MAR - 3 2004

K032733

Exhibit #1 510(K) SUMMARY

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

The assigned 510(k) number is: K032733.

Submitter:

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- **Date Prepared:**

July 28, 2003

Name of the device:

- **Trade/Proprietary Name:** PM-8000 Patient Monitor
- **Common Name:** Patient 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 870.1110	Blood pressure computer	Class II
21 CFR 880.2910	Clinical Electronic Thermometer – Temperature Monitor with Probe	Class II

21 CFR 870.2700 Oximeter, Pulse Class II

Legally Marketed Predicate Device:

K993531 Datascope Passport 2™ Vital Signs Monitor

Description:

The PM-8000 Patient Monitor is a battery or line-powered patient monitor. The PM-8000 Patient Monitor acquires the physiological signals such as ECG, respiration (RESP), non-invasive blood pressure (NIBP), Saturation of Pulse Oxygen (SpO2), temperature (TEMP) and invasive pressure (IBP). These physiological signals are converted into digital data and processed. The PM-8000 Patient Monitor examines the data for alarm conditions and presents them on the color TFT display.

The optional built-in recorder provides hard copies of all digital data and waveforms as well as Tabular and Graphic Trend Information.

Statement of intended Use:

The PM-8000 Patient Monitor is a vital signs monitor used on a human patient. The target populations are adult, pediatric and neonatal patients. The PM-8000 Patient Monitor has many features and functions, yet is easy to use through an integral keypad, knob and an intuitive menu system.

The patient parameters that can be monitored by PM-8000 are: ECG (3-lead or 5-lead selectable), Heart Rate derived from selected source (SpO2, ECG), Respiration Rate (derived from ECG), Non-invasive blood pressure (NIBP), Saturation of Pulse Oxygen (SpO2), Temperature (TEMP) and Invasive pressure (IBP). Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The PM-8000 Patient Monitor is intended for use in a health care facility setting. It is intended for use by qualified medical personnel trained in the use of the equipment.

The PM-8000 Patient Monitor is not recommended for use in a patient's home or residence, during the patient transport, or when it has not been ordered by a physician.

Comparison of Technological Characteristics:

The PM-8000 patient monitor is substantially equivalent to a combination of systems currently marketed by Datascope Corporation. The design, components, storage

technology and energy source of the PM-8000 patient monitor are similar to those of its predicate device. All these systems provide a means for interfacing with a patient, collecting parameter specific physiological data, and processing the data for alarm generation and display of numeric values and waveforms on a bedside or central monitoring system.

There is only one notable difference between the technical specifications of the PM-8000 portable patient monitor and Datascope Passport 2™ Vital Signs Monitor. This difference relates to the PM-8000 patient monitor's measurement range for Systolic and Diastolic Pressure in the Adult/Pediatric/Neonatal Mode. In this instance, however, the specifications of the PM-8000 patient monitor are met the SP-10 standard.

The pulse oximetry design is licensed from Masimo and is similar to the Masimo design used in the predicate device.

These technological differences do not affect the safety or efficacy of the device. Any safety issues that may be raised by a software controlled medical device are the same issues already addressed by the predicate device and are addressed in the systems hazard analysis and in the system validation.

Testing:

Laboratory testing was conducted to validate and verify that the PM-8000 patient monitor met all design specifications and was substantially equivalent to the Datascope Passport 2™ Vital Signs Monitor. This testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing was performed to demonstrate compliance with the ANSI/AAMI standards EC13-2002, "Cardiac monitors, heart rate meters, and alarms". Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation. Some safety testing has been performed by third party agencies to ensure the device complies to applicable industry and safety standards. The PM-8000 portable patient monitor has also been tested to assure compliance to the requirements of various published standards, including EN865-1997, IEC 601-1:1988+A1: 1991+A2: 1995 +corrigendum June, 1995, IEC 601-1-1:2000, IEC 601-1-2:2001, IEC 601-1-4:1996, IEC 601-2-27:1994, IEC 601-2-30:1995, and EN1441 (1997).

Testing of the non-invasive blood pressure portion of the system was conducted according to the requirements outlined in the ANSI/AAMI Standards SP10 "Electronic automated sphygmomanometers."

Testing of the pulse oximetry portion of the system was conducted according to Masimo's testing protocol.

Although the device is neither life supporting nor life sustaining, diagnostic information derived from the use of the device and alarms generated by the device may be critical to the proper management of the patient. So, the areas of risk for this device are the same as other devices in this class, and the following:

- Electrical shock

  Excessive electrical chassis leakage current can disturb the normal electrophysiology of the heart.

- Misdiagnosis
  - — Inadequate design of the signal processing and measurement circuitry or program can lead generation of inaccurate diagnostic data.. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - — Inadequate design of the device's software, used to make various measurements, can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - — Inadequate design of the systems ability to alert the users through audible and visual indicators, can lead to user mistrust and/or inadequate response to the patient's condition. If an inadequate response to the patient's condition should occur the patient may unnecessarily be placed at risk.

Conclusion:

The conclusions drawn from clinical and laboratory testing of the PM-8000 patient monitor demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Datascope Passport 2™ Vital Signs Monitor, K#993531

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K032733
Trade Name: PM-8000 Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer & rate alarm)
Regulatory Class: Class II (two)
Product Code: DRT
Dated: December 18, 2003
Received: December 19, 2003

Dear Ms. Goldstein-Falk:

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Exhibit B

510(k) Number (if known): K032733

Device Name: PM-8000 Patient Monitor

Indications For Use:

The PM-8000 Patient Monitor is a vital signs monitor used on human patients. The target populations are adult, pediatric and neonatal patients. The PM-8000 Patient Monitor has many features and functions, yet is easy to use through an integrated keypad, knob and an intuitive menu system.

The patient parameters that can be monitored by PM-8000 Patient Monitor are: ECG (3-lead or 5-lead selectable), Heart Rate derived from selected source (SP02, ECG), Respiration Rate (derived from ECG), Non-invasive blood pressure (NBP), Oxygen Saturation of the blood (SpO2), Temperature (TEMP) and invasive pressure (IBP). Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The PM-8000 Patient Monitor is intended for us in health care facility setting. It is intended for use by qualified medical personnel trained in the use of the equipment.

The PM-8000 Patient Monitor is not recommended for use in a patient's home or residence, during the patient transport, or when it has not been ordered by a physician.

Prescription Use X **(Per 21 CFR 801 Subpart D)** **OR** **Over-The Counter Use** ____ **(21 CFT 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 K032733