K102004

510(k) Summary
Endeavour Monitoring System

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

Date: July 13, 2010

SEP 10 2010

Submitter:

Mindray DS USA, Inc.
800 MacArthur Blvd.
Mahwah, NJ 07430
Contact: Russell Olsen
Director, Quality Assurance and Regulatory Affairs
Telephone: 201-995-8391
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Device Trade Name: Endeavour Monitoring System

Common Name: Multi-parameter patient monitor (with arrhythmia detection or alarms)

Device Classification:

§870.1025- MHX - Physiological, Patient Monitor, with arrhythmia detector or alarms
§870.1025- DSI - Arrhythmia detector and alarm
§870.1025- MLD - ST Segment with alarm monitor
§870.1110- DSK- Blood Pressure computer
§870.1130- DXN - Non-invasive blood pressure measurement system
§868.1400- CCK - Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
§870.1425- DQK - Programmable diagnostic computer
§870.2300- DRT - Cardiac Monitor (Incl. Cardiotachometer and rate alarm)
§870.2700- DQA- Oximeter
§880.2910- FLL - Clinical electronic thermometer
§870.1435- DXG - Single-function, pre-programmed diagnostic computer

Predicate Devices: Spectrum Monitor – K062098
Accutorr Plus Monitor – K983575

Device description: The Endeavour Monitoring System is a multi physiological parameter patient monitor. It is a modular system that allows users to customize monitored parameters based on a patients monitoring need or acuity level.

Indications for Use: The Endeavour Monitoring System is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The

Indications for Use for the Endeavour include the monitoring of the following human physiological parameters:

-ECG waveform derived from 3, 5, 6 and 12 lead measurements
-Heart Rate
-Pulse Oximetry (SpO_2)
-ST Segment Analysis
-Arrhythmia Detection
-Non Invasive Blood Pressure (NIBP)
-Invasive Blood Pressure (IBP)
-Cardiac Output (CO)
-Respiratory Gasses
-Respiration Rate
-Temperature

The Endeavour Monitor has the capability of performing IV Drug and Hemodynamic Calculations and interfacing with network devices.

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,

-IV Drug Calculations for which the target population is adult only, and

-Cardiac Output for which the target population is adult and pediatric only.

Technological Comparison to Predicate Device:

The Endeavour is equivalent to predicated devices respecting indications for use, basic operation, performance specifications and energy supply. The Endeavour incorporates the use of new materials for the handle, outer housing and front bezel. Additionally, the Endeavour supports a modular parameter design where as the predicate devices are internally configured.

Summary of Performance Testing: The Endeavour Monitoring System has been tested and found to be in compliance with the following recognized safety, performance and electromagnetic compatibility standards.

IEC 60601-1:1988 +A1:1991 +A2:1995	Medical electrical Equipment – General Requirements for Safety
IEC 60601-1-1:2000	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-4:1996 + A1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
IEC 60601-2-34:2000	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
IEC 60601-1-8:2003 +A1:2006	Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-27:2005	Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
IEC 60601-2-25:1993 + A1:1999	Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographs
IEC 60601-2-30:1999	Medical electrical equipment, Part 2: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment.
ISO 10993-1:2003	Biological evaluation of medical devices - Part 1: Evaluation and testing.
AAMI / ANSI HE74:2001	Human Factors Design Process for Medical Devices
ISO 15223: 2000	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
ISO 14971:2007	Medical devices -- Application of risk management to medical devices
ISO 9919:2005	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
ANSI/AAMI SP10:2002 + A1:2003 + A2:2006	Manual, electronic or automated sphygmomanometers
ASTM E1112-00 (2006)	Standard Specification for Electronic Thermometers for Intermittent Determination of Patient Temperature
EC13: 2002/(R)2007	Cardiac monitors, heart rate meters, and alarms
EC11:1991/(R)2007	Diagnostic electrocardiographic devices

EC57:1998/(R)2003	Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms
EN ISO 21647:2004 + Cor 2006	Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors

Additionally, 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.

Clinical Testing Summary: A non-significant risk study was conducted on the Endeavour Monitor to verify the clinical performance of the non-invasive blood pressure (NIBP) module to the predicate device, the Accutorr Plus Monitor (K983575). This clinical study was designed to compare the performance of the NIBP module in the Endeavour to that on the Accutorr Plus.

The analysis demonstrated that there was no statistically significant difference in the mean readings obtained with the Endeavour and the Accutorr Plus for both systolic and diastolic blood pressure. No adverse events were reported.

Conclusion: Based on the technological comparison of the subject and predicate devices, the results of clinical performance testing and compliance with applicable performance, safety and electromagnetic compatibility standards, the Endeavour Monitoring System shall be considered as safe, as effective and substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Mindray DS USA, Inc.
c/o Mr. Russell Olsen
Director, Quality Assurance and Regulatory
800 MacArthur Blvd.
Mahwah, NJ 0743

SEP 10 2010

Re: K102004
Trade/Device Name: Endeavour Monitoring System
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: July 14, 2010
Received: July 15, 2010

Dear Mr. 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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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): K102004

Device Name: Endeavour Monitoring System

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- Cardiac Output for which the target population is adult and pediatric only.

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K102004