DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 2, 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, P.R. CN

Re: K170712
Trade/Device Name: Accutorr 7/VS-900 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, DQA, DXN, FLL, CCK
Dated: March 27, 2017
Received: March 28, 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.

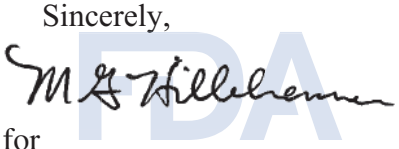
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*

K170712

Device Name
Accutorr 7/VS-900 Vital Signs Monitor

Indications for Use *(Describe)*

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

Device Common Name: Vital Signs Monitor

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

Applicant:

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Date Prepared: March 7, 2017

Classification Regulation: 21 CFR 870.2300, Class II, Cardiovascular

Panel: Cardiovascular

Primary Product Code: MWI

Secondary Product Codes:

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
DQA	21 CFR 870.2700	Anesthesiology	Oximeter.	Oximeter
DXN	21 CFR 870.1130	Cardiovascular	Non-Invasive blood pressure measurement System.	system, measurement, blood-pressure, non-invasive
FLL	21 CFR 880.2910	General Hospital	Clinical Electronic Thermometer.	thermometer, electronic, clinical
CCK	21 CFR 868.1400	Anesthesiology	Carbon dioxide gas analyzer.	analyzer, gas, carbon-dioxide, gaseous-phase

Primary Predicate Device: K132038 - Accutorr 7 Vital Signs Monitor; Shenzhen Mindray Bio-Medical Electronics Co., Ltd

Reference Predicate: K152902 - Passport Series Patient Monitors (Including Passport 12M, Passport 17M and T1); Shenzhen Mindray Bio-Medical Electronics Co., Ltd

Indication for Use:

The Accutorr 7/VS-900 Vital Signs Monitor is intended for monitoring physiologic parameters, including Pulse Oximetry (SpO_2), Pulse Rate (PR), Non Invasive Blood Pressure (NIBP), Temperature (TEMP) and Carbon Dioxide (CO_2) 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 Vital Signs Monitor is a compact, easy-to-use vital signs monitor designed to satisfy basic monitoring needs. This patient monitor consists of a main unit, parameters measurement accessories, peripheral equipments or accessories.

Performance Data:

Functional and System Level Testing: To establish the substantial equivalence of the Accutorr 7/VS-900 Vital Signs Monitor, Mindray conducted functional and system level testing on the subject devices. The testing provided an evaluation of the performance of the device relevant to each of the modifications to the subject devices since their previous clearance. 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.

Biocompatibility: Each patient contacting material and gas path material has been tested to comply with applicable requirements per ISO 10993-1.

Software: The Accutorr 7/VS-900 Vital Signs Monitor software has been fully verified and validated and documentation in accordance with FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: May 11, 2005" has been provided in this submission.

EMC and Electrical Safety: Mindray has been tested for conformance with the following electromagnetic compatibility and electrical safety standards:

- AAMI /ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-1-2: 2007 & 2014

In addition, Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.

- IEC60601-1-6: 2013

- AAMI / ANSI / IEC60601-1-8:2006 & A1:2012
- IEC80601-2-30 Edition 1.1 2013
- IEC 60601-2-49: 2011
- ISO80601-2-55: 2011
- ISO80601-2-61: 2011
- ISO80601-2-56: 2009

Wireless Coexistence: Mindray conducted wireless functionality testing to ensure the performance of the Accutorr 7/VS-900 Vital Signs Monitor meets wireless specifications and is equivalent to the predicate device.

Substantial Equivalence:

The table below compares the key technological feature of the subject devices to the primary predicate device (Accutorr 7, K132038). The features highlighted in yellow are the features that have been modified since the previous clearance and that are the subject of this 510(k).

Device Comparison Table

	Predicate Device (K132038)	**Subject Devices**
Feature	**Accutorr 7**	**Accutorr 7/VS-900**
Integrated display and touchscreen	8.4" 800*600 pixels	Same
Power supply	One rechargeable Lithium-ion batteries 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	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation	Same
WiFi	2.4G band WiFi, compatible with 802.11 b/g/n	2.4G/5G dual band WiFi compatible with IEEE 802.11 a/b/g/n
Temperature (Temp)	Mindray Temp Module : Technique: Thermal resistance Measurement range: Monitor mode:25 to 44 ℃ (77 to 111.2 °F) Predictive mode: 35 to 43 ℃ (95 to 109.4 °F) Resolution 0.1℃ Accuracy (Monitor mode) : 25 to 32℃(not include 32℃): ±0.2 ℃ 32 to 44℃(include 32℃): ±0.1 ℃(±0.2 °F) or 77 to 89.6 °F (not include 89.6°F): ±0.4 °F	Same

	Predicate Device (K132038)	**Subject Devices**
Feature	**Accutorr 7**	**Accutorr 7/VS-900**
	89.6 to 111.2 °F (include 89.6°F): ± 0.2 °F Response Time: Monitor mode: <60 s Predictive mode: <20 s (typical test: < 12s)	
Pulse oxygen saturation (SpO_2)	Is compatible with the following cleared modules to measure oxygen saturation: Mindray SpO_2 Module Masimo SpO_2 Module Nellcor SpO_2 Module <u>Mindray SpO2 Module</u> Measurement range: 0 to 100 Resolution: 1% Accuracy: 70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 0% to 69%: Not specified. Refreshing rate: 1s <u>Masimo SpO2 Module:</u> Measurement range: 1 to 100% Resolution: 1% 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. Refreshing rate: 1s <u>Nellcor SpO2 Module:</u> Measurement range: 0 to 100% Resolution: 1% Accuracy: 70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified. Refreshing rate: 1s	Same
Pulse rate (PR)	Pulse rate may be obtained from the SpO_2 module or the NIBP module. <u>PR from Mindray SpO2 Module</u>	Same

	Predicate Device (K132038)	**Subject Devices**
Feature	**Accutorr 7**	**Accutorr 7/VS-900**
	Measurement range: 20 to 254 bpm Resolution: 1bpm Accuracy: ±3 bpm (without motion) Refreshing rate: 1s <u>PR from Masimo SpO2 Module</u> Measurement range: 25 to 240 bpm Resolution: 1bpm Accuracy: ±3 bpm (without motion) ±5 bpm (with motion) Refreshing rate: 1s <u>PR from Nellcor SpO2 Module</u> Measurement range: 20 to 300 bpm Resolution: 1bpm Accuracy: 20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified Refreshing rate: 1s <u>PR from NIBP Module</u> Measurement range: 40 to 240 bpm Resolution: 1bpm Accuracy: ±3bpm or ±3%, whichever is greater	
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 Mean: 20 to 230 20 to 165 20 to 110 Accuracy: Maximum average error: ±5 mmHg Maximum standard deviation: 8mmHg Max measurement time: Adult, pediatric: 180 s Neonate: 90 s	Same

	Predicate Device (K132038)	Subject Devices
Feature	**Accutorr 7**	**Accutorr 7/VS-900**
	Static pressure measurement range: 0mmHg to 300mmHg Static pressure measurement accuracy: ±3 mmHg	
Carbon dioxide (CO_2)	The primary predicate device did not provide CO2 monitoring. This feature is substantially equivalent to the reference predicate device Passport 12m, Passport 17m and T1 (K152902).	CO2 monitoring is based on calculations from measuring the absorption of infrared (IR) light of specific wavelengths using a photodetector.

Substantial Equivalence Discussion:

The indications for use statement of the subject device has been modified to include the new parameter of CO_2. Although this feature is not present in the predicate device, it is present in the cleared Mindray Passport Series Monitors (Passport 12m, Passport 17m and T1) (K152902) and thus does not constitute a new intended use for a multi-parameter monitor. The minor changes to the indications for use do not change the fundamental intended use of the Accutorr 7/VS-900 as a multi-parameter monitor and can be found substantially equivalent to the predicate device.

Based on the detailed comparison of specifications for each of the modifications to the previously cleared Accutorr 7/VS-900 (K132038) and relevant reference predicate, as well as the performance testing and conformance with applicable standards, the Accutorr 7/VS-900 can be found substantially equivalent to the predicate device.