510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K132038

Submitter: Shenzhen Mindray Bio-medical Electronics Co., LTD
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Date Prepared: March 25, 2014

Trade/Proprietary Name: Accutorr 7 Vital Signs Monitor

Common Name: Vital Signs Monitor

Classification:

21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm)	Class II
21 CFR 870.1130 Non-Invasive blood pressure measurement System	Class II
21 CFR 880.2910 Clinical Electronic Thermometers–Temperature Monitor with Probe	Class II
21 CFR 870.2700 Oximeter, Pulse	Class II

Legally Marketed Predicate Devices:
K072235, VS-800 Vital Signs Monitor, Shenzhen Mindray Bio-medical Electronics Co., LTD

Device Description:
The Accutorr 7 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.
The Accutorr 7 Vital Signs Monitor is intended for monitoring physiologic parameters, including SpO2, PR, NIBP and TEMP, on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

Statement of intended Use:
The Accutorr 7 Vital Signs Monitor is intended for monitoring physiologic parameters, including SpO2, PR, NIBP and TEMP, on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians

Technology:
The Accutorr 7 Vital Signs Monitor is substantially equivalent to the predicate devices VS-800 Vital Signs Monitor (K072235).

Test Summary:
The Accutorr 7 Vital Signs Monitor comply with the recognized safety, performance and electromagnetic compatibility standards. A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. Mindray's product development process required that the following activities be completed during the development of those patient monitors:
Requirements specification review
Hardware and Software testing
Code design and code reviews
Environmental EMC testing
Wireless testing
Safety testing
Performance testing
Hardware and Software validation

Conclusion:
The results of all testing demonstrate that the Accutorr 7 Vital Signs Monitor is as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

Mindray North America
Russell Olsen
800 Macarthur Blvd
Mahwah, NJ 07430 US

Re: K132038
Trade/Device Name: Accutorr 7 Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II
Product Code: MWI
Dated: April 1, 2014
Received: April 3, 2014

Dear Russell Olsen:

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.

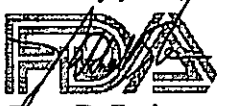
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132038

Indications for Use

510(k) Number (if known): _____

Device Name: Accutorr 7 Vital Signs Monitor

Indications for Use:

The Accutorr 7 Vital Signs Monitor is intended for monitoring physiologic parameters, including SpO2, PR, NIBP and TEMP, on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.05.02 15:01:43 -04'00'