K091834

JUL 15 2009

510(k) Summary
Passport V Monitor

This 510(k) Summary is provided in accordance with the requirements of 21 CFR 807.92.

Date: June 19, 2009

Submitter:

Datascope Patient Monitoring, Mindray DS USA, Inc.
800 MacArthur Blvd.
Mahwah, NJ 07430
Contact: Kathleen Kramer
Manager, Regulatory and Clinical Affairs
Telephone: 201-995-8169
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Device Trade Name: Passport V Monitor

Common Name: Multi-parameter patient monitor (with Arrhythmia Detection or Alarms)

Device Classification:

21 CFR 870.1025- Arrhythmia detector and alarm
21 CFR 868.1400- Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
21 CFR 870.1110- Blood Pressure computer
21 CFR 870.1130- Non-invasive blood pressure measurement system
21 CFR 870.1425- Programmable diagnostic computer
21 CFR 870.2300- Cardiac Monitor (Incl. Cardiotachometer and rate alarm)
21 CFR 870.2700- Oximeter
21 CFR 880.2910- Monitors, Temperature (with probe)

Predicate Devices:

Spectrum Monitor – K031849
PM Series Patient Monitors – K070791
Accutorr V Monitor – K091068

Device description:

The Passport 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 Passport V provides high and low alarm limit settings for systolic, diastolic, mean arterial pressure, pulse rate, and pulse oximetry (SpO_2). The Passport V may be powered by a rechargeable Lithium ion battery or through line-power. The Passport 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 Passport V monitor is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The indications for use for the Passport V include the monitoring of the following human physiological parameters:

- ECG waveform derived from 3 or 5 lead measurements
- Heart Rate derived from selected sources (ECG, SpO_2, IBP)
- Pulse Oximetry (SpO_2)
- ST Segment Analysis derived from 3 or 5 lead measurements
- Arrhythmia Detection derived from 3 or 5 lead measurements
- Non Invasive Blood Pressure (NIBP)
- Invasive Blood Pressure (IBP) - up to two (2) channels
- Carbon Dioxide (CO_2)
- Respiration Rate derived from ECG or CO_2
- Temperature
- IV Drug Calculations

The target populations are adult, pediatric and neonate with the exception of:

- Arrhythmia detection and ST Segment Analysis for which the target populations are adult and pediatric only, and
- IV Drug Calculations for which the target population is adult only.

Technological Comparison to Predicate Device:

The Passport V is substantially equivalent to the predicate devices, the Spectrum Monitor respecting the indications for use, basic operation, performance specifications, energy supply and materials (with the exception of the external housing material). The Passport V is substantially equivalent to the predicates PM Series and Accutorr V Monitors respecting CO_2 and SpO_2.

Summary of Performance Testing:

The Passport 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 Passport V Monitor is safe, effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

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

Re: K091834
Passport V Monitor
Regulation Number: 21 CFR 870. 1025
Regulation Name: Multi-Parameter Patient Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Additional Product Codes: CCK, DSK, DXN, DQK, MSK, DQA, FLL
Dated: June 19, 2009
Received: June 22, 2009

Dear Ms. Kramer:

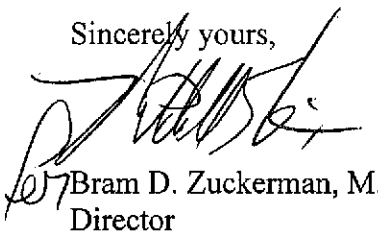
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

Indications for Use

510(k) Number (if known): K091834

Device Name: PASSPORT V_MONITOR

Indications For Use:

The Passport V monitor is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The indications for use for the Passport V include the monitoring of the following human physiological parameters:

- ECG waveform derived from 3 or 5 lead measurements
- Heart Rate derived from selected sources (ECG, SpO_2, IBP)
- Pulse Oximetry (SpO_2)
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- IV Drug Calculations for which the target population is adult only

The Passport V has the capability of interfacing with Datascope Patient Monitoring Central Station and Gas Module products.

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)

Mitchell Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091834