March 27, 2019

Shenzhen Mindray Bio-medical Electronics Co., LTD.
Yanhong Bai
Manager Regulatory Affairs, Technical Regulation Department

Hi-tech Industrial Park, Nanshan
Shenzhen, 518057 CN

Re: K182821
Trade/Device Name: Accutorr 7/VS-900/VS-900c 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
Dated: February 13, 2019
Received: February 19, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Shawn W. Forrest -S
2019.03.27 14:23:19 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182821

Device Name
Accutorr 7/VS-900/VS-900c Vital Signs Monitor

Indications for Use *(Describe)*
The Accutorr 7/VS-900/VS-900c Vital Signs Monitor is intended for monitoring physiologic parameters, including Pulse Oximetry (SpO2), Pulse Rate (PR), Non Invasive Blood Pressure (NIBP), Temperature (TEMP) and Carbon Dioxide (CO2) on adult, pediatric, and neonatal patients in professional healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

- The monitor also provides a Modified Early Warning Score (MEWS) for clinical assessment in adult patients.

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 Accutorr 7/VS-900/VS-900c Vital Signs Monitor is provided below.

Device Common Name: monitor, physiological, patient (without arrhythmia detection or alarms)

Device Proprietary Name: Accutorr 7/VS-900/VS-900c Vital Signs Monitor

Submitter:

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Date Prepared:

September 30, 2018

Classification Regulation: 21 CFR 870.2300, Class II, Cardiac monitor (including cardiotachometer and rate alarm)

Panel: Cardiovascular

Classification Regulation, Classification Name and Product Codes:

Primary				
Product Code	**Regulation Number**	**Panel**	**Regulation description**	**Device Common Name**
MWI	21 CFR 870.2300	Cardiovascular	Cardiac monitor (including cardiotachometer and rate alarm)	monitor, physiological, patient (without arrhythmia detection or alarms)
Secondary				
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	Anesthesiology	Oximeter	oximeter
DXN	21 CFR 870.1130	Cardiovascular	Noninvasive blood pressure measurement system	system, measurement, blood-pressure, non-invasive
FLL	21 CFR 880.2910	General Hospital	Clinical electronic thermometer	thermometer, electronic, clinical

Primary Predicate Device:

K170712 - Accutorr 7/VS-900 Vital Signs Monitor; SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD

Secondary Predicate Device:

K011291 - TEMPORALSCANNER THERMOMETER, SENSORTOUCH; EXERGEN CORP.

Indications for Use:

The Accutorr 7/VS-900/VS-900c Vital Signs Monitor is intended for monitoring physiologic parameters, including Pulse Oximetry (SpO2), Pulse Rate (PR), Non Invasive Blood Pressure (NIBP), Temperature (TEMP) and Carbon Dioxide (CO2) on adult, pediatric, and neonatal patients in professional healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

- The monitor also provides a Modified Early Warning Score (MEWS) for clinical assessment in adult patients.

Device Description:

The Accutorr 7/VS-900/VS-900c Vital Signs Monitors are composed of the main unit and parameter modules. The main unit has the following functions:

- Provides operation interface, such as keys, touchscreen, and display screen.
- Communicates with the parameter modules.
- Delivers the setup commands of parameters to the parameter modules.
- Obtains the parameter measurements.
- Displays and stores the parameter numeric measurements and waveforms, and sends the data to Mindray's central monitoring system or Mindray's eGateway.

The parameter measurement modules include Pulse Oximetry (SpO2), Pulse Rate (PR), Non Invasive Blood Pressure (NIBP), Temperature (TEMP) and Carbon Dioxide (CO2). Their measurement principles are as follows:

Pulse Oxygen Saturation (SpO2) monitoring is a non-invasive technique used to determine the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the emitter side of the probe is partly absorbed when it passes through the monitored tissue. The amount of transmitted light is detected in the detector side of the probe. When the pulse active part of the light signal is examined, the amount of light absorbed by the hemoglobin is measured and the pulse oxygen saturation can be calculated. The SpO2 module processes the electrical signal and displays a waveform and numeric values for SpO2 and pulse rate.

The monitor uses the oscillometric method for measuring the non-invasive blood pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. The oscillometric device uses a blood pressure cuff to sense these oscillations, which appear as tiny pulsations in cuff pressure. The Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

CO2 monitoring is based on measuring the absorption of infrared (IR) light of specific wavelengths. CO2 has its own absorption characteristic and the amount of light passing to the gas probe depends on the concentration of the measured CO2. When a specific band of IR light passes through respiratory gas samples, some of the IR light will be absorbed by the CO2 molecules. The amount of IR light transmitted after it has been passed through the respiratory gas sample is measured with a photodetector. From the amount of IR light measured, the concentration of CO2 is calculated.

The monitor supports two kinds of TEMP module: Mindray TEMP and Exergen TEMP. Different TEMP modules cannot be used at same time. The customers need to choose one kind of TEMP module before they buy the monitor.

- Mindray TEMP Module has two measuring modes, Monitor mode and Predictive mode. In the Monitor mode, the thermal resistance in the probe reflects the subject's temperature by sensing the temperature change of the subject according to the thermal equilibrium principle. In the Predictive mode, the subject's temperature is predicted by the temperature rise curve (which is obtained by collecting multiple temperature measurements) at the time of initial thermal conduction.
- The Exergen Temperature Module is an infrared thermometer designed for accurate and completely non-invasive temperature assessment by scanning the temporal artery (TA). Temperature is measured by gently swiping the Temporal Scanner across the forehead, and includes a momentary touch of the probe to the neck area behind the ear lobe to account for any cooling of the forehead as a result of diaphoresis. The patented arterial heat balance technology (AHB™) automatically measures the temperature of the skin surface over the artery and the ambient temperature. It samples these readings approximately 1000 times a second, ultimately recording the highest temperature measured (peak) during the course of the measurement. The Temporal Scanner emits nothing - it only senses the natural thermal radiation emitted from the skin.

Non-clinical testing:

EMC and Electrical Safety - To establish the substantial equivalence of the subject Accutorr 7/VS-900/VS-900c Vital Signs Monitor to the previously cleared Accutorr 7/VS-900 Vital Signs Monitor (K170712), Mindray conducted Electromagnetic Compatibility and Electrical Safety testing level testing on the subject device. The testing provides an evaluation of the EMC and electrical safety of the subject devices relevant to each of the modifications since clearance of the predicate Accutorr 7/VS-900 Vital Signs Monitor. The Electromagnetic Compatibility and Electrical Safety testing shows that the subject device continues to meet the specifications and the performance of the subject device is equivalent to the predicate device.

- AAMI ANSI 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 (Fourth Edition) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Performance Testing – Bench - To establish the substantial equivalence of the subject Accutorr 7/VS-900/VS-900c Vital Signs Monitor to the previously cleared Accutorr 7/VS-900 Vital Signs Monitor (K170712), Mindray conducted functional and system level testing on the subject devices. The testing provides an evaluation of the performance of the subject devices relevant to each of the modifications since clearance of the Accutorr 7/VS-900 Vital Signs Monitor. The functional and system level testing shows that the subject device continues to meet the specifications and the performance of the subject device is equivalent to the predicate device. In addition, Mindray has conducted testing to ensure the subject device meets relevant consensus

standards.
In addition, Mindray has conducted testing to ensure the subject device meets following consensus standards.

- IEC 80601-2-30: 2013-07 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- 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

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 subject device (Accutorr 7/VS-900/VS-900c 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.

Substantial Equivalence:

Comparison of Indications - Indications of the predicate device (Accutorr 7/VS-900) and the subject device (Accutorr 7/VS-900/VS-900c Vital Signs monitors) are the same except the new model, VS-900c, is added.

Comparison of Technological Characteristics - The table below compares the key technological feature of the subject device (Accutorr 7/VS-900/VS-900c) to the primary predicate device (Accutorr 7/VS-900) (K170712). The features in gray are the main features that have been modified since their previous clearances.

Device Comparison Table

Feature	Primary Predicate Device (K170712)	Subject Devices
	Accutorr 7/VS-900	**Accutorr 7/VS-900/VS-900c**
Integrated display and touchscreen	8.4” 800*600 pixels	Same
Power supply	One rechargeable Lithium-ion battery or AC power supply	Same
Battery	Chargeable Lithium-Ion, 11.1 VDC, 4500 mAh	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	Same

Feature	Primary Predicate Device (K170712)	Subject Devices
	Accutorr 7/VS-900	**Accutorr 7/VS-900/VS-900c**
Temperature (Temp)	Mindray Temp Module : Technique: Thermal resistance Measurement range: Monitor mode:25 to 44 ℃ (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 ℉ Response Time: Monitor mode: <60 s Predictive mode: <20 s (typical test: < 12s)	Same

Feature	Primary Predicate Device (K170712)	Subject Devices
	Accutorr 7/VS-900	**Accutorr 7/VS-900/VS-900c**
Exergen Temperature (Temp) Module	Not supported.	Integrated an optional OEM temp module (the Exergen Temporal Scanner Thermometer, cleared in K011291) Measurement range: 16.0℃ to 43.0℃（61°F~110°F) Measurement accuracy: ± 0.2°C
Pulse oxygen saturation (SpO_2)	Is compatible with the following 3 modules to measure oxygen saturation: • Mindray SpO_2 Module • Masimo SpO_2 Module • Nellcor SpO_2 Module **Mindray SpO2 Module:** Measurement range: 0 to 100% Accuracy: 70 to 100%: ±2% (without motion in adult/pediatric mode) 70 to 100%: ±3% (without motion in neonate mode) 0% to 69%: Not specified.	Same

Feature	Primary Predicate Device (K170712)	Subject Devices
	Accutorr 7/VS-900	**Accutorr 7/VS-900/VS-900c**
	Masimo SpO2 Module: Measurement range: 1 to 100% Accuracy:70 to 100%: ±2% (without motion in adult/pediatric mode) 70 to 100%: ±3% (without motion in neonate mode) 70 to 100%: ±3% (with motion) 1% to 69%: Not specified. **Nellcor SpO2 Module:** Measurement range: 0 to 100% Accuracy: 70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified.	

Feature	Primary Predicate Device (K170712)	Subject Devices
	Accutorr 7/VS-900	**Accutorr 7/VS-900/VS-900c**
Pulse rate (PR)	Pulse rate may be obtained from the SpO_2 module or the NIBP module. PR from Mindray SpO2 Module Measurement range: 20 to 254 bpm Accuracy: ±3 bpm (without motion) PR from Masimo SpO2 Module Measurement range: 25 to 240 bpm Accuracy: ±3 bpm (without motion) ±5 bpm (with motion) PR from Nellcor SpO2 Module Measurement range: 20 to 300 bpm Accuracy: 20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified PR from NIBP Module Measurement range: 40 to 240 bpm Accuracy: ±3bpm or ±3%, whichever is greater	The Measurement range of PR from the NIBP Module has been expanded to: 30 to 300 bpm Other specifications are the same

<table>
<tr><td rowspan="2">Feature</td><td>Primary Predicate Device (K170712)</td><td>Subject Devices</td></tr>
<tr><td>Accutorr 7/VS-900</td><td>Accutorr 7/VS-900/VS-900c</td></tr>
<tr><td>Non-invasive blood pressure (NIBP)</td><td>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
Mean: 20 to 230 20 to 165 20 to 110
Accuracy:
Maximum average error: ±5 mmHg
Maximum standard deviation: 8mmHg
Maximum measurement time:
Adult, pediatric: 180 s Neonate: 90 s
Static pressure measurement range: 0mmHg to 300mmHg
Static pressure measurement accuracy: ±3 mmHg</td><td>Uses the oscillometric method for measuring non-invasive blood pressure (NIBP). This measurement can be used for adult, pediatric and neonatal patients.

Expand the display range of NIBP to comply with IEC 80601-2-30: 2013:
Measurement range:
<table><tr><td></td><td>Adult</td><td>Pediatric</td><td>Neonate</td></tr><tr><td>Systolic:</td><td>25 to 290</td><td>25 to 240</td><td>25 to 140</td></tr><tr><td>Diastolic:</td><td>10 to 250</td><td>10 to 200</td><td>10 to 115</td></tr><tr><td>Mean:</td><td>15 to 260</td><td>15 to 215</td><td>15 to 125</td></tr></table>
All other specifications are the same.</td></tr>
</table>

Feature	Primary Predicate Device (K170712)	Subject Devices
	Accutorr 7/VS-900	**Accutorr 7/VS-900/VS-900c**
Carbon dioxide (CO_2)	CO2 parameter measuring. CO2 measurement range: 0-20% Resolution: 1mmHg CO2 Accuracy: After Warm-up（FULL Accuracy）: 0%≤CO2<1%: ±0.1% 1%≤CO2<5%: ±0.2% 5%≤CO2<7%: ±0.3% 7%≤CO2<12%: ±0.4% 12%≤CO2≤13%: ±0.5% 13%<CO2≤20%: ±（0.43%+8%rel） 20%<CO2≤30%, unspecified During Warm-up(ISO Accuracy): Add ±0.3%ABS to the FULL accuracy Accuracy drift: Meet the requirement for measurement accuracy within 6 hours. Sampling flow rate: 50ml/min	Same
Add a new model named VS-900c	Not supported	Supported

<table>
<tr><td rowspan="2">Feature</td><td>Primary Predicate Device (K170712)</td><td colspan="4">Subject Devices</td></tr>
<tr><td>Accutorr 7/VS-900</td><td colspan="4">Accutorr 7/VS-900/VS-900c</td></tr>
<tr><td rowspan="15">Support the new Masimo RD SpO2 accessories</td><td rowspan="15">Not supported</td><td>Mindray Part No.</td><td>Masimo Model</td><td>Description</td><td>Corresponding 510(k) Number</td></tr>
<tr><td>040-003376-00</td><td>4050</td><td>RD SET DCI, Adult Reusable Sensor</td><td>K051212</td></tr>
<tr><td>040-003377-00</td><td>4051</td><td>RD SET DCI, Pediatric Reusable Sensor</td><td>K051212</td></tr>
<tr><td>040-003378-00</td><td>4080</td><td>RD SET MD 14-05, PC 5 ft</td><td>K042536</td></tr>
<tr><td>040-003379-00</td><td>4081</td><td>RD SET MD 14-12, Patient Cable 12 ft</td><td>K042536</td></tr>
<tr><td>040-003380-00</td><td>4053</td><td>RD Set TC-I SpO2 Reusable Tip-Clip Ear Sensor, 3ft</td><td>K051212</td></tr>
<tr><td>040-003381-00</td><td>4089</td><td>RD to LNC Adapter Cable</td><td>K042536</td></tr>
<tr><td>040-003382-00</td><td>4000</td><td>RD SET Adhesive Sensor</td><td>K042346</td></tr>
<tr><td>040-003383-00</td><td>4001</td><td>RD SET PDT Adhesive Sensor</td><td>K042346</td></tr>
<tr><td>040-003384-00</td><td>4002</td><td>RD Set Infant Adhesive Sensor</td><td>K042346</td></tr>
<tr><td>040-003385-00</td><td>4003</td><td>RD Set Neo Adhesive Sensor</td><td>K042346</td></tr>
<tr><td>040-003386-00</td><td>4004</td><td>RD Set NeoPt Adhesive Sensor</td><td>K042346</td></tr>
<tr><td>040-003387-00</td><td>4005</td><td>RD Set NeoPt-500 Non-adhesive sensor</td><td>K042346</td></tr>
<tr><td>040-003426-00</td><td>4092</td><td>LNCS to RD Adapter Cable</td><td>K042346</td></tr>
<tr><td>040-003310-00</td><td>583A</td><td>8pin Masimo Cable（RD SET）</td><td>/</td></tr>
<tr><td>Support timer tool</td><td>Not supported</td><td colspan="4">Supported</td></tr>
</table>

Feature	Primary Predicate Device (K170712)	Subject Devices
	Accutorr 7/VS-900	**Accutorr 7/VS-900/VS-900c**
Support the Visit Number (VID) of the patient demographics	Not supported	Supported
Support the Facility of the location information of patient monitor	Not supported	Supported
Support DNS for ADT and EMR server address	Not supported	Supported
Support authorization of the user by the LDAP	Not supported	Supported
Support password protection for accessing the Alarm Setup Menu	Not supported	Supported
Support encrypting of patient private information sent to the network	Not supported	Supported

Feature	Primary Predicate Device (K170712)	Subject Devices
	Accutorr 7/VS-900	**Accutorr 7/VS-900/VS-900c**
Support expanded cleaning and disinfecting agents list	Not supported	Supported Please refer to Section 12.3.12 for details.
Change the material of the socket on the SpO2/CO2 signal cord	The material of the socket on the SpO2/CO2 signal cord is Polypropylene (PP).	The material of the socket on the SpO2/CO2 signal cord is changed to Polybutyene Terephthatate (PBT) + Glass Fibre (DR48).

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications for each of the modifications to the primary predicate device (Accutorr 7/VS-900) (K170712) and the secondary predicate device (Exergen Temporal Scanner Thermometer)(K011291), and the performance testing and conformance with applicable standards, the subject device (Accutorr 7/VS-900/VS-900c) can be found substantially equivalent to the primary predicate device.