March 13, 2019

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

Re: K183238
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: February 7, 2019
Received: February 8, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Arielle Drummond -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183238

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

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 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:	**November 9, 2018**
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:	K162607 – BeneVision Central Monitoring System
Reference devices:	K161531–Philips IntelliVue Patient Monitor MP2: provided as a reference device for the TM80 intelligent alarm function that has been added to the subject TM80. K172482–Nellcor™ USB Pulse Oximetry Monitor Interface Cable: provided as a reference device for the Nellcor module that has been added to the subject TM80 and TMS60 K170876– Passport 12m/17m: provided as a reference device for the beat annotation feature

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.

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

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

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.

TM80 local monitoring function has been added to the indications for use of the subject TM80 device, including local ECG, SpO2, RESP, NIBP physiology alarm, arrhythmia analysis, ST segment analysis and display, and QT analysis and display. The local functions were previously performed for the predicate TM80 (K162607) via the CentralStation and thus the modifications do not constitute a new intended use for a patient monitoring system.

Comparison of Technological Characteristics:

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

Table 1: Device Comparison Table – CentralStation, WorkStation, ViewStation, and CMS Viewer

Feature	Predicate Device - K162607 (CentralStation, WorkStation, ViewStation, and CMS Viewer)	Subject Device (CentralStation, WorkStation, ViewStation, and CMS Viewer)
Operation System	Microsoft Windows 7 Professional Embedded SP1	Added Microsoft Windows 10 and Windows Server 2016 to CentralStation, WorkStation, ViewStation.
Host	The Central Station supports 3 options for host computers: – HP Compaq 8380 Elite MT – HP EliteDesk 800 G1 SFF – Kontron KISS 2U V2 KTQ87FLEX	Added support for the following host computers: – HP EliteDesk 800 G3 SFF – Added HP ProDesk 600 G3 DM (Only supports WorkStation and ViewStation) – Added HPE Proliant DL360 Gen9 (Only supports CentralStation) No longer supports the following host computer: – HP EliteDesk 800 G1 SFF
Display (including touchscreen capability)	1920 x 1080 resolution, 16:9 widescreen LCD display 19", 21.5" and 23"	No change
Audio	Built-in speakers	No change
Recorder	Mindray thermal array module product	No change
Network	100 Mbps, Ethernet 802.3	No change
Patient Monitor Numbers – Number Supported	Up to 16 monitors in the single-screen mode for 1280*1024 resolution Up to 24 monitors in the single-screen mode for 1920 x 1080 resolution Up to 32 monitors in multi-screen mode	No change

Feature	Predicate Device - K162607 (CentralStation, WorkStation, ViewStation, and CMS Viewer)	Subject Device (CentralStation, WorkStation, ViewStation, and CMS Viewer)
	Supports up to four local displays	
Telemetry System	Supports the following telemetry systems: – TMS-6016 (K162607) – TMS60 (K162607) – Telepack-608 (K162607) – TM80(K162607)	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: CMSViewer (K162607) ViewStation (K162607) WorkStation (K162607) TM80 (K162607)	No change
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. For other devices: No change.
Calculations	Supports five calculation mode: Drug Calculation Hemodynamics Calculation Oxygenation Calculation Ventilation Calculation Renal Calculation	No change
View Other Bed	Provides the user the ability to remotely view one patient's parameters, waveforms, and alarms from a patient	Provides the user the ability to remotely view **32** patients' parameters, waveforms, and alarms from a patient monitor connected

Feature	Predicate Device - K162607 (CentralStation, WorkStation, ViewStation, and CMS Viewer)	Subject Device (CentralStation, WorkStation, ViewStation, and CMS Viewer)
	monitor connected to another BeneVision Central Monitoring System	to another BeneVision Central Monitoring System.
HL7 Output	Provide HL7 interface output	No change
Paging Interface	Enables transmission of configured alarm notifications to a third-party paging system	No change
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 1000 NIBP measurements	No change
Event review	1000 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. 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
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

Feature	Predicate Device - K162607 (CentralStation, WorkStation, ViewStation, and CMS Viewer)	Subject Device (CentralStation, WorkStation, ViewStation, and CMS Viewer)
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, Vfib/Vtac, Vtac, 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, Multif. PVC, Nonsus.Vtac, Pause, Irr. Rhythm, Pauses/min, and Afib Mortara algorithm: Asystol, Vfib, Vtac, Vent.Rhythm, Couplet, Run PVCs, PVCs/min, Bigeminy Trigeminy, R on T, Multif.PVC, Irr.Rhythm, Tachy, Brady, Pacer Not Pacing, Pacer Not Capture, Extreme Tachy, Extreme Brady, Pause and Pauses/min	Mindray algorithm: The following name changes were made to improve clarity: – 'VFib/Vtac' to 'V-Fib/V-Tach' – 'Vtac' to 'V-Tach' – 'Vent.Brady' to 'Vent Brady', – 'Nonsus.Vtac' to 'Nonsus V-Tach' – 'Vent.Rhythm' to 'Vent Rhythm' – 'Afib' to 'A-Fib' – 'Multif.PVC' to 'Multiform PVC' – 'Irr. Rhythm' to 'Irr Rhythm' Mortara algorithm: The following name changes were made to improve clarity: – 'VFIB' to 'V-Fib' – 'VTAC' to 'V-Tach' – 'Vent.Rhythm' to 'Vent Rhythm' – 'Multif.PVC' to 'Multiform PVC' – 'Irr. Rhythm' to 'Irr Rhythm'
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	No change

Feature	Predicate Device - K162607 (CentralStation, WorkStation, ViewStation, and CMS Viewer)	Subject Device (CentralStation, WorkStation, ViewStation, and CMS Viewer)
	– 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	
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 over shoot will be rejected: Amplitude: ±2 to ±700 mV Duration: 0.1 to 2 ms Rise time: 10 to 100 µs	No change
Support ECG Beat Annotation	Not provided	Provides the ability to annotate the ECG waveform in the Events review dialog and the Full Disclosure review dialog with ECG beat classification information.

Feature	Predicate Device - K162607 (CentralStation, WorkStation, ViewStation, and CMS Viewer)	Subject Device (CentralStation, WorkStation, ViewStation, and CMS Viewer)
		Although the predicate device does not support ECG Beat Annotation, the feature has been cleared in K170876.
The CMS offline technology alarm priority is configurable	Not provided. CMS offline alarm priority is fixed to low.	The CMS supports configuration of the offline technology alarm priority. The options include High, Med and Low. The default priority option is Low.
Graphical display ST Value	Not provided	The CMS ViewBed window supports an independent window for the graphical display of the ST value.
Strengthen cybersecurity features	MD2 protocol Encryption Type: XOR	MD2 protocol Encryption Type: XOR Two additional cybersecurity features have been added: 1. MD2 protocol encryption: Encrypt MD2 protocol with TLS 1.2 (Transport Layer Security). 2. MLDAP (Mindray Lightweight Directory Access Protocol) access authorization control: Access authorizations of the CMS is controlled by MLDAP.
Sending configurations to TM80 telemetry monitor via the CMS	Not provided	When multiple TM80 telemetry monitors are monitored by the CMS, the CMS supports sending the configuration of one connected TM80 telemetry monitor to another connected TM80 telemetry monitor. The following configuration settings can be transferred: - parameter alarm settings: alarm switch, alarm limit, alarm priority. - parameter setup information, such as ECG lead type, ECG filter.
Ability to turn off system alarm notifications within the CMS	Can turn off all CMS system alarm notifications	Can turn off alarm notifications based on the alarm priority. CMS can select the priority of the system alarms whose sound will be turned off. When the Med&Low or Low option is selected: - if the current highest system alarm priority of the CMS is medium or low, the CMS will not issue an alarm sound. Additionally, the audio off symbol  is displayed at the top of the CMS monitor.

Feature	Predicate Device - K162607 (CentralStation, WorkStation, ViewStation, and CMS Viewer)	Subject Device (CentralStation, WorkStation, ViewStation, and CMS Viewer)
		- If the highest system alarm priority of the CMS is high, then the alarm will not be muted. When Disable is selected, if an alarm is triggered, the alarm sound will not be muted (turned off). The default option is Disable.
The CMS can set whether to allow turning off alarm sounds for beds.	Can turn off alarm sound for all beds.	The CMS can set whether the CMS can turn off the alarm sounds for a single bed. When the option is set to Disable, the user cannot turn off an alarm sound for a single bed. When the option is set to Enable, the Audio tab is displayed in the Alarm Setup menu and the user can turn off the alarm sound for one bed without affecting the alarm sounds of other beds. This feature does not affect the settings in the remote patient monitor or telemetry monitor. The default option is Disable.
Display, storage and printing of physiological or technical alarm properties of external devices (connected to monitors via Benelink)	Supports display, storage and printing of external device information	Supports display, storage and printing of external device information Additionally, when a patient monitor is connected to an external device via device integration, the user can set the physiological or technical alarm properties for the external devices via the CMS. The following alarm properties of the external device can be set by the CMS: - whether to store and display alarms - whether to issue alarm sounds This feature does do not affect the settings of the remote patient monitor.
The CMS can bind bedside monitor and/or telemetry device to one sector.	CMS can bind an external device or a monitor to a CMS sector.	CMS can bind one bedside monitor and one telemetry device to one sector, however only one device can be active in the CMS at a time. The user determines the active device. If the

Feature	Predicate Device - K162607 (CentralStation, WorkStation, ViewStation, and CMS Viewer)	Subject Device (CentralStation, WorkStation, ViewStation, and CMS Viewer)
		active device is switched, the CMS will automatically bind the monitoring data coming from two devices to same patient.
CentralStation can be installed as a service on HPE Proliant DL360 Gen9 server.	Not Provided	CentralStation can be installed as a service mode. The CentralStation, in conjunction with the connected Workstation, provides the centralized monitoring function. In service mode, the CentralStation is connected with the bedside monitor and the telemetry device, and processes and stores the patient data. The WorkStation provides the frontend display and CMS alarms. The WorkStation can only review patient data and print reports. If the CentralStation is disconnected from the monitoring device or the WorkStation, the WorkStation will immediate activate the network disconnected alarm. When the CentralStation is installed as a service, one CentralStation can support up to 128 monitoring devices, and up to 32 WorkStations/ ViewStations.

Table 2: Device Comparison Table – TM80

Feature	Predicate Device - K162607 (TM80)	Subject Device (TM80)
Power type	Two or three AA batteries Rechargeable lithium-ion battery: DC 3.8V, 3800mAh, 14.44Wh Cover material: Sabic PC 945 Battery cell: SANYO supply, UF515155S-H003A Battery board: Level one over voltage protect circuit	Two or three AA batteries Rechargeable lithium-ion battery: DC 3.8V, 3800mAh, 14.44Wh **Cover material: PPSU RADEL R-5800** **Battery cell: ATL supply, GC-SDC-514752-010L** **Battery board: Level one and Level two over voltage protect circuit**
Display	Support touch-screen display	No change
Central Charger	Internal charging IC input： 15V Voltage monitoring：Not provided	Internal charging IC input： 5.4V Add voltage monitoring function: The charging circuit will shut down when the voltage output is abnormal.

Feature	Predicate Device - K162607 (TM80)	Subject Device (TM80)
IPX	IPX7	No change
Buttons	Power On/Off key Nurse call key Main menu key	No change
Device Disinfection	70% isopropyl alcohol 10% sodium hypocholride (bleach) solution 3% hydrogen peroxide Virkon Super Sani-cloth (0.5% Quaternary ammonium chloride and 55% Isopropyl alcohol) 50% propyl alcohol (1-propyl alcohol) 70% ethanol	Added: Propanol Alpet® D2 Surface Sanitizing Wipes CIDEX® OPA Solution Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach Clorox Healthcare® Bleach Germicidal Wipes Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipe Diversey Oxivir® TB Wipes Hydrogen peroxide Isopropanol Metrex CaviCide1™ Metrex CaviWipes™ PDI Sani-Cloth® AF3 Germicidal Disposable Wipe PDI Sani-Cloth® Bleach Germicidal Disposable Wipe PDI Sani-Cloth® HB Germicidal Disposable Wipe PDI Sani-Cloth® Plus Germicidal Disposable Cloth Sodium hypochlorite bleach VIRAGUARD Hospital Surface Disinfectants Virex® II 256 Virex® TB

Feature	Predicate Device - K162607 (TM80)	Subject Device (TM80)
Accessory Disinfection	**ECG leadset:** Ethanol 70%, Isopropanol 70%, Glutaraldehyde-type (2%) liquid disinfectants. **SPO2 sensor:** Ethanol 70%, Isopropanol 70%, Glutaraldehyde-type (2%) liquid disinfectants, Jifro(ethanol 54%-66%, n-propanol 9%-11%, trichloroacetic 0.04%-0.06%), Chlorine disinfectant 500mg/L. **NIBP cuff:** 70% ethanol 70% isopropanol	Support additional disinfecting agents as identified in **Error! Reference source not found.** of main document, column "ECG lead set", "NIBP cuff" and "SpO2 Sensor".
Cover material	Front cover material: SabicPC3412HF Soft plastic material: KE-2090-60 Back cover material: Sabic PC 945 Battery lock material: Lubriloy D20009 Battery cover material: Sabic PC 945 ECG lead connector material: Sabic PC945 Label material: PC 8010	Front cover material: Kalix 5950 HFFR Soft plastic material: 3070-60 Back cover material: Kalix 5950 HFFR Battery lock material: POM MP90-44 Battery cover material: PPSU RADEL R-5800 ECG lead connector material: Sabic 3706 Label material: PET A4300
WIFI specification		
WIFI Protocol	IEEE 802.11a/b/g/n	No change
Modulation mode	DSSS and OFDM	No change
Operating frequency	FCC: 2412Mhz-2462Mhz 5180Mhz-5240Mhz, 5745Mhz-5825Mhz ETSI: 2412Mhz-2472Mhz 5180Mhz-5240Mhz	No change
Channel spacing	IEEE 802.11b/g/n (at 2.4G): 5 MHz IEEE802.11a/n (at 5G): 20MHz	No change

Feature	Predicate Device - K162607 (TM80)	Subject Device (TM80)
Wireless baud rate (data rate)	IEEE 802.11b/g/n (at 2.4G): 1-65 Mbps IEEE 802.11a/n(at 5G): 6~65Mbps	No change
Output power (transfer power)	< 20 dBm (CE requirement: detection mode – RMS); < 30 dBm (FCC requirement: detection mode – peak power).	No change
Operating mode	Infrastructure	No change
Data security	Standard: WPA-PSK and WPA2-PSK WPA-Enterprise, WPA2-Enterprise EAP method: PEAP-GTC, PEAP- MSCHAPv2, EAP-TLS Encryption: TKIP and AES	No change
Qos	Qos setting supported	No change
Communication protocol	MD2 protocol	No change
Bluetooth specification		
Bluetooth	Bluetooth low energy 4.0	No change
Modulation mode	GFSK	No change
Operating frequency	2402 ~ 2480MHz	No change
Channel spacing	2 MHz	No change
Wireless baud rate (data rate)	1 Mbps	No change
Output power (transfer power)	≤2.5mW	No change
Data security	Private protocol	No change
Bluetooth function	Configuration transfer Connect to BP10 NIBP module	No change
ECG Specifications		
Lead type	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V 6-lead: II, III, aV, aVL, aVF, Va, Vb Automatic lead recognition	No change
Maximum Input	±8 mV (Peak to Peak Value)	No change
Frequency Response	ST mode: 0.05-40 Hz Monitoring mode: 0.5-40 Hz	No change
CMRR	> 105dB	No change
Noise	≤ 30 μV (p-v RTI)	No change
Defibrillation Proof	Meets IEC 60601-2-27	No change
Resp Specifications		

Feature	Predicate Device - K162607 (TM80)	Subject Device (TM80)
Measurement range	Adult: 0 to 120 rpm Pediatric:0 to 150 rpm	No change
Resolution	1rpm	No change
Accuracy	7 to 150 rpm: ±2 rpm or ±2%, whichever is greater 0 to 6 rpm: Not specified	No change
SpO2 Specifications		
Nonin SpO2 Module		
SpO2 range	0% to 100%	No change
SpO2 accuracy	70-100%: ± 3 % (digital); 0-69%: Not specified	No change
PR range	20 bpm to 300 pm	No change
PR accuracy	±3 bpm	No change
Masimo SpO2 Module		
SpO2 Measurement range	1% to 100%	No change
SpO2 Accuracy	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified.	No change
PR Measurement range	25 bpm to 240 bpm	No change
PR Accuracy	± 3 bpm (without motion) ± 5 bpm (with motion)	No change
Nellcor SpO2 Module (Added): Although the predicate device does not support Nellcor SpO2 module, the feature has been cleared in K172482.		
SpO2 Measurement range	Not provided	0~100 %
SpO2 Accuracy	Not provided	70%~100%: ±2% ABS; 70%~100%: 0~69%: not specified.
PR Measurement range	Not provided	20~300 bpm
PR Accuracy	Not provided	20~250 bpm ±3 bpm; 251~300 bpm, not specified
BP10 NIBP module		
Power type	Two AA batteries Rechargeable lithium-ion battery: DC 3.7V, 1800mAh, 6.66Wh Cover material: Sabic PC 945 Battery cell: SANYO supply, UF103450P-N01EA Battery board: Level one over voltage protect circuit	Two AA batteries Rechargeable lithium-ion battery: DC 3.7V, 1800mAh, 6.66Wh **Cover material: PPSU RADEL R-5800** **Battery cell: SANYO supply, UF103450P-H01UA** **Battery board: Level one and Level two over voltage protect circuit**
Display	2.4”, 320*240 pixels	No change

Feature	Predicate Device - K162607 (TM80)	Subject Device (TM80)
Buttons	Power On/Off key Nurse call key Main menu key	No change
Protocol	Bluetooth low energy 4.0	No change
Modulation mode	GFSK	No change
Operating frequency	2402 ~ 2480MHz	No change
Channel spacing	2 MHz	No change
Wireless baud rate (data rate)	1 Mbps	No change
Output power (transfer power)	≤2.5mW	No change
Data security	Private protocol	No change
Bluetooth function	Connect to TMS60/TM80 transmitter	No change
Measurement ranges (mmHg)	Adult： Systolic: 25-290mmHg； Diastolic: 10-250mmHg； Mean: 15-260mmHg。 Pediatric： Systolic: 25-240mmHg； Diastolic: 10-200mmHg； Mean: 15-215mmH	No change
Accuracy	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg	No change
PR from NIBP Module	Measurement ranges:30-300bpm Accuracy:±3bpm or ±3%, whichever is greater; Resolution:1bpm	No change
Cover material	Cover material: Sabic PC 945 LCD glass: PC Soft plastic material: KE-2090-60 Battery lock material: Lubriloy D20009 Battery cover material: Sabic PC 945	Cover material: Kalix 5950 HFFR LCD glass: HWC-PC Soft plastic material: 3070-60 Battery lock material: POM MP90-44 Battery cover material: PPSU RADEL R-5800
TM80 monitoring function		

Feature	Predicate Device - K162607 (TM80)	Subject Device (TM80)
Arrhythmia analysis and alarm.	Provided by the CentralStation	Added the ability to perform Arrhythmia analysis locally using the same methods employed by the Central station. The types of arrhythmia have not been changed, they are just implemented locally within the TM80 instead of being implemented by the CentralStation.
ARR	Provided by the CentralStation	Asystole, V-Fib/V-Tach, V-Tach, Vent Brady, Extreme Tachy, Extreme Brady, R on T, Run PVCs, Couplet, Multif.PVC, PVC, Bigeminy, Trigeminy, Tachy, Brady, Pacer Not Capture, Pacer Not Pacing, Missed Beats, Nonsus V-Tach, Vent Rhythm, Pause, Irr Rhythm, A-Fib, PVCs/min, Pauses/min
ECG, SpO2, RESP, NIBP physiology alarm	Provided by the CentralStation	Added Local SpO2, RESP, NIBP physiology alarm function.
Intelligent arrhythmia alarm	Not provided	Arrhythmia Alarm Chains; Alarm Refractory Period; Arrhythmia Alarm Timeout Although the predicate device does not support an intelligent arrhythmia alarm functionality, the feature has been cleared in K161531
ST segment analysis and display	Provided by the CentralStation	Added the ability to perform ST segment analysis locally using the same methods employed by the Central Station. The specifications of ST segment analysis are the same as in the predicate device, only they are implemented locally instead of by the CentralStation.
QT analysis and display	Provided by the CentralStation	Added the ability to perform QT analysis locally using the same methods as the CentralStation. The specifications of QT analysis are the same as in the predicate device, only they are implemented locally instead of by the CentralStation.
Mindray ECG algorithm modifications	ARR, HR, ST, QT analysis	ARR, HR, ST, QT analysis enhanced performance: – Enhance premature ventricular contraction (PVC) recognition sensitivity. Reduced threshold for detecting baseline wander or electromyography signals.
Patient management	Provided by the CentralStation	Allows users to enter or change patient demographic information, or discharge patients via TM80.

Feature	Predicate Device - K162607 (TM80)	Subject Device (TM80)
Data storage	Provided by the CentralStation	Allows users to store ECG, RESP, NIBP, SpO2 data in TM80.
Local History review	Provided by the CentralStation	Allows users to review history data of ECG, RESP, NIBP, SpO2 in TM80.
Data retransmission	10s real time data can be resent to the CentralStation after reconnected.	More than 2 hours of ECG, SPO2, NIBP, and RESP data generated during a disconnection from the network can be resent to the CentralStation after the CentralStation is reconnected.
Other Change		
Other changes		Design improvement: • WiFi firmware upgrade. • SPO2 connector: add the pin touch length from 0.85mm to 2mm. • End of life material substitute: LCD, Flash.

Table 3: Device Comparison Table – TMS60

Feature	Predicate Device - K162607 (TMS60)	Subject Device (TMS60)
Transmitter		
Power type	Two or three AA batteries Rechargeable lithium-ion battery: DC 3.8V, 3800mAh, 14.44Wh Cover material: Sabic PC 945 Battery cell: SANYO supply, UF515155S-H003A Battery board: Level one over voltage protect circuit	Two or three AA batteries Rechargeable lithium-ion battery: DC 3.8V, 3800mAh, 14.44Wh **Cover material: PPSU RADEL R-5800** **Battery cell: ATL supply, GC-SDC-514752-010L** **Battery board: Level one and Level two over voltage protect circuit**
Display	Support touch-screen display	No change
Central Charger	Internal charging IC input： 15V Voltage monitoring：Not provided	**Internal charging IC input：** **5.4V** **Add voltage monitoring function, shut down when voltage output abnormal.**
IPX	IPX7	No change
Buttons	Power On/Off key Nurse call key Main menu key	No change

Feature	Predicate Device - K162607 (TMS60)	Subject Device (TMS60)
Cover material	Top cover material: SabicPC3412HF Soft plastic material: KE-2090-60 Back cover material: Sabic PC 945 Battery lock: Lubriloy D20009 Battery holder cover: Sabic PC 945 ECG lead connector material: Sabic PC945 Label material: PC 8010	Top cover material: Kalix 5950 HFFR Soft plastic material: 3070-60 Back cover material: Kalix 5950 HFFR Battery lock: POM MP90-44 Battery holder cover: PPSU RADEL R-5800 ECG lead connector material: Sabic 3706 Label material: PET A4300
Device Disinfection	70% isopropyl alcohol 10% sodium hypocholride (bleach) solution 3% hydrogen peroxide Virkon Super Sani-cloth (0.5% Quaternary ammonium chloride and 55% Isopropyl alcohol) 50% propyl alcohol (1-propyl alcohol) 70% ethanol	**Added:** Propanol Alpet® D2 Surface Sanitizing Wipes CIDEX® OPA Solution Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach Clorox Healthcare® Bleach Germicidal Wipes Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipe Diversey Oxivir® TB Wipes Hydrogen peroxide Isopropanol Metrex CaviCide1™ Metrex CaviWipes™ PDI Sani-Cloth® AF3 Germicidal Disposable Wipe PDI Sani-Cloth® Bleach Germicidal Disposable Wipe PDI Sani-Cloth® HB Germicidal Disposable Wipe PDI Sani-Cloth® Plus Germicidal Disposable Cloth Sodium hypochlorite bleach VIRAGUARD Hospital Surface Disinfectants Virex® II 256 Virex® TB

Feature	Predicate Device - K162607 (TMS60)	Subject Device (TMS60)
Accessory Disinfection-	**ECG leadset:** Ethanol 70%, Isopropanol 70%, Glutaraldehyde-type (2%) liquid disinfectants. **SPO2 sensor:** Ethanol 70%, Isopropanol 70%, Glutaraldehyde-type (2%) liquid disinfectants, Jifro(ethanol 54%-66%, n-propanol 9%-11%, trichloroacetic 0.04%-0.06%), Chlorine disinfectant 500mg/L. **NIBP cuff:** 70% ethanol 70% isopropanol	Supports additional disinfecting agents
Receiver		
Antenna connector	Quantity: 2 Connector type: TNC	No change
Ethernet interface	Protocol: IEEE 802.3 Speed: 10M/100M (self-adaptive) Connector type: RJ45	No change
WMTS specification		
frequency range	608 to 614MHz (WMTS band)	No change
Modulation mode	GFSK	No change
Channel spacing	25KHz	No change
Wireless baud rate	8 kbps±3%	No change
Transmit power	<10mW	No change
Receiver sensitivity	≤-110dBm （Bit error rate ≤1%）	No change
Data security	Private protocol	No change
Bluetooth specification		
Protocol	Bluetooth low energy 4.0	No change
Modulation mode	GFSK	No change
Operating frequency	2402 ~ 2480MHz	No change
Channel spacing	2 MHz	No change
Wireless baud rate (data rate)	1 Mbps	No change

Feature	Predicate Device - K162607 (TMS60)	Subject Device (TMS60)
Output power (transfer power)	≤2.5mW	No change
Data security	Private protocol	No change
Wireless function	Configuration transfer Connect to BP10 NIBP module	No change
ECG Specifications		
Lead type	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V Automatic 3/5 lead recognition	No change
Maximum Input	±8 mV(Peak to Peak Value)	No change
Frequency Response	ST mode: 0.05-40 Hz Monitoring mode: 0.5-40 Hz	No change
CMRR	> 105dB	No change
Noise	≤ 30 μV (p-v RTI)	No change
Defibrillation Proof	Meets IEC 60601-2-27	No change
Resp Specifications		
Measurement range	Adult: 0 to 120 rpm Pediatric:0 to 150 rpm	No change
Resolution	1rpm	No change
Accuracy	7 to 150 rpm: ±2 rpm or ±2%, whichever is greater 0 to 6 rpm: Not specified	No change
Supported external devices		
Nonin SpO2 Module (K150632**)**		
SpO2 range	0% to 100%	No change
SpO2 accuracy	70-100%: ± 3 % (digital); 0-69%: Not specified	No change
PR range	20 bpm to 300 pm	No change
PR accuracy	±3 bpm	No change
Masimo SpO2 Module (K150632**)**		
SpO2 Measurement range	1% to 100%	No change
SpO2 Accuracy	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified.	No change

Feature	Predicate Device - K162607 (TMS60)	Subject Device (TMS60)
PR Measurement range	25 bpm to 240 bpm	No change
PR Accuracy	± 3 bpm (without motion) ± 5 bpm (with motion)	No change
Nellcor SpO2 Module (Added**):** Although the predicate device does not support Nellcor SpO2 module, the feature has been cleared in K172482.		
SpO2 Measurement range	Not provided	0~100 %
SpO2 Accuracy	Not provided	70%~100% : ±2% ABS; 0~69%: not specified.
PR Measurement range	Not provided	20~300 bpm
PR Accuracy	Not provided	20~250 bpm ±3 bpm; 251~300 bpm, not specified
BP10 NIBP module		
Power type	Two AA batteries Rechargeable lithium-ion battery: DC 3.7V, 1800mAh, 6.66Wh Cover material: Sabic PC 945 Battery cell: SANYO supply, UF103450P-N01EA Battery board: Level one over voltage protect circuit	Two AA batteries Rechargeable lithium-ion battery: DC 3.7V, 1800mAh, 6.66Wh **Cover material: PPSU RADEL R-5800** **Battery cell: SANYO supply, UF103450P-H01UA** **Battery board: Level one and Level two over voltage protect circuit**
Display	2.4", 320*240 pixels	No change
Buttons	Power On/Off key Nurse call key Main menu key	No change
Protocol	Bluetooth low energy 4.0	No change
Modulation mode	GFSK	No change
Operating frequency	2402 ~ 2480MHz	No change
Channel spacing	2 MHz	No change
Wireless baud rate (data rate)	1 Mbps	No change
Output power (transfer power)	≤2.5mW	No change
Data security	Private protocol	No change
Bluetooth function	Connect to TMS60/TM80 transmitter	No change

Feature	Predicate Device - K162607 (TMS60)	Subject Device (TMS60)
Measurement ranges (mmHg)	Adult： Systolic: 25-290mmHg； Diastolic: 10-250mmHg； Mean: 15-260mmHg。 Pediatric： Systolic: 25-240mmHg； Diastolic: 10-200mmHg； Mean: 15-215mmH	No change
Accuracy	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg	No change
PR from NIBP Module	Measurement ranges:30-300bpm Accuracy:±3bpm or ±3%, whichever is greater; Resolution:1bpm	No change
Cover material	Cover material: Sabic PC 945 LCD glass: PC Soft plastic material: KE-2090-60 Battery lock material: Lubriloy D20009 Battery cover material: Sabic PC 945	Cover material: Kalix 5950 HFFR LCD glass: HWC-PC Soft plastic material: 3070-60 Battery lock material: POM MP90-44 Battery cover material: PPSU RADEL R-5800
Other Change		
Other change	/	Design improvement: • SPO2 connector: add the pin touch length from 0.85mm to 2mm. • End of life material substitute: LCD, Flash.

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness.

Performance Data:

Biocompatibility Testing

The CentralStation, ViewStation, WorkStation and CMS viewer are software only devices, therefore biocompatibility is not applicable. There have been no changes to the patient contacting materials of the telemetry systems.

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 device works as designed. Validation was conducted to check the design and performance of the device.

Electromagnetic Compatibility and Electrical Safety

The BeneVision Central Monitoring System were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.
- IEC 62133:2012 (Second Edition) Secondary cell and batteries containing alkaline or other non-acid electrolytes

Bench Testing

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.

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

- IEC 60601-1-8:2006 + Am1:2012 Medical electrical equipment - part 1-8: general requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment IEC80601-2-30 Edition 1.1 2013-07
- IEC 60601-2-49:2011 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-61: 2011 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment

Conclusion:

Based on the detailed comparison between the predicate devices and the subject devices, the performance testing and conformance with applicable standards, the BeneVision Central Monitoring System can be found substantially equivalent to the predicate devices.