APR - 3 2008

510(K) SUMMARY

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

The assigned 510(k) number is: K080192

Submitter:

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- **Date Prepared:**

January 4, 2008

Name of the Device:

- **Trade/Proprietary Name:** HYPERVISOR VI Central Monitoring System (including TMS)
- **Common Name:** Central Monitoring System (CMS)
- **Classification:**

MSX, 21 CFR Part 870.2300	System, Network and Communication, Physiological Monitors
MHX, 21 CFR Part 870.1025	Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)
DQA, 21 CFR Part 870.2700	Oximeter
DPZ, 21 CFR Part 870.2710	Oximeter, Ear
DRG, 21 CFR Part 870.2910	Transmitters and Receivers, Physiological Signal, Radiofrequency

Legally Marketed Predicate Device:

K062194 HYPERVISOR VI Central Monitoring System, Shenzhen Mindray Bio-Medical Electronics Co., LTD.

K983996 Spacelabs Medical Ultraview Digital Telemetry System, Spacelabs Medical, Inc.

Description:

Central Monitoring System network is a kind of medical information system, which consists of different networked devices (which have separate 510(k) clearance). Hypervisor VI Central Monitoring System (CMS) is the primary maintainer of communication between other networked devices. It can store, print, review or process information from networked devices. It can also realize remote monitor management function to free doctors from clinical monitoring work and conduct centralized monitoring management.

In this submission, CMS adds the function of supporting communication with Telemetry Monitoring System. Besides this, CMS is improved to include some new functions, such as, add the function of ViewOtherBed and add the function of real-time print.

By using radiofrequency signal, TMS is intended to monitor Electrocardiogram (ECG), Heart Rate (HR), Arrhythmia Detection, ST Segment Analysis, Saturation of Pulse Oxygen (SpO2) and Pulse Rate (PR) for adult and pediatric patients. Physical signals are collected by sensors and wirelessly transmitted by transmitters in WMTS band, receivers get the signals and forward to CMS for processing, displaying, storing, printing, etc. It can be used within a defined coverage area in hospitals or medical institutions.

CMS is based on the PC platform, and the PC can be configured by users according to the requirements on the operator's manual.

Statement of Intended Use:

The CMS network transfers information between HYPERVISOR VI Central Monitoring System and other networked devices. It also allows information transfer between several CMS. Network connections consist of hardwired network cables and/or WLAN connections. CMS can be used for remote monitor management, storing, printing, reviewing or processing of information from networked devices, and it is operated by medical personnel in hospitals or medical institutions.

Telemetry Monitoring System is a sub-system of CMS, intended to obtain ECG and SpO2 physiological information from adult and pediatric patients, and send it to CMS via WMTS frequency within a defined coverage area.

Comparison of Technological Characteristics:

The CMS is substantially equivalent to the previously cleared CMS (K062194) in technological characteristics. Both of them apply the same design principles, and the

modifications are concentrated on software consummating and network testing.
The TMS is substantially equivalent to Ultraview Digital Telemetry System (K983996). Both of them monitor similar parameters of patients, and apply similar design principles.

Testing:

Laboratory testing has been conducted to validate and verify that the CMS (including TMS) meet all design specifications. Results of these tests demonstrate compliance to the requirements of all applied standards.

Conclusion:

The Central Monitoring System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2008

Shezhen Mindray Bio-Medical Electronics Co., Ltd
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, NY 11021

Re: K080192
HYPERVISOR VI Central Monitoring System (including Telemetry Monitoring System, Model TMS-6016)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (two)
Product Code: MSX
Dated: January 4, 2008
Received: January 25, 2008

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): K080192

Device Name: HYPERVISOR VI Central Monitoring System (including TMS)

Indications for Use:

The CMS network transfers information between HYPERVISOR VI Central Monitoring System and other networked devices. It also allows information transfer between several CMS. Network connections consist of hardwired network cables and/or WLAN connections. CMS can be used for remote monitor management, storing, printing, reviewing or processing of information from networked devices, and it is operated by medical personnel in hospitals or medical institutions.

Telemetry Monitoring System is a sub-system of CMS, intended to obtain ECG and SpO2 physiological information from adult and pediatric patients, and send it to CMS via WMTS frequency within a defined coverage area.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080192