JUL 0 1 2014

510(K) SUMMARY

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

The assigned 510(k) number is: K132036

Submitter:

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- **Contact Person:**

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VP Quality & Regulatory Affairs

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- **Date Prepared:**

Jun 24, 2013

Name of the devices:

- **Trade/Proprietary Name:**

Hypervisor Central Monitoring System (including Telemetry Monitoring System, TMS-6016)

- **Common Name:** Central Monitoring System

- **Classification**

21 CFR 870.2300	System, Network and Communication, Physiological Monitors	Class II
21 CFR 870.1025	Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)	Class II
21 CFR 870.1025	Detector and Alarm, Arrhythmia	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm	Class II
21 CFR 870.2300	Cardiac monitor (including cardio tachometer and rate alarm)	Class II
21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 870.2710	Oximeter, Ear	Class II
21 CFR Part 870.2910	Transmitters and Receivers, Physiological Signal, Radiofrequency	Class II

Legally Marketed Predicate Devices:

K080192, HYPERVISOR VI Central Monitoring System (including Telemetry Monitoring System, TMS-6016), Shenzhen Mindray Bio-medical Electronics Co., LTD

Device Description:

The CMS network is a kind of medical information system, which consists of different networked devices (which have separate 510(k) clearance). 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.

Statement of intended Use:

The CMS network transfers information between Hypervisor 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 SpO_2 physiological information from adult and pediatric patients, and send it to CMS via WMTS frequency within a defined coverage area.

Technology:

The Hypervisor Central Monitoring System (including Telemetry Monitoring System, TMS-6016) is substantially equivalent to the predicate devices HYPERVISOR VI Central Monitoring System (including Telemetry Monitoring System, TMS-6016) (K080192).

Test Summary:

The Hypervisor Central Monitoring System (including Telemetry Monitoring System, TMS-6016) comply with the recognized safety, performance and electromagnetic compatibility standards. A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. Mindray's product development process required that the following activities be completed during the development of those patient monitors:

Requirements specification review
Hardware and Software testing
Code design and code reviews
Environmental EMC testing
Safety testing
Performance testing
Hardware and Software validation

Conclusion:

The results of all testing demonstrate that the Hypervisor Central Monitoring System (including Telemetry Monitoring System, TMS-6016) is as safe, as effective, and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 1, 2014

Shenzhen Mindray Bio-Meidcal Electronics Co., Ltd
Russell Olsen
VP Quality & Regulatory Affairs
800 Macarthur Blvd.
Mahwah, New Jersey 07430

Re: K132036
Trade/Device Name: Hypervisor central monitoring system (including telemetry monitoring system, tms-6016)
Regulation Number: 21 CFR 870.2300
Regulation Name: Arrhythmia Detector And Alarm (Including St-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MSX, MHX, DQA, DPZ, DRQ
Dated: May 23, 2014
Received: May 29, 2014

Dear Russell 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

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): K132036

Device Name: Hypervisor Central Monitoring System (including Telemetry Monitoring System, TMS-6016)

Indications for Use:

The CMS network transfers information between Hypervisor 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 SpO_2 physiological information from adult and pediatric patients, and send it to CMS via WMTS frequency within a defined coverage area.

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)

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