OCT 19 2007

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: K072235

Submitter:

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- **Contact Person:**

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Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

July 31, 2007

Name of the device:

Trade/Proprietary Name	PM-50 Pulse Oximeter	VS-800 Vital Signs Monitor
Common Name	Pulse Oximeter	Vital Signs Monitor
Classification	**21 CFR 870.2700, Oximeter, Pulse, 74 DQA** 21 CFR 870.2710, Ear Oximeter, Pulse, 74 DQA	21 CFR 870.2700, Oximeter, Pulse, 74 DQA 21 CFR 870.2710, Ear Oximeter, Pulse, 74 DQA **21 CFR 870.2300, Cardiac monitor (including cardiotachometer and rate alarm), 74 MWI** 21 CFR 870.1130, Non-Invasive blood pressure measurement System ,74 DXN 21 CFR 880.2910, Clinical Electronic Thermometer, 80 FLL
Predicate Device	K061442, PM-50 Pulse Oximeter, cleared on Sep 5, 2006	K063055, VS-800 Vital Signs Monitor, cleared on Dec 21, 2006

Device Description:

PM-50 Pulse Oximeter:

The PM-50 is a flexible, portable, battery powered Pulse Oximeter. The PM-50 Pulse Oximeter acquires the physiological signals – oxygen saturation (SpO2) and pulse rate (PR). The signals are converted into digital data and processed, and the SpO2 and pulse rate values are calculated and displayed on LCD screen.

PM-50 uses a two-wavelength pulsatile system - red and infrared light – to obtain SpO2 based on the different light absorption of oxygenated and reduced hemoglobin. The light source in the finger sensor emits red and infrared light, which are partially absorbed and modulated by the arterial blood pulsation at the sensor site. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The electronic signals are sent to the oximeter and processed by the oximeter's circuitry. Thereafter, the SpO2 and pulse rate are obtained and indicated on the LCD screen.

VS-800 Vital Signs Monitor:

The VS-800 Vital Signs Monitor is a prescription device intended for use by health care professionals. And the device is capable of operation from an external AC mains powers source or an internal battery including rechargeable lead-acid battery and lithium battery. The device uses the same or similar technology and materials as the predicate devices, see Legally Marketed Predicate Devices listed above.

The VS-800 Vital Signs Monitor is a configurable monitor with options selected by customer preference. Device's options including module configuration and language setting are configured at the time the monitor is manufactured. Options may be upgrade via upgrade port by the manufacturer. The monitor also provides customer with the convenient operating control and human-machine interface (HMI). All of the patient cable connections are located on the monitor. The LCD and LED display patient information and the menu provides single control operations of all main functions. Operator can adjust parameter alarm settings that give audible and visual indication when a violation occurs. The VS-800 provides option for printing information by a thermal recorder.

This monitor has the following parameters measurement functions:

- ✓ SpO2 measurement: pulse oxygen saturation (SpO2), pulse rate (PR), and SpO2 plethysmogram.
- ✓ NIBP measurement: systolic pressure (S), diastolic pressure (D), mean pressure (M), and pulse rate (PR).
- ✓ Rectal / oral / axillary TEMP measurement: temperature (TEMP).

Intended Use:

The PM-50 Pulse Oximeter is a non-invasive, spot-check, oxygen saturation and pulse rate monitor. It operates only on battery power using existing PM-50 disposable and reusable sensors labeled for patients ranging from neonates to adults.

The VS-800 Vital Signs Monitor is used to monitor physiologic parameters including SpO2, PR and NIBP, and to measure Temperature parameter on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for transport or home use.

Comparison of Technological Characteristics:

The PM-50 Pulse Oximeter and VS-800 Vital Signs Monitor employ the same functional technology as the predicate devices.

Testing:

The device modification only involved the addition of SpO2 probes to PM-50 Pulse Oximeter and VS-800 Vital Signs Monitor. Bench testing and clinical study was conducted based on the modification to verify and validate that the PM-50 Pulse Oximeter and VS-800 Vital Signs Monitor met all design specifications and were substantially equivalent to predicate devices.

The following quality assurance measures were applied to the devices:

- Design Change and Modification Influence Analysis
- Biocompatibility Testing
- Performance Testing
- Safety& Environmental &EMC Testing
- Clinical Study according to ISO9919

Conclusion:

The conclusions drawn from clinical and bench testing of the PM-50 Pulse Oximeter and VS-800 Vital Signs Monitor demonstrate that the devices is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2007

Shenzhen Mindray Bio-Medical Electronics Company, Limited
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K072235
Trade/Device Name: PM-50 Pulse Oximeter and VS-800 Vital Signs Monitor
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 13, 2007
Received: September 19, 2007

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.

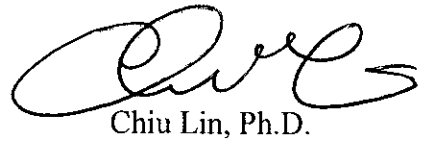
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: PM-50 Pulse Oximeter and VS-800 Vital Signs Monitor

Indications For Use:

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K072235

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