December 2, 2022

Shenzhen Mindray Bio-Medical 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: K221113
Trade/Device Name: Accutorr 3 Vital Signs Monitor, Rosebud 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, DXN, DQA, FLL
Dated: November 2, 2022
Received: November 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)*
K221113

Device Name
Accutorr 3/Rosebud Vital Signs monitor

Indications for Use *(Describe)*
The Accutorr 3/Rosebud Vital Signs monitor is intended for spot-check monitoring physiologic parameters, including Pulse Oximetry (SpO2), Pulse Rate (PR), Non-Invasive Blood Pressure (NIBP) and Temperature (TEMP) on adult, pediatric, and neonatal patients in healthcare facilities by physicians or appropriate medical staff under the direction of physicians.

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.

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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the Accutorr 3 and Rosebud Vital Signs 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: Li Lei
Title: Manager Regulatory Affairs
Phone: +86 755 81885953
Fax: +86 755 26582680
E-mail: lilei.js@mindray.com

Date Prepared: November 1, 2022

2. DEVICE

Device Trade Name:	Vital Signs Monitors (specifically Accutorr 3, Rosebud)
Device Common Name:	Vital Signs Monitors
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
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: K132037 - Accutorr 3 Vital Signs Monitor (SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD)

Reference Device: K182821 - Accutorr 7/VS-900 Vital Signs Monitor (SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD): provided as a reference device for the expanded cleaning and disinfecting agents that has been added to the subject

4. DEVICE DESCRIPTION

The subject Vital Signs Monitors includes two monitors:

- Accutorr 3 Vital Signs Monitor
- Rosebud Vital Signs Monitor

The Vital Signs Monitors are for use for adult, pediatric, and neonatal patients. The monitors are to be used in healthcare facilities by physicians or appropriate medical staff under the direction of physicians.

5. INTENDED USE/INDICATIONS FOR USE

The Accutorr 3/Rosebud Vital Signs monitor is intended for spot-check monitoring physiologic parameters, including Pulse Oximeter (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP) and Temperature (TEMP) on adult, pediatric, and neonatal patients in healthcare facilities by physicians or appropriate medical staff under the direction of physicians.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Indications of the predicate device (Accutorr 3) and the subject device (Accutorr 3/Rosebud) are the same except for some minor grammar changes.

Technological Comparisons

Table 2 compares the key technological feature of the subject device to the predicate device (Accutorr 3 Vital Signs Monitor, K132037). 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 (K132037) **Accutorr 3**	Subject Devices **Accutorr 3/Rosebud**
Integrated display	LED Segment display, 90mm × 99mm	Same
LEDs	Power on LED: 1 (two color: yellow/green) AC power LED: 1 (green) Battery LED: 1 (green)	Same
Buzzer	Give pulse tone, power-on self check tone.	Same
Power supply	Rechargeable Lithium-ion battery or AC power supply	Same
Battery	Rechargeable Lithium-ion battery, 11.1 VDC, 4500 mAh	Same
Monitor Interface	RS 232 connector	Same
Temperature	Mindray Temp Module (SmarTemp): Technique: Thermal resistance Measurement range: Monitor mode:25 to 44 ℃v (77 to 111.2 ℉) Predictive mode: 35 to 43 ℃ (95 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)	**Similar.** The performance of the module is validated by the clinical trial. New Mindray Temp Module (TrueTemp): Technique: Thermal resistance Measurement Range 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><th rowspan="2">Feature</th><th>Predicate Devices (K132037)</th><th>Subject Devices</th></tr>
<tr><td>Accutorr 3</td><td>Accutorr 3/Rosebud</td></tr>
<tr><td></td><td>
<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℃</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>
<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>0.03°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>Pulse oxygen saturation (SpO2)</td><td>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 specifications of the various SpO2 functions provided by each manufacturer are the same across platforms.</td><td>Same</td></tr>
</table>

Feature	Predicate Devices (K132037)	Subject Devices
	Accutorr 3	**Accutorr 3/Rosebud**
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 (without motion) 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: 40 to 240 bpm Resolution: 1bpm Accuracy: ±3bpm or ±3%, whichever is greater	Same
Non-invasive blood pressure (NIBP)	Uses the oscillometric method for measuring non-invasive blood pressure (NIBP), This measurement can be used for adults, pediatrics and neonates. Measurement range: Adult Pediatric Neonate Systolic: 40 to 270 40 to 200 40 to 135 Diastolic:10 to 210 10 to 150 10 to 100 Accuracy: Maximum average error: ±5 mmHg Maximum standard deviation: 8mmHg	Same
Cleaning and disinfecting	Supported	Supported. Provides an expanded list of cleaning and disinfecting agents.

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 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 Vital Signs Monitors are not patient contacting.

The Accutorr 3/Rosebud has a new Mindray Temperature Module (TrueTemp) and TrueTemp temperature probe. The Mindray Temperature Module is non-patient contacting. The only component of the 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 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 that 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 2011)

- 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 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. The 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.

8. CONCLUSION

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