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510(k) Summary
Accutorr V Monitor

MAY - 8 2009

This 510(K) Summary is provided in accordance with 21 CFR 807.92.

Date: April 10, 2009

Submitter:

Datascope Patient Monitoring, Mindray DS USA, Inc.
800 MacArthur Blvd.
Mahwah, NJ 07430
Contact: Kathleen Kramer
Manager, Clinical and Regulatory Affairs
Telephone: 201-995-8169
Facsimile: 201-995-8605

Device Trade Name: Accutorr V Monitor

Common Name: Noninvasive Blood Pressure Management System

Device Classification: Cardiovascular, Class II, 21 CFR 870.1130, Product Code DXN.

Predicate Devices: Accutorr Plus Noninvasive Blood Pressure Monitor - K983575

Device description: The Accutorr V Monitor is a vital signs monitor intended for use in a health care facility under the direct supervision of a licensed healthcare practitioner.

The Accutorr V provides high and low alarm limit settings for systolic, diastolic, mean arterial pressure, pulse rate, and pulse oximetry (SpO_2). The Accutorr V may be powered by a rechargeable Lithium ion battery or through line-power. The Accutorr V may be equipped with optional infrared or predictive temperature and recorder modules and may be mounted on an optional rolling stand for easy portability.

Indications for Use: The intended use of the Accutorr V is to monitor physiologic parameter data on adult, pediatric and neonatal patients. The physiologic parameters measured includes: noninvasive blood pressure (NIBP), pulse oximetry (SpO_2), pulse rate and temperature.

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Technological Comparison to Predicate Device: The Accutorr V is substantially equivalent to the predicate device, the Accutorr Plus respecting the indications for use, basic operating, performance specifications, energy supply and materials (with the exception of the external housing material).

Summary of Performance Testing: The Accutorr V Monitor has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards.

A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. The device's software has been verified and validated in accordance with the appropriate test requirements.

Conclusion: Based on the description, technological comparison, performance testing and the supporting documentation it can be concluded that the Accutorr V Monitor is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2009

Datascope Patient Monitoring, Mindray DS USA, Inc.
c/o Ms. Kathleen Kramer
Manager, Clinical and Regulatory Affairs
800 MacArthur Blvd.
Mahwah, NJ 07430

Re: K091068
Trade/Device Name: ACCUTORR V MONITOR
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Codes: DXN
Dated: April 17, 2009
Received: April 20, 2009

Dear Ms. Kramer:

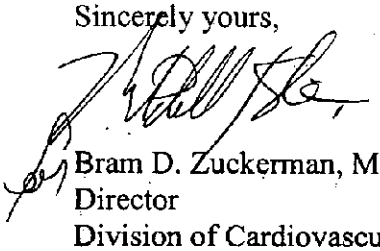
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K091068

Indications for Use

510(k) Number (if known): _____

Device Name: ACCUTORR V

Indications For Use:

The intended use of the Accutorr V is to monitor physiologic parameter data on adult, pediatric and neonatal patients. The physiologic parameters measured includes: noninvasive blood pressure (NIBP), pulse oximetry (SpO_2), heart rate and temperature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 5/8/09
Division of Cardiovascular Devices

510(k) Number K091068