DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 20, 2017

Shenzhen Mindray Bio-medical Electronics Co., Ltd.
% Yanhong Bai
Manager Regulatory Affairs, Technical Regulation Department
Shenzhen Mindray Bio-medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South Hi-tech Industrial Park
Nanshan, Shenzhen, CN 518057 Guangdong

Re: K162607
Trade/Device Name: BeneVision Central Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm).
Regulatory Class: Class II
Product Code: MSX, DRQ, MHX, DRT, DXN, DQA, DSB
Dated: March 22, 2017
Received: March 23, 2017

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,

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)*
K162607

Device Name
BeneVision Central Monitoring System

Indications for Use *(Describe)*
The indications for use of the BeneVision Central 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 BeneVision Central Monitoring System is a networked patient monitoring system intended for use in a fixed location, installed in professional healthcare facilities 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 BeneVision Central Monitoring System supports one or more Mindray compatible physiological monitors and will display, store, print, and transfer information received from the compatible monitors; The BeneVision Central Monitoring System supports bi-directional configuration of the compatible monitors. No data processing is done by the BeneVision Central Monitoring System for data received from compatible monitors.
The telemetry monitoring systems are designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The BeneVision Central Monitoring System supports Telemetry Systems: TMS-6016, Telepack-608, TMS60, and TM80.
• The TMS-6016 transmitter is intended for use on Adult and Pediatric patients to monitor ECG and SpO2 physiological data.
• The Panorama Telepack-608 transmitter is intended for use on Adult patients to monitor ECG and SpO2 physiological data.
• The TMS60 transmitter is intended for use on Adult and Pediatric patients over three years old to monitor ECG, SpO2, NIBP and Resp physiological data. The physiological data can be reviewed locally on the display of the transmitter. The CentralStation will support ECG, Heart Rate, SpO2, NIBP, Resp, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TMS60.
• The TM80 telemetry monitor is intended for use on Adult and Pediatric patients over three years old to monitor ECG, SpO2, NIBP and Resp physiological data. The physiological data can be reviewed locally on the display of the monitor. The CentralStation will support ECG, Heart Rate, SpO2, NIBP, Resp, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TM80.
The BeneVision Central Monitoring System is intended for use in professional healthcare facilities 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.

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510(K) SUMMARY

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

Device Common Name:	System, network and communication, physiological monitors
Device Trade Name:	BeneVision Central 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 81888998 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 81888998 Fax: +86 755 26582680 E-mail: baiyanhong@mindray.com
Date Prepared:	**March 22nd, 2017**
Classification Regulation:	870.2300 – Cardiac Monitor (including cardiotachometer and rate alarm) Class II
Panel:	Cardiovascular
Product Code:	MSX –System, network and communication, physiological monitors

Subsequent Product Codes:	DRQ- amplifier and signal conditioner, transducer signal MHX - monitor, physiological, patient (with arrhythmia detection or alarms) DRT - monitor, cardiac (incl. cardiotachometer & rate alarm) DXN - system, measurement, blood-pressure, non-invasive DQA- Oximeter DSB- Impedance plethysmograph
Predicate Device:	K150632 –Hypervisor IX Monitoring System
Reference Predicates:	K152902–Passport Series Patient Monitors (Passport 12m, Passport 17m and T1)

Indication for Use:

The indications for use of the BeneVision Central 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 BeneVision Central Monitoring System is a networked patient monitoring system intended for use in a fixed location, installed in professional healthcare facilities 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 BeneVision Central Monitoring System supports one or more Mindray compatible physiological monitors and will display, store, print, and transfer information received from the compatible monitors; The BeneVision Central Monitoring System supports bi-directional configuration of the compatible monitors. No data processing is done by the BeneVision Central Monitoring System for data received from compatible monitors.

The telemetry monitoring systems are designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The BeneVision Central Monitoring System supports Telemetry Systems: TMS-6016, Telepack-608, TMS60, and TM80.

- The TMS-6016 transmitter is intended for use on Adult and Pediatric patients to monitor ECG and SpO_2 physiological data.
- The Panorama Telepack-608 transmitter is intended for use on Adult patients to monitor ECG and SpO_2 physiological data.
- The TMS60 transmitter is intended for use on Adult and Pediatric patients over three years old to monitor ECG, SpO_2, NIBP and Resp physiological data. The physiological data can be reviewed locally on the display of the transmitter. The CentralStation will support ECG, Heart Rate, SpO2,

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

- The TM80 telemetry monitor is intended for use on Adult and Pediatric patients over three years old to monitor ECG, SpO_2, NIBP and Resp physiological data. The physiological data can be reviewed locally on the display of the monitor. The CentralStation will support ECG, Heart Rate, SpO2, NIBP, Resp, Pulse Rate, Arrhythmia analysis, QT monitoring, and ST Segment Analysis for the TM80.

The BeneVision Central Monitoring System is intended for use in professional healthcare facilities under the direct supervision of a licensed healthcare practitioner.

Device Description:

The BeneVision Central Monitoring System is a networked patient monitoring system intended for use in a fixed location, installed in professional healthcare facilities 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 BeneVision Central Monitoring System supports one or more Mindray compatible physiological monitors and will display, store, print, and transfer information received from the compatible monitors; The BeneVision Central Monitoring System supports bi-directional configuration of the compatible monitors. No data processing is done by the BeneVision Central Monitoring System for data received from compatible monitors.

The BeneVision Central Monitoring System consists of the following components：

1. CentralStation
2. ViewStation
3. WorkStation
4. CMSViewer
5. Telemetry Systems (TMS 6016, Telepak-608, TMS60,TM80)

The TMS 6016, Telepak-608, TMS60 telemetry monitoring systems 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 TM80 telemetry monitor uses the Wireless WIFI connection to transmit data to the CentralStation for processing, display, and alarm.

Performance Data:

- To establish the substantial equivalence of the BeneVision Central 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 conducted Wireless functionality testing to ensure the performance of the BeneVision Central 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)
- Mindray has conducted testing to ensure the subject device meets relevant consensus standards.
  - AAMI /ANSI ES60601-1:2005/(R)2012 and A1:2012,C1:2009/(R)2012 and A2:2010/(R)2012
  - IEC 60601-1-2: 2007
  - IEC60601-1-6: 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
  - IEC 60601-2-27 Edition 3.0 2011-03
  - IEC80601-2-30 Edition 1.1 2013-07
  - IEC 60601-2-49: 2011
  - AAMI ANSI:EC53:2013

Comparison of Technological Characteristics:

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

	Predicate Device	**Subject Device**
Device Name	Hypervisor IX Monitoring System	BeneVision Central Monitoring System
Manufacturer	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD
510(k)	K150632	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	Microsoft Windows 7 Professional Embedded SP1	Same
Network	100 Mbps, Ethernet 802.3	Same
Display	19" or larger LCD display Support Touch-Screen 1280 x 1024 resolution, length-width ratio 4:3 or 5:4	Add 21" or larger widescreen LCD display Support Touch-Screen 1920 x 1080 resolution, length-width ratio 16:9

Host Computers	HP Compaq 8380 Elite MT HP EliteDesk 800 G1 SFF Kontron KISS 2U V2 KTQ87FLEX	Same
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	Add up to 24 monitors in the single-screen mode with 1920 x 1080 resolutions. Support up to four local displays
Patient Monitor Connectivity	Supports the following patient monitors: DPM3 (K072235) DPM4/5 (K070791) DPM6/7 (K092449) Passport 12M/17M (K152902) Passport8/12 (K153448) Accutorr 7 (K132038) T1 (K152902) TMS-6016 (K132036) Spectrum (K062098) Spectrum OR (K062098) Passport II (K020550) Passport V (K091834) V12/21 (K150352)	Same
Telemetry System	TMS-6016 Telepack-608 TMS60 （K150632）	TMS-6016 Telepack-608 TMS60 TM80 Subject in this 510（k）
Calculations	Supports five calculation modes: Drug Calculation Hemodynamics Calculation Oxygenation Calculation Ventilation Calculation Renal Calculation	Same
Remote Monitoring	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.	Same

Data Review Features	Dynamic short trend Trend review Wave review NIBP review Event Review 12-lead eview ST review Cardiac output review Print and Display Records	1.Change the display time of Dynamic short trend from 4 hours to 8 hours 2. Change the storage of NIBP review from most recent 240 hours to most recent 1000 NIBP measurements. 3. Change the storage of Event review from 720 events to 1000 events. The other features have no change.
Data storage	The patient data will be saved in MySQL database.	The patient data will be saved in encryption file.
ECG Features	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	Mindray or Mortara ECG Algorithms - selectable 3-lead, 5-lead and 6-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
SpO2 Features	Support SpO2 modules: Nonin SpO2 module (XPOD 3012LP) and sensors Masimo SpO2 module (SET uSpO2) and sensors	Same
Resp Features	Not provided	Calculate Resp rate (RR) Display Resp waveform View and change Resp settings
NIBP Features	Not provided	Oscillometry method NIBP Can measure, display, store NIBP parameter, and send them to TMS60/TM80

WiFi Features	Not provided	TM80 communicates with the CentralStation via WiFi network : IEEE 802.11a/b/g/n Protocol Support WPA-PSK, WPA2-PSK, WPA-Enterprise, WPA2-Enterprise Security standard Support PEAP-GTC, PEAP- MSCHAPv2, EAP-TLS EAP method

Comparison of Indications:

The indication for use statement of the BeneVision Central 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 professional healthcare facilities under the direction of clinical professionals. Additional modules for the transmitter allow the addition of NIBP monitoring to the TMS60 and TM80. Resp monitoring is also added in TMS60 and TM80. WiFi function and 6-lead ECG function is added in TM80. Although NIBP and Resp monitoring, WiFi function and 6-lead ECG function was not included in the predicate Hypervisor device, it is present in the cleared T1 patient monitor (K152902), and thus does not constitute a new intended use.

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications for each of the modifications to the previously cleared Hypervisor IX 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 BeneVision Central Monitoring System can be found substantially equivalent to the predicate device.