03 + AMD1:2018 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ASTM E1112-00 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature (Reapproved 2018)
- ASTM E1104-98 Standard Specification for Clinical Thermometer Probe Covers and Sheaths (Reapproved 2016)

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 TEMP measurement of the new Mindray Temp Module (TrueTemp), Mindray conducted clinical investigation according to the requirements of the standard ISO 80601-2-56 Second edition 2017-03 + AMD1:2018: Medical electrical equipment- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. A clinical accuracy study evaluated 106, 110, 109 valid cases of oral, axillary and rectal temperature, which were performed on the following three age groups: infants (newborn to one year), children (greater than one to five years), and adults (greater than five years old) in accordance with ISO 80601-2-56 :2017/Amd.1:2018(E) to compare the direct mode of WelchAllyn SureTemp PLUS 690. The age of subjects is from 4 days to 67 years old. The total number of febrile subjects are not less than 30 % and not greater than 50 % of all subjects in the selected age group and body site. Statistical results show that, the temperature Measurement function of the TrueTemp module of the VS 9 Vital Signs Monitor in Predictive mode meets the requirements of ISO 80601-2-56:2017/ Amd.1:2018(E) for temperature measurement and meets the acceptance criteria in clinical protocol; the performances of the test device and the RCT are equivalent. During the entire clinical trial, all subjects are in good condition, and none of the subjects have discomfort

symptoms or adverse reactions due to the use of Mindray VS 9 Vital Signs Monitor for temperature measurement.

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.