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 6, 2015

Shenzhen Mindray Bio-medical Electronics Co., Ltd
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Kenji 12th Road South,
Hi-tech Industrial Park, Nanshan
Shenzhen, 518057 CN

Re: K150632
Trade/Device Name: Hypervisor IX Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, MHX, DRQ
Dated: March 9, 2015
Received: March 11, 2015

Dear Yanhong Bai:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150632

Device Name
Hypervisor IX Monitoring System

Indications for Use *(Describe)*
The indications for use of the Hypervisor IX Monitoring System include:
• Real time viewing of patient clinical data and alarms
• Storage and Historical review of patient clinical data and alarms
• Printing of real time and historical patient data
• Configuration of local settings as well as synchronizing settings across the network to a remote device
• Transfer of patient clinical data and settings between several CentralStations
The Hypervisor IX Monitoring System is a networked patient monitoring system intended for use in a fixed location, installed in a hospital or clinical environment to provide clinicians remote patient monitoring. The network connections between the various devices can be any combination of Ethernet (Wired), Wireless WiFi (WLAN), and Wireless WMTS. The Hypervisor IX Monitoring System supports one or more Mindray compatible physiological monitors and will display, store, print, and transfer information received from the compatible monitors; The Hypervisor IX Monitoring System supports bi-directional configuration of the compatible monitors. No data processing is done by the Hypervisor IX Monitoring System for data received from compatible monitors.
The Hypervisor IX Monitoring System includes several Telemetry monitoring subsystems all of which operate in the 608M WMTS frequency range within a defined coverage area. All of the supported telemetry systems transmit data to the CentralStation for processing, display, and alarm.
• The TMS-6016 transmitter is intended for use on Adult and Pediatric patients to monitor ECG and SpO2 physiological data. The CentralStation will support ECG, Heart Rate, SpO2, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TMS-6016.
• The Panorama Telepack-608 transmitter is intended for use on Adult patients to monitor ECG and SpO2 physiological data. The CentralStation will support ECG, Heart Rate, SpO2, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the Panorama Telepack-608.
• The TMS60 transmitter is intended for use on Adult and Pediatric patients to monitor ECG and SpO2 physiological data. The physiological data can be reviewed locally on the display of the transmitter. The CentralStation will support ECG, Heart Rate, SpO2, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TMS60.

The Hypervisor IX Monitoring System is intended for use in a hospital or other clinical environment under the direct supervision of a licensed healthcare practitioner.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Hypervisor IX Monitoring System is provided below.

Device Common Name:	Physiological Monitors, Network and Communication System
Device Trade Name:	Hypervisor IX Monitoring System
Applicant:	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. Mindray Building, Keji 12th Road South High-tech Industrial Park, Nanshan Shenzhen 518057, P.R. China Tel: +86 755 81885635 Fax: +86 755 26582680
Contact:	Yanhong Bai Manager Regulatory Affairs SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. Mindray Building, Keji 12th Road South High-tech Industrial Park, Nanshan 518057, P.R. China Tel: +86 755 81885635 Fax: +86 755 26582680 E-mail: baiyanhong@mindray.com
Prepared by:	Donna-Bea Tillman, Ph.D. Biologics Consulting Group, Inc. 400 N. Washington St, Suite 100 Alexandria, VA 22314 Phone: 410-531-6542 Email: dtillman@bcg-usa.com
Date Prepared:	**March 20, 2015**
Classification Regulation:	870.2300 – Cardiac Monitor (including cardiotachometer and rate alarm) Class II
Panel:	Cardiovascular
Product Code:	MSX – Physiological Monitors Network and Communication System

Subsequent Product Codes: DRQ- Transducer signal amplifier and conditioner

MHX - Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Predicate Device: K132036 – Hypervisor Central Monitoring System

Indication for Use:

The indications for use of the Hypervisor IX Monitoring System include:

- Real time viewing of patient clinical data and alarms
- Storage and Historical review of patient clinical data and alarms
- Printing of real time and historical patient data
- Configuration of local settings as well as synchronizing settings across the network to a remote device
- Transfer of patient clinical data and settings between several CentralStations

The Hypervisor IX Monitoring System is a networked patient monitoring system intended for use in a fixed location, installed in a hospital or clinical environment to provide clinicians remote patient monitoring. The network connections between the various devices can be any combination of Ethernet (Wired), Wireless WiFi (WLAN), and Wireless WMTS.

The Hypervisor IX Monitoring System supports one or more Mindray compatible physiological monitors and will display, store, print, and transfer information received from the compatible monitors; The Hypervisor IX Monitoring System supports bi-directional configuration of the compatible monitors. No data processing is done by the Hypervisor IX Monitoring System for data received from compatible monitors.

The Hypervisor IX Monitoring System includes several Telemetry monitoring subsystems all of which operate in the 608M WMTS frequency range within a defined coverage area. All of the supported telemetry systems transmit data to the CentralStation for processing, display, and alarm.

- The TMS-6016 transmitter is intended for use on Adult and Pediatric patients to monitor ECG and SpO2 physiological data. The CentralStation will support ECG, Heart Rate, SpO2, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TMS-6016.
- The Panorama Telepack-608 transmitter is intended for use on Adult patients to monitor ECG and SpO2 physiological data. The CentralStation will support ECG, Heart Rate, SpO2, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the Panorama Telepack-608.
- The TMS60 transmitter is intended for use on Adult and Pediatric patients to monitor ECG and SpO2 physiological data. The physiological data can be reviewed locally on the display of the transmitter. The CentralStation will support ECG, Heart Rate,

SpO2, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TMS60.

The Hypervisor IX Monitoring System is intended for use in a hospital or other clinical environment under the direct supervision of a licensed healthcare practitioner.

Device Description:

The Hypervisor IX Monitoring System is a networked patient monitoring system intended for use in a fixed location, installed in a hospital or clinical environment to provide clinicians remote patient monitoring. The network connections between the various devices can be any combination of Ethernet (Wired), Wireless WiFi (WLAN), and Wireless WMTS.

The Hypervisor IX Monitoring System supports one or more Mindray compatible physiological monitors and will display, store, print, and transfer information received from the compatible monitors; The Hypervisor IX Monitoring System supports bi-directional configuration of the compatible monitors. No data processing is done by the Hypervisor IX Monitoring System for data received from compatible monitors.

The Hypervisor IX Monitoring System includes three telemetry monitoring systems all of which operate in the 608M WMTS frequency range within a defined coverage area. All of the supported telemetry systems transmit data to the CentralStation for processing, display, and alarm.

The Hypervisor IX Monitoring System consists the following components:

1. Central Station
2. View Station
3. Work Station
4. Telemetry Systems (TMS 6016, Telepak-608, TMS60)

Performance Data:

- To establish the substantial equivalence of the Hypervisor IX Monitoring System, Mindray conducted functional and system level testing on the subject device. The testing provided an evaluation of the performance of the device relevant to each of the differences between the subject device and the predicate device. The functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.
- Mindray has conducted testing to ensure the subject device meets relevant consensus standards.
- Mindray conducted Wireless functionality testing to ensure the performance of the Hypervisor IX Monitoring System meets wireless specifications and is equivalent to the predicate device.
- Mindray has followed the following FDA Guidance Documents relevant to this device:

- Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm Guidance for Industry and FDA (10/28/2003)
- Cardiac Monitor Guidance (Including Cardiotachometer and Rate Alarm)
- Class II Special Controls Guidance Document: Electrocardiograph Electrodes

Comparison of Technological Characteristics:

The technological characteristics of the subject device are compared to the predicate device in the table below.

Device Comparison Table

	Predicate Device	**Subject Device**
Device Name	HYPERVISOR CENTRAL MONITORING SYSTEM (INCLUDING TELEMETRY MONITORING SYSTEM, TMS-6016)	Hypervisor IX Monitoring System
Manufacturer	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD
510(k)	K132036	TBD
Regulation	870.2300 – Cardiac Monitor (including cardiotachometer and rate alarm) Class II	870.2300 – Cardiac Monitor (including cardiotachometer and rate alarm) Class II
Product Code	MSX – Physiological Monitors Network and Communication System	MSX – Physiological Monitors Network and Communication System
Operating System	Windows XP Professional Embedded SP3	Microsoft Windows 7 Professional Embedded SP1
Network Configuration	100 Mbps, Ethernet 802.3	Same
Host Computers	HP Compaq 8380 Elite MT	HP Compaq 8380 Elite MT HP EliteDesk 800 G1 SFF Kontron KISS 2U V2 KTQ87FLEX
Patient Monitor Numbers	Up to 16 monitors in the single-screen mode and 32 monitors in the dual- or multi-screen mode simultaneously Support up to four local displays	Same

	Predicate Device	**Subject Device**
Patient Monitor Connectivity	Supports the following patient monitors: DPM3 (K072235） DPM4/5 (K070791) DPM6/7 (K092449) Passport 12M/17M (K143195) Passport8/12 (K132662) Accutorr 7 (K132038) T1 (K143195)	Supports the following patient monitors: DPM3 (K072235） DPM4/5 (K070791) DPM6/7 (K092449) Passport 12M/17M (K143195) Passport8/12 (K132662) Accutorr 7 (K132038) T1 (K143195) Spectrum (K062098) Spectrum OR (K062098) Passport II (K020550) Passport V (K091834) V12/21 (K132026)
Telemetry System	TMS-6016 (K132036)	TMS-6016 (K132036) Telepack-608 (K142601) TMS60
Calculations	Supports five calculation modes: Drug Calculation Hemodynamics Calculation Oxygenation Calculation Ventilation Calculation Renal Calculation	No change
Remote Monitoring	Provided on supported monitors	Provided on supported monitor and on the ViewStation and WorkStation. WorkStation allows for remote users to enter or change patient demographic information, change alarm limits and priorities, or discharge patients.
Data Review Features	Dynamic short trend Trend review Wave review NIBP review Event Review 12-lead review ST review Cardiac output review Print and Display Records	Dynamic short trend Trend review Wave review NIBP review Event Review 12-lead review ST review Cardiac output review Print and Display (now includes QT View) Records

	Predicate Device	**Subject Device**
ECG Features	Mindray or Mortara ECG Algorithms - selectable 3-lead or 5-lead selectable arrhythmia detection ST segment analysis heart rate Pace Mark Pace Pulse Rejection	Mindray or Mortara ECG Algorithms - selectable 3-lead or 5-lead selectable arrhythmia detection with adjustable leads ST segment analysis heart rate Pace Mark Pace Pulse Rejection QT Analysis J Point Auto detection QRS Detection Threshold

Comparison of Indications:

The indication for use statement of the Hypervisor IX Monitoring System includes the indication for the system as whole as well as cleared indications for each of the components of the system. Both the predicate device and the subject device are patient monitoring systems intended to be used in healthcare facilities under the direction of clinical professionals. Additional language has been added to the indications for use of the current device to more clearly describe existing functions, as well as to include the new feature of QT monitoring. Although QT monitoring was not included in the predicate Hypervisor device, it is present in the cleared Philips ST/AR ST and Arrhythmia Software (K101521), and thus does not constitute a new intended use for a patient monitoring system.

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications for each of the modifications to the previously cleared Hypervisor Central Monitoring System, the functional and performance testing and conformance with applicable standards as well as the comparison of indications, the differences do not raise new questions of safety and effectiveness and the Hypervisor IX Monitoring System can be found substantially equivalent to the predicate device.