May 21, 2020

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, Guangdong 518057
China

Re: K193391
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: April 22, 2020
Received: April 23, 2020

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/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
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193391

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, 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 configure 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 Monitoring System is provided below.

1. SUBMITTER

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:	Contact Person: Yanhong Bai Title: Manager Regulatory Affairs Phone: +86 755 81885635 Fax: +86 755 26582680 E-mail: baiyanhong@mindray.com
Date Prepared:	April 22, 2020

2. DEVICE

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

Table 1: Secondary Product Codes

Regulation Number/Class	Product Code	Regulation description	Device Common Name
870.2300, II	DRT	Cardiac Monitor (including cardiotachometer and rate alarm)	Monitor, cardiac (incl. cardiotachometer & rate alarm)
870.1130, II	DXN	Noninvasive blood pressure measurement system	System, measurement, blood-pressure, non-invasive
870.2700, II	DQA	Oximeter	Oximeter
880.2770, II	DSB	Impedance plethysmograph.	Plethysmograph, impedance
870.1025, II	MHX	Arrhythmia detector and alarm (including ST-segment measurement and alarm).	Monitor, physiological, patient(with arrhythmia detection or alarms)
870.2060, II	DRQ	Transducer signal amplifier and conditioner.	Amplifier and signal conditioner, transducer signal

3. PREDICATE DEVICE

- Primary predicate device

The cleared BeneVision Central Monitoring System (K183238) is provided as the primary predicate device for both Indications for Use and technology.

Primary Product Code: MSX

Subsequent Product Codes: DQA, DRQ, DRT, DSB, DXN, MHX

- Secondary predicate device

The cleared Philips MX40 Release B.07 (cleared in K172226) is provided as a second predicate device that uses the WMTS-1.4G wireless network function. This wireless network function has been added to the subject TM70 of the BeneVision Central Monitoring System.

Primary Product Code: MHX

Subsequent Product Codes: DQA, DRG, DRW, DSA, DSI, MLD, MSX

4. 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 or the TM80/TM70 Telemetry Monitors.

The BeneVision Central Monitoring System consists of the following components：

1. CentralStation
2. ViewStation
3. WorkStation
4. CMS Viewer
5. Telemetry Systems (TMS 6016, Telepak-608, TMS60, TM80, TM70)

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 display, storage, and printing.

The TM70 telemetry monitor operates in the 608M or the 1.4G WMTS frequency range within a defined coverage area, and transmits data to the CentralStation for display, storage, and printing.

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

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, 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 configure 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. LIST OF CONSENSUS STANDARDS

The proposed device is in conformity with the requirements of the following consensus standards:

Table 2: List of consensus standards

Recognition Number	Standard Name and Version
Not recognized	IEC 60950-1:2005+A1:2009+A2:2013 Information technology equipment - Safety - Part 1: General requirements
Not recognized*	IEC 60601-2-49: 2018,Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
19-4*	ANSI/AAMI ES60601-1:2005/(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
19-8	IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

19-30	AIM Standard 7351731: 2017 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
5-89*	IEC 60601-1-6: 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5-76*	IEC 60601-1-8: 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
3-126	IEC 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
3-123*	IEC 80601-2-30:2018 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers
1-139*	ISO 80601-2-61: 2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
5-40	ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices
2-220*	ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
2-245*	ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2-174*	ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
3-129*	ANSI/AAMI:EC53:2013 ECG cables and lead wires
3-118*	ANSI AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
19-29	ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

19-22	AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
13-79	ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

*Indicates standards the predicate device was tested to but were not repeated for this 510(k).

7. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Both the predicate devices and the subject device are patient monitoring systems intended to be used in healthcare facilities under the direction of clinical professionals.

The new device type TM70 is added to the intended use. There are no other modifications to the intended use.

Technological Comparison

The table below compares the key technological features of subject device to the predicate device (BeneVision Central Monitoring System) cleared in K183238. The features in grey are the features that are different from the predicate device and that are the subject of this 510(k).

Comparison of CentralStation, ViewStation, WorkStation and CMS Viewer

Table 3:Device Comparison Table – CentralStation, WorkStation, ViewStation, and CMS Viewer

Feature	As Cleared in K183238	Modifications Made to Subject Device	Comparison analysis
Operation System	Unchanged, as previously submitted		
Host	The Central Station supports 5options for host computers: – HP Compaq 8380 Elite MT – HP EliteDesk 800 G3 SFF – HP EliteDesk 600 G3DM(Only supports WorkStation and ViewStation) – HPE Proliant DL360 Gen9 (Only supports CentralStation) – Kontron KISS 2U V2 KTQ87FLEX	Added support for the following host computers: – **HP EliteDesk 800 G4 SFF** – **Added HP ProDesk 600 G4 DM (Only supports WorkStation and ViewStation)** – **Added HPE Proliant DL360 Gen10 (Only supports CentralStation)** No longer supports the following host computer: – **HP Compaq 8380 Elite MT**	While there are 3 new host options being added, they do not raise different questions of safety and effectiveness.
Network	Unchanged, as previously submitted		
Max connections are supported for one CentralStation	Up to 16 WorkStation or ViewStation connections are supported for one CentralStation	Up to **32** WorkStation or ViewStation connections are supported for one CentralStation	Only changed a number from 16 to 32 in the code. The change does not raise different questions of safety and effectiveness.
Patient Monitor Numbers – Number Supported	1.Running as application 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 Supports up to four local displays 2. Running as service Up to 128 monitors with no patient display, the display is provided by WorkStations	Support **32** monitors in the single screen mode for 1920 x 1080 resolution running as application	Only changed a number from 24 to 32 in the code. The change does not raise different questions of safety and effectiveness.

Feature	As Cleared in K183238	Modifications Made to Subject Device	Comparison analysis
Telemetry Systems and monitors	Supports the following telemetry systems and monitors: – TMS-6016 (K183238) – TMS60 (K183238) – Telepack-608 (K183238) – TM80 (K183238)	Supports same telemetry systems and added support got **TM70**	The BeneVision Central Monitoring System and patient monitors communicate via the MD2 protocol, CMS+ protocol and ELAN protocol. The Central Monitoring System does not differentiate the models of patient monitors. The change does not raise different questions of safety and effectiveness.
Communication protocol (and compatible monitors)	CMS+ protocol: DPM3 (K072235) DPM4/5 (K070791) DPM6/7 (K092449) Passport 12m/17m/T1 (190011) Passport8/12 (K153448) Passport V (K091834) Accutorr 7/VS-900 (K170712) ELAN protocol: Spectrum (K062098) Spectrum OR (K062098) Passport II (K020550) V12/21 (K150352) MD2 protocol: CMS Viewer (K183238) ViewStation (K183238) WorkStation (K183238) TM80 (K183238)	Supports same communication protocols as predicate. Added **TM70 and BeneVision N22/N19/N17/N15/N12/N1.** They use MD2 protocol.	
Bi-directional Configuration	Unchanged, as previously submitted		
Calculations	Unchanged, as previously submitted		
View Other Bed	Unchanged, as previously submitted		
HL7 Output	Unchanged, as previously submitted		
Paging Interface	Unchanged, as previously submitted		
Data Review			
NIBP review	Most recent 1000 NIBP measurements	NIBP review Support most recent **3000** NIBP measurements	For this change, the only change was a number from 1000 to 3000 in the code.

Feature	As Cleared in K183238	Modifications Made to Subject Device	Comparison analysis
Event review	1000 events	Event review Support **3000** events	The change does not raise different questions of safety and effectiveness.
Dynamic short trend Trend review Wave review 12-lead review ST review Cardiac output review	Unchanged, as previously submitted		
ECG Features			
ECG Algorithm ECG Functions HR ST ARR QT Analysis Pace mark Pace pulse rejection	Unchanged, as previously submitted		
New Features			
WorkStation support to delete discharged patients	Not provided	**The WorkStation provides the ability to set whether to allow deleting discharged patients**	In the predicate BeneVision Central Monitoring System (K183238), only CentralStation supports deletion of discharged patients. The subject CMS adds the ability for authorized users to have the capability to delete discharged patients. The change does not raise different questions of safety and effectiveness.

Comparison of TM80

Table 4: Device Comparison Table – TM80

Feature	As cleared in K183238	Subject Device (modifications in grey and/or bolded)	Comparison analysis
Device Hardware			
Power type	Unchanged, as previously submitted		

Display	Unchanged, as previously submitted		
Central Charger	Unchanged, as previously submitted		
IPX	Unchanged, as previously submitted		
Main WIFI specification			
Supplier	Alinket: ALX850B	Silex: SX-SDMAC-2832S+	New supplier and WIFI module
WIFI Protocol	IEEE 802.11a/b/g/n	IEEE 802.11a/b/g/n/**ac**	The new WIFI module supports 802.11ac
Modulation mode	Unchanged, as previously submitted		
Operating frequency	Unchanged, as previously submitted		
Channel spacing	IEEE 802.11b/g/n (at 2.4G): 5 MHz IEEE802.11a/n (at 5G): 20MHz	IEEE 802.11b/g/n (at 2.4G): 5 MHz IEEE802.11a/n/**ac** (at 5G): 20MHz	The new Wi-Fi module supports 802.11ac
Wireless baud rate (data rate)	IEEE 802.11b/g/n (at 2.4G): 1-65 Mbps IEEE 802.11a/n(at 5G): 6~65Mbps	IEEE 802.11b: **1 Mbps to 11 Mbps** IEEE 802.11a/g: **6 Mbps to 54 Mbps** IEEE 802.11n: **MCS0 (6.5Mbps) to MCS7 (72.2Mbps)** **IEEE 802.11ac: MCS0 (6.5 Mbps) to MCS8 (86.7 Mbps)**	Baud rate specifications are more specific for 802.11a/b/g/n, and the new WIFI module support 802.11ac
Output power (transfer power)	Unchanged, as previously submitted		
Operating mode	Unchanged, as previously submitted		
Data security	Standard: WPA-PSK and WPA2-PSK WPA-Enterprise, WPA2-Enterprise EAP method: PEAP-GTC, PEAP-MSCHAPv2, EAP-TLS Encryption: TKIP and AES	Standards: WPA/ WPA2 PSK, WPA/WPA2 EAP, **WPA/WPA2 CCKM** EAP methods: **LEAP, TTLS, TLS, FAST,** PEAP-MsChapV2, PEAPGTC, PEAP-TLS Encryption modes: TKIP and AES	The new WIFI module support more security standard
Qos	Unchanged, as previously submitted		
Communication protocol	Unchanged, as previously submitted		
Main Bluetooth specification			
Main Bluetooth specification	Unchanged, as previously submitted		

ECG Specifications			
Pace mark	Detects and marks pace pulse: Amplitude: ±2 to ±700 mV Duration: 0.1 to 2 ms Rise time: 10 to 100 µs Pace detected by hardware circuit which includes pacer pulse edge detection, amplification and comparison.	Detects and marks pace pulse: Amplitude: ±2 to ±700 mV Duration: 0.1 to 2 ms Rise time: 10 to 100 µs **Adds ADC conversion in the pacer pulse detection channel and supports software pace detection function.**	The subject TM80 adds ADC (analog-to-digital) conversion in the pacer pulse detection channel. The differences do not raise additional questions of safety and effectiveness.
ECG Algorithm ECG Functions HR ST ARR QT Analysis Pace pulse rejection	Unchanged, as previously submitted		
Resp Specifications			
Resp Specifications	Unchanged, as previously submitted		
SpO2 Specifications			
SpO2 Specifications	Unchanged, as previously submitted		
BP10 NIBP module			
BP10 NIBP module	Unchanged, as previously submitted		

Summary of main changes for TM80

WIFI module difference

The WIFI module of the subject TM80 has been replaced because the previous components are no longer available from the supplier. The subject TM80 with the new WIFI module has passed the FCC certification test. The FCC ID is ZLZ-PMACS.

The differences of the WIFI module do not raise additional questions of safety and effectiveness through the safety impact analysis.

These differences do not raise different questions of safety and effectiveness, and testing demonstrates that the new WIFI module complies with relevant safety standards and has equivalent performance.

Software Pace Detection

The predicate TM80 detects pacemakers by a hardware circuit which includes pacer pulse edge detection, amplification and comparison. The subject TM80 now adds ADC conversion in the

pacer pulse detection channel and supports software pace detection function. The pace detection specifications have not been changed. The modification is only for pace detect channel, the ECG channel is not changed, so the modification will not impact HR, ST, QT, ARR performance.

The subject TM80 adds ADC conversion in the pacer pulse detection channel. The differences do not raise additional questions of safety and effectiveness through safety impact analysis. Mindray conducted EMC (IEC 60601-1-2) and performance (IEC 60601-2-27) testing

These differences do not raise different questions of safety and effectiveness, and testing demonstrates that the software pace detection modification comply with relevant safety standards and have equivalent performance.

Comparison of TM70

Table 5: Device Comparison Table – TM70

Feature	**Predicate TM80 cleared in K183238**	**Subject TM70 Device (modifications in grey and/or bolded)**		**Comparison analysis**
Power type	Unchanged, as previously submitted			
Display	Unchanged, as previously submitted			
Central Charger	Unchanged, as previously submitted			
IPX	Unchanged, as previously submitted			
Main Wireless Specification				
Modulation mode	DSSS and OFDM	**GFSK**		**The difference between the subject TM70 and the subject TM80 is that TM70 used WMTS instead of WIFI.** **The WMTS wireless function is not used in TM80, but the WMTS (608MHz band) is already used in TMS60 (K183238), and the WMTS (1.4GHz band) already used in Philips MX40 (K172226).** **The details of WMTS-608M have been discussed in Table 6: Detailed Comparison of WMTS-608M Specifications** **The details of WMTS-1.4G have been discussed in Table 7: Detailed Comparison of WMTS-1.4G Specifications**
Operating frequency	FCC: 2412Mhz-2462Mhz 5180Mhz-5240Mhz, 5745Mhz-5825Mhz ETSI: 2412Mhz-2472Mhz 5180Mhz-5240Mhz	**WMTS-608M:** **608MHz(608~614MHz)**	**WMTS-1.4G:** **1.4GHz(1395~1400 MHz and 1427~1432MHz)**	
Channel spacing	IEEE 802.11b/g/n (at 2.4G): 5 MHz IEEE802.11a/n (at 5G): 20MHz	**WMTS-608M:** **600kHz**	**WMTS-1.4G:** **800kHz or 600kHz**	
Wireless baud rate (data rate)	IEEE 802.11b/g/n (at 2.4G): 1-65 Mbps IEEE 802.11a/n(at 5G): 6~65Mbps	**WMTS-608M:** **Max 400kbps**	**WMTS-1.4G:** **433kbps for 800kHz channel spacing.** **400kbps for 600kHz channel spacing.**	

Max Output power (transfer power)	<20 dBm (CE requirement: detection mode – RMS); <30 dBm (FCC requirement: detection mode – peak power).	**10 dBm**	
Data security	Standard: WPA-PSK and WPA2-PSK WPA-Enterprise, WPA2-Enterprise EAP method: PEAP-GTC, PEAP-MSCHAPv2, EAP-TLS Encryption: TKIP and AES	**Authentication: based on TLS** **Encryption : AES-128bit**	
Main Bluetooth specification			
Main Bluetooth specification	Unchanged, as previously submitted		
ECG Specifications			
Pace mark	Detects and marks pace pulse: Amplitude: ±2 to ±700 mV Duration: 0.1 to 2 ms Rise time: 10 to 100 µs Pace detected by hardware circuit which includes pacer pulse edge detection, amplification and comparison.	Detects and marks pace pulse: Amplitude: ±2 to ±700 mV Duration: 0.1 to 2 ms Rise time: 10 to 100 µs **Adds ADC conversion in the pacer pulse detection channel and supports software pace detection function.**	The subject TM70 adds ADC conversion in the pacer pulse detection channel. The differences do not raise additional questions of safety and effectiveness.
ECG Algorithm ECG Functions HR ST ARR QT Analysis Pace pulse rejection	Unchanged, as previously submitted		
Resp Specifications			
Resp Specifications	Unchanged, as previously submitted		
SpO2 Specifications			
SpO2 Specifications	Unchanged, as previously submitted		
BP10 NIBP module			

BP10 NIBP module	Unchanged, as previously submitted

Table 6: Detailed Comparison of WMTS-608M Specifications

Feature	Predicate TMS60 WMTS 608M function (K183238)	Subject TM70 WMTS 608M function	Comparison analysis
Modulation mode	GFSK	GFSK	Same
Operating frequency	608~614MHz (WMTS band)	608~614MHz	Same
Channel spacing	25kHz	**600KHz**	TMS60 is narrowband communication and TM70 is broadband communication
Wireless baud rate (data rate)	8 kbps±3%	**Max 400kbps**	TMS60 is narrowband communication and TM70 is broadband communication
Max Output power	10 dBm (10 mW)	10 dBm	Same
Receiver sensitivity	≤-110dBm (Bit error rate < 1%)	**≤-90 dBm for AP** **≤-87 dBm for TM70**	TMS60 was a unidirectional narrowband communication and TM70 is bi-directional broadband communications. So, there are receiver sensitivity specifications at both sides of AP and TM70 transmitter
Data security	Private protocol	**Authentication based on TLS** **Encryption using AES-128 bit**	TM70 data security has improved, to be in line with industry security standards
Radio Frequency Accuracy	Not claimed	**<±50 kHz relative to channel frequency**	TM70 has a more precise definition
Occupied bandwidth	Not claimed	**<±300 kHz**	TM70 has a more precise definition

Feature	Predicate TMS60 WMTS 608M function (K183238)	Subject TM70 WMTS 608M function	Comparison analysis
Communication with the central station	TMS60 Transmitters send waveforms, parameters, status and technique alarms of ECG, SPO2; and parameters, status and technique alarms of RESP, NIBP to the central station.	TM70 transmits waveforms, parameters, status and alarms of ECG, SPO2, **RESP**; and parameters, status and alarms of NIBP to the central station.	TM70 can send RESP waveforms to the central station.
Data Integrity	Bit error rate ≤1%	The time percentage when a TM70 fails to transmit data to the central station shall not exceed **0.1%** over a 24-hour period.	TM70 has a more precise definition and improved data integrity
Data Latency	Total delay for uploading of data from the transmitter to CS is equal to or smaller than 3 s	Total delay of data transmitted from the TM70 to the central station: ≤ 3 s	Same
Transmission distance	The maximum distance of distinct vision from the transmitter to the receiver direct-connected antenna shall be no less than 50 m.	The maximum distance of distinct vision from the transmitter to the receiver direct-connected antenna shall be no less than 50 m.	Same
Roaming	Not supported	**The network switchover is automatically implemented when TM70 moves from the coverage area of AP1 to the coverage area of AP2**	TM70 supports roaming between multiple APs
Receiver capacity	16 beds	Number of TM70s supported by a single AP: **14for 5-lead ECG;** **12 for 6-lead ECG;** Each TM70 can communicate with the central station.	TMS60 capacity was scaled by adding more receivers, TM70 capacity is scaled by adding more APs. Both can scale to meet the overall system capacity requirements

Feature	Predicate TMS60 WMTS 608M function (K183238)	Subject TM70 WMTS 608M function	Comparison analysis
Resistance to wireless interference	When the distance between interfering devices (wireless equipment operated at 2.4GHz, cellular mobile communications network device, microwave oven, and cordless phone) and TMS60 Transmitters farther than 20cm; and there is a -118dBm co-channel WMTS interference at antenna of the receiver. The wireless functions of the TMS60 are normal.	When the distance between interfering devices (wireless equipment operated at 2.4GHz, cellular mobile communications network device, microwave oven, and cordless phone) and TMS70 Transmitter is farther than 20cm; **The co-channel interference WMTS network (should be no greater than -85dBm) and an adjacent–channel WMTS network (adjacent–channel power should be no greater than -40dBm@1.2MHz) also exist; TMS70 does not encounter network interruption alarm event.**	TM70 has a more precise definition
Dynamic networking stability	The wireless functions of the TMS60 are normal when TMS60 Transmitters are moving at the rate of no more than 3.75 m/s within the coverage area of Antenna array.	When TM70 is moving at the rate of no more than 3.75 m/s within a 15m non-blocking linear distance, it does not encounter network interruption alarm event.	Same
Network interruption alarm	When the communication between the TMS60 transmitter and receiver is interrupted, the CS should generate an alarm within 8s.	When the network interruption occurs, the central station initiates the related alarms in 8s.	Same
Wireless Networking stability	Not claimed	Each of the TM70 roam 30 times, at least 3 TM70s roam at the same time, the amount of time each TM70 transporting data to central station is not available shall be less than 0.1% over a 24 hour period.	TM70 has a more precise definition

Table 7: Detailed Comparison of WMTS-1.4G Specifications

Feature	Predicate MX40 WMTS 1.4G function (K172226)	Subject TM70 WMTS 1.4G function	Comparison analysis
System main components	Telemetry Monitor Core Access Point Access Point Controller Synchronization Unit	Telemetry Monitor (TM70) WMTS Access Point (AP70) WMTS Access Controller (AC70) Synchronous Server (SYNC70)	Just different names, their functions are same
Modulation mode	GFSK	GFSK	Same
Operating frequency	1395~1400 MHz and 1427~1432MHz	1395~1400 MHz and 1427~1432MHz	Same

Feature	Predicate MX40 WMTS 1.4G function (K172226)	Subject TM70 WMTS 1.4G function	Comparison analysis
Channel spacing	1.6MHz	**800kHz or 600kHz**	TM70 offers additional flexibility in spectrum utilization by offering multiple channel sizes
Wireless baud rate (data rate)	Not claimed	**Max 433kbps for 800kHz channel spacing.** **Max 400kbps for 600kHz channel spacing.**	TM70 has a more precise definition
Max Output power	10 dBm (10 mW)	10 dBm	Same
Radio Frequency Accuracy during normal operation	<+60/-100 kHz relative to channel frequency	**<±50 kHz relative to channel frequency**	TM70 has a better Radio Frequency Accuracy
Occupied bandwidth as defined by power in 99% BW	< +/- 800 kHz	**<± 400 kHz**	TM70 requires less bandwidth
Receiver sensitivity	Not claimed	**≤-90 dBm for AP** **≤-87 dBm for TM70**	TM70 has a more precise definition
Data security	Not claimed	**authentication: based on TLS** **encryption : AES-128bit**	TM70 has a more precise definition
Communication with the central station	Not claimed	**TM70 transmits waveforms, parameters, status and alarms of ECG, SPO2, RESP; and parameters, status and alarms of NIBP to the central station.**	TM70 has a more precise definition
Data Integrity	Not claimed	**The time percentage when a TM70 fails to transmit data to the central station shall not exceed 0.1% over a 24-hour period.**	TM70 has a more precise definition
Data Latency	Not claimed	**Total delay of data transmitted from the TM70 to the central station: ≤ 3 s**	TM70 has a more precise definition
Transmission distance	Not claimed	**Distinct vision distance from theTM70 to the AP shall be no less than 50 m for LOS.**	TM70 has a more precise definition
Roaming	Not claimed	**The network switchover is automatically implemented when TM70 moves from the coverage area of AP1 to the coverage area of AP2**	TM70 has a more precise definition

Feature	Predicate MX40 WMTS 1.4G function (K172226)	Subject TM70 WMTS 1.4G function	Comparison analysis
System capacity	16	Number of TM70s supported by a single AP: **16 for 800kHz channel spacing&5-lead ECG;** **14 for 800kHz channel spacing &6-lead ECG;** **14for 600kHz channel spacing &5-lead ECG;** **12 for 600kHz channel spacing &6-lead ECG;** Each TM70 can communicate with the central station.	TM70 has a more precise definition; The MX40 and TM70 capacity are scaled by adding more APs. Both can scale to meet the overall system capacity requirements.
Resistance to wireless interference	Not claimed	**When the distance between interfering devices (wireless equipment operated at 2.4GHz, cellular mobile communications network device, microwave oven, and cordless phone) and TMS70 Transmitter is farther than 20cm; The co-channel interference WMTS network (should be no greater than -85dBm) and an adjacent–channel WMTS network (adjacent–channel power should be no greater than -40dBm@1.2MHz) also exist; TMS70 does not encounter network interruption alarm event.**	TM70 has a more precise definition
Dynamic networking stability	Not claimed	**When TM70 is moving at the rate of no more than 3.75 m/s within a 15m non-blocking linear distance, it does not encounter network interruption alarm event.**	TM70 has more precise definition
Network interruption alarm	Not claimed	**When the network interruption occurs, the central station initiates the related alarms in 8s.** **When the network is reconnected, wireless connection recovers automatically.**	TM70 has more precise definition
Wireless Networking stability	Not claimed	**Each of the TM70 roam 30 times, at least 3 TM70s roam at the same time, the amount of time each TM70 transporting data to central station is not available shall be less than 0.1% over a 24 hour period.**	TM70 has a more precise definition

Summary of main changes for TM70

Wireless modification

The main difference between the subject TM70 and the subject TM80 is that the TM70 uses WMTS instead of WIFI, as shown in **Table 5**.

The WMTS wireless function is not used in TM80; but the WMTS (608MHz band) is already used in TMS60 (K183238), and the WMTS (1.4GHz band) is already used in Philips MX40 (K172226).

The comparison and analysis between predicate device TMS60 (K183238) and subject TM70 device regarding WMTS-608M feature is provided in **Table 6**.

The comparison and analysis between predicate device MX40 (K172226) and subject TM70 device regarding WMTS-1.4G feature is provided in **Table 7**.

The subject TM70 with the new WMTS technology have passed the FCC certification testing. And the FCC IDs are: ZLZ-WMTSTM70 and ZLZ-WMTSAP70.

The subject TM70 uses WMTS circuit instead of the WIFI circuit of TM80. This wireless module differences do not raise additional questions of safety and effectiveness, through safety impact analysis.

Mindray conducted safety (UL 60950-1) testing for the AP70, SYNC70, AC70 of BeneVision TM70 Telemetry Monitoring System.

Mindray conducted EMC (IEC 60601-1-2) , wireless coexistence testing (according to AAMI TIR 69 and ANSI C63.27), testing for interaction with radio frequency identification (RFID) systems (AIM Standard 7351731) and software testing to the TM70.

These differences do not raise different questions of safety and effectiveness, and testing demonstrates that the new wireless modification comply with relevant safety standards and have equivalent performance.

Software Pace

The subject TM70 has the same software pace detection function as TM80 which has been changed in this 510K submitting.

The predicate TM70 detects pacemakers by a hardware circuit which includes pacer pulse edge detection, amplification and comparison. The subject TM70 now adds ADC conversion in the pacer pulse detection channel and supports software pace detection function. The pace detection specifications have not been changed. The modification is only for pace detect channel, the ECG channel is not changed, so the modification will not impact HR, ST, QT, ARR performance.

The subject TM80 adds ADC conversion in the pacer pulse detection channel. The differences do not raise additional questions of safety and effectiveness through safety impact analysis. Mindray conducted EMC (IEC 60601-1-2) and performance (IEC 60601-2-27) testing.

8. PERFORMANCE DATA

To establish the substantial equivalence of the BeneVision Central Monitoring System, Mindray conducted functional and system level testing on the subject device. The testing provided an evaluation of the performance of the device relevant to each of the differences between the subject device and the predicate device. The functional and system level testing showed that the

devices continue to meet specifications and the performance of the device is equivalent to the predicate.

Mindray conducted wireless functionality testing to ensure the performance of the BeneVision Central Monitoring System meets wireless specifications and is equivalent to the predicate device. Mindray has conducted testing to ensure the subject device meets relevant consensus standards.

. • Mindray has followed the following FDA Guidance Documents relevant to this device:

– Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm Guidance for Industry and FDA (10/28/2003)

– Cardiac Monitor Guidance for Industry (Including Cardiotachometer and Rate Alarm) (11/5/1998)

Biocompatibility Testing

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

Sterilization and Shelf Life

The BeneVision Central Monitoring System (CentralStation, ViewStation, WorkStation, and CMS Viewer) is non-sterile when used. The devices are considered non-critical as defined in FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (3/17/2017). There have been no changes to the reprocessing instructions.

No shelf life is claimed for the device and similar to the predicate devices, shelf-life is not applicable because of the low likelihood of time dependent product degradation, therefore performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.

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.

Electromagnetic Compatibility and Electrical Safety

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

–IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Bench Testing

To establish the substantial equivalence of the BeneVision Central Monitoring System, Mindray conducted IEC 60601-2-27:2011 *Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment* 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.

Wireless performance and coexistence testing

Testing was performed per AAMI TIR 69: 2017 and ANSI C63.27: 2017. Both the TM70 (608 MHz and 1.4 GHz) and TM80 (2412-2472 MHz and 5180-5825 MHz) were tested. For the TM80 up to 16 wireless medical devices can operate within a single AP, with each telemetry module communicating with the central station. For TM70, up to 14 wireless medical devices per single AP for 608 MHz and 16 wireless medical devices per single AP for 1.4 GHz. The device was tested for possible sources of interference in the co-channel and adjacent band.

9. CONCLUSION

Based on the detailed comparison of specifications for each of the modifications to the previously cleared predicates the performance testing, and conformance with applicable standards, the BeneVision Central Monitoring System can be found substantially equivalent to the predicate devices.