K063055

510(K) SUMMARY

DEC 2 1 2006

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: _____.

Date Prepared:

Sep. 29, 2006

Submitter:

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Trade/Proprietary Name:

VS-800 Vital Signs Monitor

Common Name:

Vital Signs Monitor

Classification

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 870.2700	Oximeter, Pulse	74 DQA
21 CFR 870.2710	Ear Oximeter, Pulse	74 DQA
21 CFR 880.2910	Thermometer, Electronic, Clinical	80 FLL

0037

Legally Marketed Predicate Devices:

DINAMAP PRO MONITOR, MODEL 200 with Temperature parameter (K# 992638, by CRITIKON COMPANY)
SpO2, PR and NIBP Parameters have been previously cleared and included in:
VS-800 Vital Signs Monitor (K# 060281, by Mindray Co., Ltd.)

Device Description:

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:

- ✓ SpO_2 measurement: pulse oxygen saturation (SpO_2), pulse rate (PR), and SpO_2 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 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.

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Technological Characteristics:

This VS-800 Vital Signs Monitor is developed on the basis of previously VS-800 Vital Signs Monitor (K# 060281) by incorporating Temp parameter module.

The SpO_2, PR and NIBP Parameters specifications in this VS-800 Vital Signs Monitor remain unchanged as compared to the previously VS-800 Vital Signs Monitor (K# 060281). And This VS-800 Vital Signs Monitor is substantially equivalent to currently marketed VS-800 Vital Signs Monitor (K# 060281) for SpO_2, PR and NIBP Parameters.

For TEMP Parameter, the comparative Performance verification Testing has been done. The results show that the VS-800 Vital Signs Monitor is substantially equivalent to the predicate device named DINAMAP PRO200 MONITOR (K# 992638) for Temp Parameter.

Testing Summary:

Performance testing including clinical and laboratory testing was conducted to validate and verify that the VS-800 Vital Signs Monitor met all design specifications and was substantially equivalent to the predicate devices. This testing consisted of all testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. 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 with applicable industry and safety standards. The VS-800 Vital Signs Monitor has also been tested to assure compliance with the requirements of various published standards, including ASTM E1112, ISO9919, IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-30, and ISO14971 and so on.

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."

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 VS-800 Vital Signs Monitor demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, VS-800 Vital Signs Monitor (K# 060281, Mindray), and PRO 200 Monitor (K#043348, CRITIKON COMPANY).

0040

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2006

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

Re: K063055
Trade Name: VS-800 Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: September 29, 2006
Received: October 5, 2006

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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): _____

Device Name: VS-800 Vital Signs Monitor

Indications For Use:

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.

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

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B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063055