July 31, 2025

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

Re: K242728
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: July 24, 2025
Received: July 24, 2025

Dear Lei Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. SHIH -S

Jennifer 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242728

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 from compatible physiological monitors. Viewing of non-real time patient clinical data of compatible anesthesia devices (i.e. not indicated for real-time monitoring of clinical data of compatible anesthesia devices).
• Storage and Historical review of patient clinical data and alarms from compatible physiological monitor, and anesthesia devices.
• Printing patient data from compatible physiological monitor, and anesthesia devices.
• Configuration of local settings as well as synchronizing settings across the network to remote compatible physiological monitors.
• 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, anesthesia systems and will display, store, print, and transfer information received from the compatible monitors, anesthesia systems.

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 Mindray BeneVision Central System is provided below.

1 SUBMITTER

Applicant:	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Contact:	Mindray Building, Keji 12th Road South High-tech Industrial Park, Nanshan Shenzhen 518057, P.R. China Tel: +86 755 81888998 Fax: +86 755 26582680 E-mail: lilei.js@mindray.com
Date Prepared:	July 21, 2025

2 DEVICE

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

Table 1: Secondary Product Codes

Regulation Number/Class	Product Code	Regulation description	Device Common Name
21 CFR 870.2300	DRT	Cardiac Monitor (including cardiotachometer and rate alarm)	Monitor, cardiac (incl. cardiotachometer & rate alarm)
21 CFR 870.2700	DQA	Oximeter	Oximeter
21 CFR 870.1130	DXN	Noninvasive blood pressure measurement system	System, measurement, blood-pressure, noninvasive
21 CFR 870.2770	DSB	Impedance plethysmograph	Plethysmograph, impedance

21 CFR 870.1025	MHX	Arrhythmia detector and alarm (including ST-segment measurement and alarm).	Monitor, physiological, patient (with arrhythmia detection or alarms)
21 CFR 870.2060	DRQ	Transducer signal amplifier and conditioner	Amplifier and signal conditioner, transducer signal

3 PREDICATE DEVICE

Predicate Device:

- K220058 - BeneVision Central Monitoring System (SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD)

4 REFERENCE DEVICES

- K211900 - Patient Information Center iX - Philips Medizin Systeme Böblingen GmbH
- K161164 - CareEvent inclusive of the CareEvent Mobile Application accessory -PHILIPS MEDICAL SYSTEMS

5 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.

When connected to a compatible anesthesia device, BeneVision CMS can display the parameters, waveforms and alarms of the anesthesia device. The device does not contain bi-directional capabilities for the compatible anesthesia devices.

The BeneVision CMS includes the AlarmGUARD application. AlarmGUARD supports delivering notifications of physiological and technical alarms to clinical professionals' mobile devices. AlarmGUARD is not intended for real time monitoring of patients and is not intended to act as a primary source for alarms.

6 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 from compatible physiological monitors. Viewing of non-real time patient clinical data of

compatible anesthesia devices (i.e. not indicated for real-time monitoring of clinical data of compatible anesthesia devices).

- Storage and Historical review of patient clinical data and alarms from compatible physiological monitor, and anesthesia devices.
- Printing patient data from compatible physiological monitor, and anesthesia devices.
- Configuration of local settings as well as synchronizing settings across the network to remote compatible physiological monitors.
- 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, anesthesia systems and will display, store, print, and transfer information received from the compatible monitors, anesthesia systems.

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.

7 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 device compatibility for the subject BeneVision Central Monitoring System has been expanded to include anesthesia systems. The subject BeneVision Central Monitoring System supports data storage and viewing (but not real time monitoring) for compatible anesthesia devices.
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 system compared to the predicate system in K220058. Differences between the subject device and predicate are marked in grey. Each row applies to all modules of the system (CentraStation, WorkStation, ViewStation, CMSViewer and Multi Patient Viewer unless otherwise noted).

Table 2 Technological Comparison

Feature	**As Cleared in K220058**	**Subject Device**
Operation System	1. CentralStation: supports Windows 10/Server 2016/Server 2019 2. WorkStation and ViewStation: supports Windows 10 3. CMS Viewer: supports Windows 10 4. The CentralStation supports installation on the Virtual Machine Platform when running as service such as VMWare and Hyper-V	1. No change 2. No change **3. CMS Viewer, Multi Patient Viewer support Windows11** 4. No change
Host configurations	1.CentralStation is Running as an Application on a host computer, the configurations are as below:	1.CentralStation is Running as an Application on a host computer, the configurations are as below:

	1.1 CPU: 4 cores and 2.9 GHz minimum 1.2 Memory: 4GB minimum 1.3 Hard disk: 500 GB minimum 1.4 Network adapter: 100M (minimum), Ethernet 802.3 2.CentralStation is Running as a service : 1) on a host computer, the configurations are as below: 2.1 CPU: 4 cores and 2.4 GHz minimum 2.2 Memory: 12GB minimum 2.3 Hard disk: 1TB minimum 2.4 Network adapter: 1000M (minimum) self-adapting, Ethernet 802.3 2) on virtual machine, the configurations are as below: 2.1 CPU: 4 cores and 2.4 GHz minimum 2.2 Memory: 12GB minimum 2.3 Hard disk: 1TB minimum 2.4 Network adapter: 1000M (minimum), Ethernet 802.3 3.The configurations of host computer where WorkStation/ViewStation is running are as below: 3.1 CPU: dual cores and 2.0 GHz minimum 3.2 Memory: 2GB minimum 3.3 Hard disk: 100 GB minimum 3.4 Network adapter: 100M (minimum) self-adapting, Ethernet 802.3	1.1 No change **1.2 Memory: 16GB minimum** 1.3 No change **1.4 Network adapter: 1000M (minimum), Ethernet 802.3** 2. CentralStation is Running as a service: 1) on a host computer: the configurations are as below: **2.1 CPU: 8 cores and 2.4 GHz minimum** **2.2 Memory: 16GB minimum** 2.3 No change 2.4 No change 2) on virtual machine, the configurations are as below: **2.1 CPU: 8 cores and 2.4 GHz minimum** 2.2 No change 2.3 No change 2.4 No change 3.The configurations of host computer where WorkStation/ViewStation is running are as below: **3.1 CPU: quad-cores and 2.4 GHz minimum** **3.2 Memory: 8GB minimum** 3.3 No change 3.4 No change 4. The configurations of CMS Viewer have no change **5. The configurations of host computer where Multi Patient viewer is running are as below:**

	4.The configurations of host computer where CMSviewer is running are as below: 4.1 CPU: 2 cores and 3.0 GHz minimum 4.2 Memory: 2GB minimum 4.3 Hard disk: 80GB minimum 4.4 Network adapter: 100M, Ethernet 802.3	**4.1 CPU: 4 cores and 2.9 GHz minimum** **4.2 Memory: 4GB minimum** **4.3 Hard disk: 100GB minimum** **4.4 Network adapter: 100M, Ethernet 802.3**
Display (including touchscreen capability)	Resolution:1920 x 1080,1280*1024	No change
Audio Applies to all except CMS viewer and Multi Patient Viewer	Built-in speakers	No change
Recorder Applies to all except CMS viewer and Multi Patient Viewer	Mindray thermal array module product	No change
Network	100 Mbps, Ethernet 802.3	No change
Max connections are supported for one CentralStation Applies to Central Station	Up to 32 WorkStation or ViewStation connections are supported for one CentralStation	Up to 128 WorkStation or ViewStation connections are supported for one CentralStation
Patient Monitor Numbers –	1. Support 64 monitors running as application. 2. When Running as service	No change

Number Supported	Up to 128 monitors with no patient display, the display is provided by WorkStations 3. CMS Viewer only supports one monitor 4. Multi Patient Viewer supports 36 monitors	
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
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 (K220058) ViewStation (K220058) WorkStation (K220058) TM80 (K193391) TM70(K193391)	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 (K220058) ViewStation (K220058) WorkStation (K220058) TM80 (K193391) TM70(K193391)

	BeneVision N22/N19/N17/N15/N12/N1 (K199391) VS8/8A/9(K211475) ePM Series Patient Monitors (ePM 10/ePM12/ePM 15/ ePM 10M/ePM 12M/ePM 15M) (K200015)	BeneVision N22/N19/N17/N15/N12/N1 (K199391) VS8/8A/9(K211475) ePM Series Patient Monitors (ePM 10/ePM12/ePM 15/ ePM 10M/ePM 12M/ePM 15M) (K200015) **Anesthesia Systems (Mindray A8, A9) (K201957)**
Bi-directional Configuration Applies to Central Station WorkStation	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
Calculations Applies to Central Station WorkStation ViewStation	Supports five calculation mode: Drug Calculation Hemodynamics Calculation Oxygenation Calculation Ventilation Calculation Renal Calculation	No change
View Other Bed Applies to all but Multi Patient Viewer	Provides the user the ability to remotely view 32 patient's parameters, waveforms, and alarms from a patient monitor connected to another BeneVision Central Monitoring System	No change
HL7 Output Applies to: CentralStation	Provide HL7 interface output	No change
Paging Interface	Enables transmission of configured alarm notifications to a third-party paging system	No change

Applies to: CentralStation WorkStation		
Dynamic short trend	8 hours	No change
Trend review	240 hours	No change
Wave review	240 hours of full-disclosure waveforms and compressed waveforms	No change
NIBP review	Most recent 3000 NIBP measurements	No change
Event review	3000 events	No change
12-lead review	720 12-lead analysis results, 12 analysis waveforms for each analysis result	No change
ST review	Most recent 240 hours of ST segments	No change
Cardiac output review	720 measurements	No change
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
Records	Patient information, real-time waveform, real-time alarm, waveform review, C.O.	No change

	measurement, events, 12-lead Review, ST review, drug calculation, hemodynamics calculations, oxygenation calculations, ventilation calculations, renal calculations, ICG hemodynamic parameter, CCO hemodynamic parameter, SvO2/ScvO2 oxygenation parameters	
Data storage	The patient data will be saved in an encrypted file.	No change
ECG Algorithm	Supports Mindray and Mortara	No change
ECG Functions	3-lead, 5-lead, 6-lead selectable, Arrhythmia detection, ST segment analysis, QT Analysis, Heart rate	No change
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
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
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
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,	No change

	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	
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
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:	No change

	– 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	
QRS Detection Threshold	Adjustable QRS Detection threshold. QRS threshold range: 0.16-0.48mV.	No change
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
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
Multi Patient Viewer Applies to: new software component	Previously part of the CMS Viewer Ran as a Single Instance	Separated From CMS viewer. Supports Multi- instances
Supports to AlarmGUARD	Not provided	If the device connected to the CMS triggers an alarm, then CMS

Applies to: new software component		can send a notification to the AlarmGUARD APP of the caregiver.

Substantial Equivalence Conclusion

In conclusion, the subject device has the same intended use, and minor difference in the technological characteristics. The differences in technology compared to the predicate BeneVision Central Monitoring System (K220058) do not raise different questions of safety and effectiveness based on the supportive testing referenced in this section and can be found substantially equivalent to the predicate device.

8 PERFORMANCE DATA

Biocompatibility Testing

Not applicable. The changes are just concerned with Software, not related 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 "Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff". 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 related to Electrical safety and electromagnetic compatibility.

Bench Testing

The following performance testing was conducted to support the subject device:

- AlarmGUARD IEC 60601-2-27
- AlarmGUARD IEC 60601-1-8
- AlarmGUARD Human Factors
- Waveform Display Accuracy from compatible Anesthesia Machine

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.

9 CONCLUSION

Based on the detailed comparison of specifications for each of the characteristics to the predicate devices, the software verification and validation testing, the BeneVision Central Monitoring System can be found substantially equivalent to the predicate devices.