June 1, 2022

Shenzhen Mindray Bio-Medical Electronics Co., LTD
Li Lei
Manager Regulatory Affairs, Technical Regulation Department
Mindray Building, Keji 12th Road South, Hi-tech
Industrial Park, Nanshan
Shenzhen, Guangdong 518057
China

Re: K220058
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, DRT, DQA, DXN, DSB, MHX, DRQ
Dated: December 27, 2021
Received: January 6, 2022

Dear Li Lei:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220058

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
- Provides a Resting 12 Lead interpretation of previously stored data

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.

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, TM80 and TM70.

- 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/TM70 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 analyzed, alarmed, stored, reviewed locally on the display of the monitor, and the CentralStation can config and display the physiological parameters from the TM80/TM70.

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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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.

1. SUBMITTER

Applicant: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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Date Prepared: December 27, 2021

2. DEVICE

Device Trade Name:	BeneVision Central Monitoring System
Device Common Name:	System, network and communication, physiological monitors
Classification Name and Regulation	21 CFR 870.2300, Cardiac monitor (including cardiotachometer and rate alarm)
Primary Product Code:	MSX - System, network and communication, physiological monitors
Regulatory Class	Class II
Panel	Cardiovascular

Table 1: Secondary Product Codes

Product Code	Regulation Number	Panel	Regulation description	Device Common Name
DRT	21 CFR 870.2300	Cardiovascular	Cardiac Monitor (including cardiotachometer and rate alarm)	Monitor, cardiac (incl. cardiotachometer & rate alarm)
DQA	21 CFR 870.2700	Anesthesiology	Oximeter	Oximeter
DXN	21 CFR 870.1130	Cardiovascular	Noninvasive blood pressure measurement system	System, measurement, blood-pressure, non-invasive
DSB	21 CFR 870.2770	Cardiovascular	Impedance plethysmograph	Plethysmograph, impedance
MHX	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm).	Monitor, physiological, patient (with arrhythmia detection or alarms)
DRQ	21 CFR 870.2060	Cardiovascular	Transducer signal amplifier and conditioner	Amplifier and signal conditioner, transducer signal

3. PREDICATE DEVICE

Predicate Device: K193391 - BeneVision Central Monitoring System (SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD)

Reference Device: K163584 - M3290B Patient Information Center iX Release C.01(Philips Medical Systems)

K202405 - BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1) (SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD)

4. DEVICE DESCRIPTION

The BeneVision Central Monitoring System (CMS) is a networked patient monitoring system intended for use in healthcare settings by, or under the direction of, a physician to provide clinicians remote patient monitoring. The target patient population is adult patients and pediatrics.

5. INTENDED USE/INDICATIONS 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
- Provides a Resting 12 Lead interpretation of previously stored data

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.

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, TM80 and TM70.

- 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/TM70 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 analyzed, alarmed, stored, reviewed locally on the display of the monitor, and the CentralStation can config and display the physiological parameters from the TM80/TM70.

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

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

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.

The indications for use statement of the subject BeneVision Central Monitoring System has been modified to include support a resting 12 Lead interpretation. Although this feature is not present in the predicate BeneVision Central Monitoring System, it is present in Mindray's N Series Monitors (K202405).

In conclusion, the difference of the indications for use do not change the fundamental intended use of the BeneVision Central Monitoring System.

Technological Comparisons

The table below provides a comparison of the technological features of the BeneVision CentralStation, WorkStation, ViewStation, and CMS Viewer compared to the CentralStation, WorkStation, ViewStation, and CMS Viewer cleared in K193391. The features in gray are features which are different between the predicate device and the subject devices. These changes marked with an asterisks (*) are non-significant.

Table 2: Technological Comparison

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	**WorkStation**	**ViewStation**	**CMS Viewer**
Operation System	Microsoft Windows 7/8/10/Server 2012/Server 2016	1.Added Microsoft Windows Server 2019 * 2. Deleted Microsoft Windows 7 3.The CentralStation supports installation on the Virtual Machine Platform when running as service such as VMWare and Hyper-V	A (CentralStation only supports Windows 10/Server 2016/Server 2019)	A (WorkStation only supports Windows 10)	A (ViewStation only supports Windows 10)	A (CMS Viewer only supports Windows 8/10/Server 2012)
Display (including touchscreen capability)	resolution:1920 x 1080,1280*1024	No change	A	A	A	A
Audio	Built-in speakers	No change	A	A	A	NA
Recorder	Mindray thermal array module product	No change	A	A	A	NA
Network	100 Mbps, Ethernet 802.3	No change	A	A	A	A
Max connection sare supported for one CentralStation	Up to 32 WorkStation or ViewStation connections are supported for one CentralStation	No change	A	NA	NA	NA

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	WorkStation	ViewStation	CMS Viewer
Patient Monitor Numbers – Number Supported	1.Support 32 monitors running as application. 2. Running as service Up to 128 montors with no patient display, the display is provided by WorkStations	Support 64 monitors running as application *	A	A	A	A (CMSViewer only support 36 monitors) *

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	WorkStation	ViewStation	CMS Viewer
Telemetry Systems and monitors	Supports the following telemetry systems and monitors: – TMS-6016 (K183238) – TMS60 (K183238) – Telepack-608 (K183238) – TM80(K193391) – TM70(K193391)	No change	A	A	A	A
Communication protocol (and compatible monitors)	CMS+ protocol: DPM3 (K072235） DPM4/5 (K070791) DPM6/7 (K092449) Passport 12m/17m (170876) Passport8/12 (K153448) Passport V (K091834) Accutorr 7/VS-900 (K170712) T1 (K152902) ELAN protocol: Spectrum (K062098) Spectrum OR (K062098) Passport II (K020550) V12/21 (K150352) MD2 protocol: CMS Viewer (K193391) ViewStation (K193391) WorkStation (K193391) TM80 (K193391) TM70(K193391) BeneVision N22/N19/N17/N15/N12/N1(K199391)	1.Added VS 8/8A/9(K211475) * 2.Added ePM Series Patient Monitors (Including ePM 10, ePM12, ePM 15, ePM 10M, ePM 12M, ePM 15M) (K200015) *	A	A	A	A

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	WorkStation	ViewStation	CMS Viewer
Bi-directional Configuration	Patient demographics, alarm settings and parameter settings For TM80: patient demographics, alarm settings and parameter setup information can be set by both the CentralStation and TM80. The QRS threshold, ST point/ISO point/J point, and ST and QT template can only be set by the CentralStation.	No change	A	A	NA	NA
Calculations	Supports five calculation mode: Drug Calculation Hemodynamics Calculation Oxygenation Calculation Ventilation Calculation Renal Calculation	No change	A	A	A	NA
View Other Bed	Provides the user the ability to remotely view 32 patient's parameters, waveforms, and alarms from a patient monitor connected to anotherBeneVision Central Monitoring System	No change	A	A	A	NA
HL7 Output	Provide HL7 interface output	No change	A	NA	NA	NA
Paging Interface	Enables transmission of configured alarm notifications to a third-party paging system	No change	A	A	NA	NA
Data Review						
Dynamic short trend	8 hours	No change	A	A	A	A
Trend review	240 hours	No change	A	A	A	A

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	WorkStation	ViewStation	CMS Viewer
Wave review	240 hours of full-disclosure waveforms and compressed waveforms	No change	A	A	A	A
NIBP review	Most recent 3000 NIBP measurements	No change	A	A	A	A
Event review	3000 events	No change	A	A	A	A
12-lead review	720 12-lead analysis results, 12 analysis waveforms for each analysis result	No change	A	A	A	A
ST review	Most recent 240 hours of ST segments	No change	A	A	A	A
Cardiac output review	720 measurements	No change	A	A	A	A
Print	Patient information, real-time waveform, real-time alarm, Alarm Settings, Multi-lead ECG Report, CSA Report, waveform review, Arrhythmia Statistic Result, Trend Review, C.O. measurement, events, 12-lead Review, ST review, QT View Report, drug calculations, hemodynamics calculations, oxygenation calculations, ventilation calculations, renal calculations, ICG hemodynamic parameter, CCO hemodynamic parameter, SvO2/ScvO2 oxygenation parameters	No change	A	A	A	A

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	WorkStation	ViewStation	CMS Viewer
Records	Patient information, real-time waveform, real-time alarm, waveform review, C.O. measurement, events, 12-lead Review, ST review, drug calculation, hemodynamics calculations, oxygenation calculations, ventilation calculations, renal calculations, ICG hemodynamic parameter, CCO hemodynamic parameter, SvO_2/$ScvO_2$ oxygenation parameters	No change	A	A	A	NA
Data storage	The patient data will be saved in an encrypted file.	No change	A	NA	NA	NA
ECG Features						
ECG Algorithm	Supports Mindray and Mortara	No change	A	A	A	A
ECG Functions	3-lead, 5-lead, 6-lead selectable, Arrhythmia detection, ST segment analysis, QT Analysis, Heart rate	No change	A	A	A	A
HR	Adult: Range:15～300 bpm Accuracy：±1 bpm or ±1%, whichever is greater Pediatric: Range:15～350 bpm accuracy：±1 bpm or ±1%, whichever is greater	No change	A	A	A	A
ST	Range: -2.0~2.0mV Accuracy: ±0.02mV or ±10%, whichever is greater, in the range of -0.8mV to +0.8mV; not specified in other range	No change	A	A	A	A

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	WorkStation	ViewStation	CMS Viewer
J Point Auto Detection	J-point Auto detection for ST algorithm. Supports automatically detecting the location of the J-point on the ST template.	No change	A	A	A	A
ARR	Mindray algorithm: Asystol, V-Fib/V-Tach, V-Tach, Vent Brady, Extreme Tachy, Extreme Brady, PVCs/min, Vent Rhythm, Couplet, Bigeminy Trigeminy, R on T, Run PVCs, PVC, Tachy, Brady, Missed Beats, Pacer Not Pacing, Pacer Not Capture, Multiform PVC, Nonsus V-Tach, Pause, Irr Rhythm, Pauses/min, and A-Fib Mortara algorithm: Asystol, V-Fib, V-Tach, Vent Rhythm, Couplet, Run PVCs, PVCs/min, Bigeminy Trigeminy, R on T, Multiform PVC, Irr Rhythm, Tachy, Brady, Pacer Not Pacing, Pacer Not Capture, Extreme Tachy, Extreme Brady, Pause and Pauses/min	No change	A	A	A	A (CMS Viewer receives ARR alarms from CentralStation and only displays ARR alarms, therefore there are no modification)
Adjustable Leads for Arrhythmia Analysis	Adjustable Leads for Arrhythmia Analysis. Supports selectable ECG leads as primary detection lead, secondary detection lead and beat classification lead for arrhythmia analysis	No change	A	A	NA	NA

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	WorkStation	ViewStation	CMS Viewer
QT Analysis	Mindray algorithm: – QT measurement range: [200, 800] ms – QT accuracy [200, 800] ms: ± 30 ms, beyond this range is not specified – QT resolution: [200, 800] ms: 4 ms, beyond this range is not specified – QTc measurement range: [200, 800] ms – QTc resolution [200, 800] ms: 1 ms, beyond this range is not specified – QT-HR measurement range: Adult: [15, 150] bpm, pediatric: [15, 180] bpm Mortara algorithm: – QT measurement range: [300, 600] ms – QT accuracy [300, 600] ms: ± 30 ms, beyond this range is not specified – QT resolution: [300, 600] ms: 2 ms, beyond this range is not specified – QTc measurement range: [300, 600] ms – QTc resolution [300, 600] ms: 1 ms, beyond this range is not specified – QT-HR measurement range: Adult: [43, 130] bpm, – pediatric: [43, 130] bpm	No change	A	A	A	A

Feature	As Cleared in K193391	Modifications Made to Subject Device	Applied To			
			CentralStation	WorkStation	ViewStation	CMS Viewer
QRS Detection Threshold	Adjustable QRS Detection threshold. QRS threshold range: 0.16-0.48mV.	No change	A	A	NA	NA
Pace mark	Detects and marks pace pulse. Amplitude: ±2 to ±700 mV Duration: 0.1 to 2 ms Rise time: 10 to 100 µs	No change	A	A	A	A
Pace pulse rejection	Meets the requirements of IEC60601-2-27 2011: Section 201.12.1.101.13. The following pulses without overshoot will be rejected: Amplitude: ±2 to ±700 mV Duration: 0.1 to 2 ms Rise time: 10 to 100 µs	No change	A	A	A	A
New Features						
The system provides a resting 12 Lead interpretation of previously stored data	Not provided	Supports the user to select a period of waveform from the historical data storage to analyze, the result will be saved in 12 lead review	A	A	NA	NA

Substantial Equivalence Conclusion

In conclusion, the differences in respect to the indications for use and technological characteristics do not raise new questions of safety and effectiveness as compared to the predicate device.

To establish the substantial equivalence of the BeneVision Central Monitoring System, Mindray conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its specifications and is substantially equivalent to the predicate device.

In addition, Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.

7. PERFORMANCE DATA

Biocompatibility Testing

Not applicable. The changes are just concerned with Software, not relate to Biocompatibility Testing.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided, as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Verification of the BeneVision Central Monitoring System was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable. The changes are just concerned with Software, not relate to Electrical safety and electromagnetic compatibility.

Bench Testing

To establish the substantial equivalence of the BeneVision Central Monitoring System, Mindray conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification, and is substantially equivalent to the predicate device.

In addition, Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.

- IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical testing is not required to establish substantial equivalence to the predicate device.

8. CONCLUSION

Based on the detailed comparison between the predicate devices and the subject devices, and the functional and system level testing, the BeneVision Central Monitoring System can be found substantially equivalent to the predicate devices.