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January 07, 2021

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Yanhong Bai
Manager Regulatory Affairs, Technical Regulation Department
Mindray Building, Keji 12th Road South
High-tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
China

Re: K202405
Trade/Device Name: BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: December 10, 2020
Received: December 11, 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,

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202405

Device Name
BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1)

Indications for Use *(Describe)*
BeneVision N12/N15/N17/N19/N22

The BeneVision N12/N15/N17/N19/N22 patient monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, 6-lead or 12-lead selectable, Arrhythmia Detection, ST Segment Analysis, QT Analysis, and Heart Rate (HR)), Respiration Rate (Resp), Temperature (Temp), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure(IBP), Pulmonary Artery Wedge Pressure (PAWP), Cardiac Output (C.O.), Continuous Cardiac Output (CCO), Mixed/Central Venous Oxygen Saturation (SvO2/ScvO2), Carbon Dioxide (CO2), Oxygen (O2), Anesthetic Gas (AG), Impedance Cardiograph (ICG), Bispectral Index (BIS), Respiration Mechanics (RM), Neuromuscular Transmission Monitoring (NMT), Electroencephalograph (EEG), and Regional Oxygen Saturation (rSO2). The system also provides an interpretation of resting 12-lead ECG.
All the parameters can be monitored on single adult, pediatric, and neonatal patients except for the following:
• BIS, RM, CCO, SvO2/ScvO2, PAWP, and NMT monitoring, PNP, and PNC are intended for adult and pediatric patients only;
• C.O. monitoring and A-Fib are intended for adult patients only;
• ICG monitoring is intended for only adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 155kg.
• rSO2 monitoring is intended for use in individuals greater than 2.5kg.
The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use. The BeneVision N12/N15/N17/N19/N22 monitors are not intended for helicopter transport, hospital ambulance, or home use.

(Continue on next page for N1 indications for Use)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Number (if known): K202405

Indications for Use (con't)

BeneVision N1 Patient Monitor:

The BeneVision N1 Patient Monitor is intended for monitoring, displaying, reviewing, storing , alarming, and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, 6-lead or 12-lead selectable, Arrhythmia Detection, ST Segment Analysis, QT Analysis, and Heart Rate (HR)), Respiration (Resp), Temperature (Temp), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP) , Pulmonary Artery Wedge Pressure (PAWP), Carbon Dioxide (CO2) and Oxygen (O2). The system also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients except for the following:

• PAWP, PNP, and PNC are intended for adult and pediatric patients only;

• A-Fib is intended for adult patients only;

The BeneVision N1 monitor is to be used in healthcare facilities. It can also be used during patient transport inside and outside of the hospital environment. It should be used by clinical professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for home use.

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Mindray BeneVision N Series Monitors 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:	December 08, 2020

2. DEVICE

Device Trade Name:	BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1)
Device Common Name:	Patient Monitor
Classification Name:	21 CFR 870.1025, Class II, Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class:	Class II
Primary Product Code:	MHX - Monitor, Physiological, Patient (with arrhythmia detection or alarms)
Panel:	Cardiovascular

Table 1: Secondary Product Codes

Regulation Number/Class	Product Code	Regulation description	Device Common Name
870.1025, II	DSI	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Detector and alarm, arrhythmia
870.1025, II	MLD	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Monitor, st segment with alarm
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
870.1110, II	DSK	Blood pressure computer	Computer, blood-pressure
880.2770, II	DSB	Impedance plethysmograph.	Plethysmograph, impedance
880.2700, II	MUD	Oximeter	Oximeter, tissue saturation
870.2340, II	MLC	Electrocardiograph	Monitor, st segment
870.2370, II	KRC	Electrocardiograph surface electrode tester.	Tester, electrode, surface, electrocardiographic
880.2910, II	FLL	Clinical electronic thermometer	Thermometer, electronic, clinical
870.2700, II	DQA	Oximeter	Oximeter
870.2300, II	MSX	Cardiac monitor (including cardiotachometer and rate alarm).	System, network and communication, physiological monitors
870.2910, II	DRG	Radiofrequency physiological signal transmitter and receiver.	Transmitters and receivers, physiological signal, radiofrequency
868.1400, II	CCK	Carbon dioxide gas analyzer	Analyzer, gas, carbon-dioxide, gaseous-phase
870.1435, II	DXG	Single-function, preprogrammed diagnostic computer	Computer, diagnostic, pre-programmed, single-function
870.1100, II	DSJ	Blood pressure alarm	Alarm, blood-pressure
870.2850, II	DRS	Transducer, blood-pressure, extravascular	Extravascular blood pressure transducer.
868.1500, II	CBQ	Enflurane gas analyzer.	Analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)
868.1500, II	NHO	Enflurane gas analyzer.	Analyzer, gas, desflurane, gaseous-phase (anesthetic concentration)
868.1500, II	NHP	Enflurane gas analyzer.	Analyzer, gas, sevoflurane, gaseous-phase (anesthetic concentration)
868.1500, II	NHQ	Enflurane gas analyzer.	Analyzer, gas, isoflurane, gaseous-phase (anesthetic concentration)

Regulation Number/Class	Product Code	Regulation description	Device Common Name
868.1620, II	CBS	Halothane gas analyzer.	Analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
868.1700, II	CBR	Nitrous oxide gas analyzer.	Analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
868.1720, II	CCL	Oxygen gas analyzer.	Analyzer, gas, oxygen, gaseous-phase
868.2775, II	KOI	Electrical peripheral nerve stimulator.	Stimulator, nerve, peripheral, electric
882.1400, II	OLW	Electroencephalograph.	Index-generating electroencephalograph software
882.1400, II	OLT	Electroencephalograph	Non-normalizing quantitative electroencephalograph software
882.1400, II	OMC	Electroencephalograph.	Reduced- montage standard electroencephalograph
882.1400, II	ORT	Electroencephalograph	Burst suppression detection software for electroencephalograph
882.1320, II	GXY	Cutaneous electrode.	Electrode, cutaneous

3. PREDICATE DEVICES

- Predicate: K192972 – BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1)

4. REFERENCE DEVICES

- K200015 - ePM series Patient Monitors (ePM 10/ePM 12/ePM 15/ePM 10M/ePM 12M/ePM 15M): provided a provided as reference devices for ECG algorithm supporting arrhythmia detection in neonate that has been added to the subject BeneVision N Series Patient Monitors.

5. DEVICE DESCRIPTION

The subject BeneVision N Series Patient Monitors includes six monitors:

- BeneVision N12 Patient Monitor
- BeneVision N15 Patient Monitor
- BeneVision N17 Patient Monitor
- BeneVision N19 Patient Monitor
- BeneVision N22 Patient Monitor
- BeneVision N1 Patient Monitor

Mindray's BeneVision N Series Patient Monitors provide a flexible software and hardware platform to meet the clinical needs of patient monitoring.

6. INTENDED USE/INDICATIONS FOR USE

BeneVision N12/N15/N17/N19/N22 Patient Monitors:

The BeneVision N12/N15/N17/N19/N22 patient monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, 6-lead or 12-lead selectable, Arrhythmia Detection, ST Segment Analysis, QT Analysis, and Heart Rate (HR)), Respiration Rate (Resp), Temperature (Temp), Pulse Oxygen Saturation (SpO_2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Pulmonary Artery Wedge Pressure (PAWP), Cardiac Output (C.O.), Continuous Cardiac Output (CCO), Mixed/Central Venous Oxygen Saturation (SvO_2/$ScvO_2$), Carbon Dioxide (CO_2), Oxygen (O_2), Anesthetic Gas (AG), Impedance Cardiograph (ICG), Bispectral Index (BIS), Respiration Mechanics (RM), Neuromuscular Transmission Monitoring (NMT), Electroencephalograph (EEG), and Regional Oxygen Saturation (rSO_2). The system also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients except for the following:

- BIS, RM, CCO, SvO_2/$ScvO_2$, PAWP, NMT monitoring, PNP, and PNC are intended for adult and pediatric patients only;
- C.O. monitoring and A-Fib are intended for adult patients only;
- ICG monitoring is intended for only adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 155kg.
- rSO2 monitoring is intended for use in individuals greater than 2.5kg.

The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use. The BeneVision N12/N15/N17/N19/N22 monitors are not intended for helicopter transport, hospital ambulance, or home use.

BeneVision N1 Patient Monitor:

The BeneVision N1 Patient Monitor is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, 6-lead or 12-lead selectable, Arrhythmia Detection, ST Segment Analysis, QT Analysis, and Heart Rate (HR)), Respiration (Resp), Temperature (Temp), Pulse Oxygen Saturation (SpO_2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP) , Pulmonary Artery Wedge Pressure (PAWP), Carbon Dioxide (CO_2) and Oxygen (O_2). The system also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients except for the following:

- PAWP, PNP and PNC are intended for adult and pediatric patients only;
- A-Fib is intended for adult patients only;

The BeneVision N1 monitor is to be used in healthcare facilities. It can also be used during patient transport inside and outside of the hospital environment. It should be used by clinical professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for home use.

7. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Both the predicate devices and the subject devices are multiparameter patient monitors intended to be used under the direction of clinical professionals.

The indications for use statement of the subject BeneVision N1/N12/N15/N17/N19/N22 has been modified to include support for arrhythmia detection in neonates when used with the MPM 3.0 module. Although this feature is not present in the primary predicate devices, it is present in other cleared multiparameter patient monitors such as the Mindray ePM series Patient Monitors (K200015, ePM 10/ePM 12/ePM 15/ePM 10M/ePM 12M/ePM 15M). The inclusion of supporting arrhythmia detection in neonates in the indications for use does not constitute a new fundamental intended use.

In conclusion, the minor difference in the indications for use statement does not change the fundamental intended use of the N Series monitors as multiparameter monitors.

Technological Comparison

The tables below compare the key technological feature of the subject devices to the predicate device (N series Patient Monitors, K192972). The features in green are features which are different between the predicate devices and the subject devices.

Table 2: Device Comparison Table (BeneVision 22/N19/N17/N15/N12)

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
Primary display and touchscreen	22” 1680*1050 pixels.	19” 1680*1050 pixels.	18.5” 1920*1080 pixels.	15.6” 1920*1080 pixels.	12.1” 1280*800 pixels.	No change	No change	No change	No change	No change
Secondary display	Independent control and display.		Independent control and display. Size: 21.5”; Model:2203 L.	Mirrored display. Size: 21.5”; Model: 2203L.		No change		No change	No change	
iView	Change the PC platform Capacity of RAM: 8GB Model of CPU: N4200 Windows 10			Not supported.		No change			No change	
Wireless radio module	The 2.4G/5G module for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS). WiFi module: MSD45N					The 2.4G/5G module for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS). WiFi module: MSD45N **and SX-SDMAC-2832S+**				
Module rack	Must be connected to the main unit to provide up to 8 standard module slots.		Optional for the patient monitors, adding 8 standard module slots to extend the measurement capabilities of the system.	Not supported.		No change				
Power supply	One rechargeable Lithium-ion battery or AC power supply.					No change				
Battery	Chargeable Lithium-Ion, 10.8 VDC, 5600 mAh.		Chargeable Lithium-Ion, 10.95 VDC, 4500 mAh.			No change		No change		

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
Data storage	Solid State Hard Drive (SDD)		Embedded Multi Media Card (eMMC).			No change				
Data recorder	Supports the thermal recorder module, needs to be plugged into the SMR.		Supports the thermal recorder module and the built-in thermal recorder, but they cannot work at the same time.			No change				
Speaker	Provides audible alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation.					No change				
Alarm system	Supports alarm volume escalation. The alarm lamp will light cyan, yellow, or red depending on alarm type.					No change				
Support T1/N1 as a Module	Support T1/N1 acting as a module.					No change				
Connect with Mindray telemetry monitors	Connect with the TM80 and the BP10 NIBP module to receive ECG, SpO_2, RESP, and NIBP waveforms and parameters.					Connect with the TM80/**TM70** and the BP10 NIBP module to receive ECG, SpO_2, RESP, and NIBP waveforms and parameters.				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
ECG	3-lead, 5-lead, 6-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, J-point Auto detection, Dual Channel Pace detection, adjustable QRS threshold, Multi-lead ECG synchronization analysis and heart rate (HR). Can be configured with either the Mindray or Mortara algorithm for ECG arrhythmia monitoring and arrhythmia detection. • MPM 3.0: supports Mindray Algorithm. • MPM 2.0, and TM80: support Mindray or Mortara algorithm Supports intelligent arrhythmia alarms HR Measurement range: 15~350 bpm (neonate, pediatric), 15~300 bpm (adult); Accuracy: ±1 bpm or ±1%, whichever is greater. ST Measurement range: -2.0mV~+2.0mV; Accuracy: -0.8mV~+0.8mV, ±0.02mV or ±10%, whichever is greater, other range: not specified. QT Measurement range: 200~800ms; Accuracy: ±30ms. This measurement can be used for adults, pediatrics, and neonates, except that: 1. The arrhythmia detection of MPM 3.0 is intended for adult and pediatric patients only; 2. The arrhythmia detection and ST segment analysis of Mortara algorithm in MPM 2.0 is intended for adult and pediatric patients only; 3. The arrhythmia detection of Mindray algorithm in MPM 2.0 is intended for adult and pediatric patients only; 4. The ST Segment analysis of Mindray algorithm in MPM 2.0 is intended for adult patients only.					3-lead, 5-lead, 6-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, J-point Auto detection, Dual Channel Pace detection, adjustable QRS threshold, Multi-lead ECG synchronization analysis and heart rate (HR). Can be configured with either the Mindray or Mortara algorithm for ECG arrhythmia monitoring and arrhythmia detection. • MPM 3.0: supports Mindray Algorithm. • MPM 2.0: support Mindray or Mortara algorithm Supports intelligent arrhythmia alarms HR Measurement range: 15~350 bpm (neonate, pediatric), 15~300 bpm(adult); Accuracy: ±1 bpm or ±1%, whichever is greater. ST Measurement range: -2.0mV~+2.0mV; Accuracy: -0.8mV~+0.8mV, ±0.02mV or ±10%, whichever is greater, other range: not specified. QT Measurement range: 200~800ms; Accuracy: ±30ms. **Pace detection enhancement** **Expand the PVCs/min range: for adult mode is [0,300], For pediatric and neonate mode is [0,350]** This measurement can be used for adults, pediatrics, and neonates, except that: 1. The arrhythmia detection and ST segment analysis of Mortara algorithm in MPM2.0 is intended for adult and pediatric patients only; 2. The arrhythmia detection of Mindray algorithm inMPM2.0 is intended for adult and pediatric patients only; 3. The ST Segment analysis of Mindray algorithm in MPM2.0 is intended for adult patients only. **Add arrhythmia detection for neonatal patients when used with the MPM 3.0 module.**				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
Respiration rate (Resp)	Measure the respiration waveforms and respiratory rate through trans-thoracic impedance method. Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm. Accuracy: 7 to 150 rpm: ±2 rpm or ±2%, whichever is greater; 0 to 6 rpm: Not specified. This measurement can be used for adults, pediatrics and neonates.					No change				
Temperature (Temp)	Uses the MPM (Multi Parameter Module), T1, N1 or the Temperature Module to measure temperature using the thermal resistance method. Measurement range: 0 to 50°C (32 to 122°F). Accuracy: ±0.1°C or ±0.2°F (without probe). This measurement can be used for adults, pediatrics and neonates.					No change				
Pulse oxygen saturation (SpO_2)	Uses the MPM (Multi Parameter Module), T1, N1 or the SpO_2 Module to measure Pulse oxygen saturation. N Series patient monitors are compatible with the following 3 types of modules to measure oxygen saturation: Mindray SpO_2 module Measurement range: 0~100 % Accuracy: 70%~100%: ±2% ABS (Adult/pediatric); 70%~100%: ±3% ABS (neonate); 0~69%: not specified. Masimo SpO_2 module Measurement range: 1~100 %, Accuracy: without motion 70%~100%: ±2% ABS (Adult/pediatric), 70%~100%: ±3%ABS (neonate), 1~69%: not specified; With motion 70%~100%: ±3% ABS, 1~69%: not specified. Nellcor SpO_2 module Measurement range: 0~100 %, Accuracy: 70%~100% : ±2% ABS (Adult/pediatric); 70%~100% : ±3% ABS (neonate); 0~69%: not specified. This measurement can be used for adults, pediatrics and neonates.					Uses the MPM (Multi Parameter Module) or the SpO_2 Module to measure Pulse oxygen saturation. N Series patient monitors are compatible with the following 3 types of modules to measure oxygen saturation: Mindray SpO_2 module Measurement range: 0~100 % Accuracy: 70%~100%: ±2% ABS(Adult/pediatric); 70%~100%: ±3% ABS (neonate); 0~69%: not specified. Masimo SpO_2 module **Replace the Masimo SpO2 module(MS2040) in the MPM3.0 module to Masimo SpO2 module (MSX2040) (cleared in K053269)** Measurement range: 1~100 %, Accuracy: without motion 70%~100%: ±2% ABS (Adult/pediatric), 70%~100%: ±3%ABS (neonate), 1~69%: not specified; With motion 70%~100%: ±3% ABS, 1~69%: not specified. **Receives and displays SIQ waveforms from the Masimo module and allows enabling and disabling FastSat.** Nellcor SpO_2 module				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
						Measurement range: 0~100 %, Accuracy: 70%~100% : ±2% ABS (Adult/pediatric); 70%~100% : ±3% ABS (neonate); 0~69%: not specified. This measurement can be used for adults, pediatrics and neonates.				
Pulse rate (PR)	Pulse rate may be obtained from all sources of SpO_2, or the IBP module. Measurement range: 20~254 bpm (Mindry SpO_2), 25~240 bpm (Masimo SpO_2), 20~300 bpm (Nellcor SpO_2), 25~350 bpm (IBP). Accuracy: ±3 bpm (Mindray SpO_2), ±3 bpm without motion, ±5 bpm with motion (Masimo SpO_2); 20~250 bpm ±3 bpm; 251~300 bpm, not specified (Nellcor SpO_2); ±1 bpm or ±1%, whichever is greater (IBP). This measurement can be used for adults, pediatrics and neonates.					No change				
Non-invasive blood pressure (NIBP)	Uses the MPM (Multi Parameter Module), T1 or N1 to measure NIBP. The MPM uses the oscillometric method for measuring non-invasive blood pressure (NIBP). Measurement range: Systolic: 25~290 mmHg (Adult), 25~240 mmHg (Pediatric), 25~140 mmHg (Neonate). Diastolic: 10~250 mmHg (Adult), 10~200 mmHg (Pediatric), 10~115 mmHg (Neonate). Mean: 15~260 mmHg (Adult), 15~215 mmHg (Pediatric), 15~125 mmHg (Neonate). PR: 30~300bpm. Accuracy: NIBP: Max mean error: ±5mmHg; Max standard deviation: 8mmHg. PR: ±3 bpm or ±3%, whichever is greater. This measurement can be used for adults, pediatrics and neonates.					Uses the MPM (Multi Parameter Module) to measure NIBP. The MPM uses the oscillometric method for measuring non-invasive blood pressure (NIBP). Measurement range: Systolic: 25~290 mmHg (Adult), 25~240 mmHg (Pediatric), 25~140 mmHg (Neonate). Diastolic: 10~250 mmHg (Adult), 10~200 mmHg (Pediatric), 10~115 mmHg (Neonate). Mean: 15~260 mmHg (Adult), 15~215 mmHg (Pediatric), 15~125 mmHg (Neonate). PR:30~300bpm. Accuracy: NIBP: Max mean error: ±5mmHg; Max standard deviation: 8mmHg. PR: ±3 bpm or ±3%, whichever is greater. This measurement can be used for adults, pediatrics and neonates. **NIBP inflation pressure had been optimized for pediatric and neonatal patients.**				
Invasive blood	Uses the MPM (Multi Parameter Module), T1, N1 or the IBP Module to measure invasive blood pressure. The monitor can monitor up to 8					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
pressure (IBP)	invasive blood pressures and displays systolic, diastolic and mean pressures and a waveform for each pressure. The IBP supports Pulse Pressure Variation (PPV) and Pulmonary Artery Wedge Pressure (PAWP) function. Measurement range: -50~300mmHg, Accuracy of module: ±2% or ±1mmHg, whichever is greater (without sensor) This measurement can be used for adults, pediatrics and neonates except that PAWP is not for neonates.									
Cardiac output (C.O.)	The cardiac output (C.O.) measurement invasively measures cardiac output and other hemodynamic parameters using the right heart (atria) thermodilution method. The temperature change is displayed as a curve in the C.O. split screen, and the monitor calculates the C.O. value from this curve. The monitor can store up to 6 measurements. Measurement range: C.O. : 0.1~20 L/min. TB: 23~43℃, TI: 0~27℃. Accuracy: C.O.: ±5% or ±0.1L/min, whichever is greater. TB, TI: ±0.1℃ (without sensor). This measurement can be used for adults.					No change				
Continuous cardiac output (CCO)	The CCO/SvO2 interface module is used to interface with Edwards Vigilance II monitor (cleared in K043103)/ Vigileo monitor (cleared in K103094)/ EV1000 monitor (cleared in K160552) / HemoSphere monitor (cleared in K163381) which measures continuous cardiac output (CCO). This measurement can be used for adults and pediatrics.					No change				
Mixed/central venous oxygen saturation	The CCO/SvO2 interface module is used to interface with Edwards Vigilance II monitor (cleared in K043103)/ Vigileo monitor (cleared in K103094)/ EV1000 monitor (cleared in K160552) / HemoSphere					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
(SvO_2/$ScvO_2$)	monitor (cleared in K163381) which measures mixed venous oxygen saturation (SvO_2) and central venous oxygen saturation ($ScvO_2$). This measurement can be used for adults and pediatrics.									
Central venous oxygen saturation ($ScvO_2$)	Central venous oxygen saturation ($ScvO_2$) is measured using spectrophotometry. Measurement range: 0 to 99% Accuracy: 50% to 80%: ±3%, Other ranges: Not specified. This measurement can be used for adults and pediatrics.					No change				
Carbon dioxide (CO_2)	CO2 can be measured using the Mindray Sidestream CO2 module, Mindray AG module or third-party CO2 modules, Microstream module and Mainstream module. Type: Sidestream CO2 module. Measurement range: CO2: 0~150mmHg, awRR: 0~150rpm. Accuracy: CO2: Full accuracy mode: 0~40 mmHg: ±2mmHg, 41~76 mmHg: ±5% of reading, 77~99 mmHg: ±10% of reading, 100~150mmHg: ±(3mmHg + 8% of reading), ISO accuracy mode: Add ±2mmHg to the full accuracy mode. awRR: <60rpm, ±1rpm, 60~150rpm, ±2rpm Type: Microstream CO2 module Measurement range: CO2: 0~99mmHg, awRR: 0~150rpm Accuracy: CO2: 0~38mmHg: ±2mmHg; 39~99mmHg: ±5% of the reading+0.08% of (the reading-38); awRR: 0~70rpm: ±1rpm, 71~120rpm: ±2rpm, 121~150rpm: ±3rpm. Type: Mainstream CO2 module. Measurement range: CO2: 0~150mmHg; awRR: 0~150rpm. Accuracy: CO2: 0~40mmHg: ±2mmHg, 41~70mmHg: ±5% of the reading, 71~100mmHg: ±8% of the reading, 101~150mmHg: ±10% of the reading; awRR: ±1rpm AG module: Measurement range: 0~30%;					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
	Accuracy: Full accuracy mode: 0%≤CO2≤1%, ±0.1%ABS, 1%< CO2≤5%, ±0.2% ABS, 5%< CO2≤7%, ±0.3% ABS, 7%< CO2≤10%, ±0.5% ABS, 10%< CO2 not specified, ISO mode: Add ±0.3% ABS. CO2 monitoring is based on calculations that come from measuring the absorption of infrared (IR) light of specific wavelengths using a photodetector. This measurement can be used for adults, pediatrics and neonates.									
Oxygen (O_2)	Oxygen values are measured by the Sidestream CO_2 module or the AG module using a paramagnetic method. Measurement range: 0~100% (CO_2 and AG), Accuracy: 0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3% (CO_2 and AG). This measurement can be used for adults, pediatrics and neonates.					No change				
Anesthetic gas (AG)	The AG module analyzes gas samples from the patient and calculates CO_2, O_2, N_2O, and AA waveforms and related numerics that include airway respiratory rate and MAC (minimum alveolar concentration). Measurement range: HAL, ENF, ISO, SEV, DES: 0~30 %, N_2O: 0~100 %; awRR: 2~100 rpm Accuracy: Full accuracy mode: N_2O: 0~20%$_{REL}$: ±2% $_{ABS}$, 20~100%$_{REL}$: ±3% $_{ABS}$; HAL, ENF, ISO: 0~1%$_{REL}$: ±0.15% $_{ABS}$, 1~5%$_{REL}$: ±0.2% $_{ABS}$, >5%$_{REL}$, not specified; SEV: 0~1%$_{REL}$: ±0.15% $_{ABS}$, 1~5%$_{REL}$: ±0.2% $_{ABS}$, 5~8%$_{REL}$: ±0.4% $_{ABS}$, >8%$_{REL}$, not specified; DES：0~1%$_{REL}$: ±0.15% $_{ABS}$, 1~5%$_{REL}$: ±0.2% $_{ABS}$, 5~10%$_{REL}$: ±0.4% $_{ABS}$, 10~15%$_{REL}$: ±0.6% $_{ABS}$,15~18%$_{REL}$: ±1% $_{ABS}$,>18%$_{REL}$, not					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
	specified; awRR:2~60rpm, ±1rpm, >60rpm, not specified This measurement can be used for adults, pediatrics and neonates.									
Impedance cardiograph (ICG)	ICG measures a patient's hemodynamic status using a non-invasive method based on thoracic electrical bioimpedance (TEB) technology. Measurement range: C.O.:1.4~15L/min; SV:5~250ml; HR: 44~185bpm. Accuracy: HR: ±2bpm; other parameter: not specified. This measurement can be used for adults.					No change				
Bispectral index (BIS)	The BIS Module monitors the state of the brain by data acquisition of EEG signals. Bispectral index (BIS) is a processed EEG variable that can be used as an aid in monitoring the effects of certain anesthetic agents. Measurement range: BIS, BIS L, BIS R: 0~100. Accuracy: not specified. This measurement can be used for adults and pediatrics.					No change				
Respiration mechanics (RM)	The RM module measures respiration mechanics for adult and pediatric patients.					No change				
	Measurement range:		Accuracy:							

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
	FLOW: Adult/Pediatric: ±(2~120)L/min; Infant: ± (0.5 to 30) L/min PAW:-20~120 cmH_2O; MVe/MVi: Adult/Pediatric: 2~60L/min; Infant: 0.5 to 15 L/min TVe/TVi: Adult/Pediatric: 100~1500ml; Infant: 0.5 to 15 L/min Calculated Parameters: awRR:4~120rpm; I:E:4:1~1:8; FEV1.0: 0~100%; Pmean:0~120 cmH_2O; PEEP:0~120 cmH_2O; PEF:2~120L/min; PIF:2~120L/min; PIP: 0~120 cmH_2O; Pplat:0~120 cmH_2O; Compl: 0~200ml/ cmH_2O; RSBI:0~4095rpm/L;		FLOW: Adult/Pediatric: 1.2L/min or ±10% of reading, whichever is greater; Infant: 0.5 L/min or ±10% of the reading, whichever is greater PAW: ±3% of reading; MVe/MVi: ±10% of reading; TVe/TVi: Adult/Pediatric: ±15ml or ±10% of reading, whichever is greater; Infant: ±6 ml or ±10%×reading, whichever is greater Calculated Parameters: awRR:4~99rpm: ±1rpm, 100~120rpm, ±2rpm; I:E: not specified; FEV1.0: not specified; Pmean: ±10%; PEEP: not specified; PEF: ±10%; PIF: ±10%; PIP: ±10%; Pplat: not specified; Compl: not specified; RSBI: not specified;							

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
Neuromuscular transmission monitoring (NMT)	NMT evaluates muscle relaxation of patients under a neuromuscular block by measuring the strength of muscle reaction after electrically stimulating the dedicated motor nerve. Measurement range: ST-Ratio:0 ~ 200%; TOF-Count: 0~4; TOF-Ratio: 5%~160%; TOF-T1%: 0~200%; PTC-Count:0~20; DBS-Count:0~2; DBS-Ratio:5%~160% This measurement can be used for adults and pediatrics.					No change				
Electroencephalograph (EEG)	The EEG module measures the spontaneous, rhythmic electrical activity of the cortex. The EEG module can continuously monitor EEG signals from up to 4 channels. It can also display Density Spectral Arrays (DSA) and Compressed Spectral Arrays (CSA). Frequency response: 0.5Hz~50Hz(-3dB) Input range: 4mVpp DC offset: ±500 mV CMRR: ≥100 dB@51 kΩ and 60Hz Noise level: ≤0.5 uVrms (1Hz to 30 Hz Differential input resistance: >15MΩ@10Hz Electrode resistance: 0 to 90 kΩ, resolution: ±1 KΩ or 10%, whichever is the greater This measurement is intended to be used for adults, pediatrics and neonates.					No change				
Regional oxygen saturation (rSO_2)	The rSO2 module provides noninvasive and continuous information of changes in regional oxygen saturation of blood. The measurement takes place in real time, providing an immediate indication of a change in the					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
	critical balance of regional oxygen delivery and oxygen consumption. Measurement range: rSO_2: 15~95. This measurement can be used for adults, pediatrics and neonates.									
ECG 24h Summary	Provides an option to view a summary of a patient's ECG statistics from the previous 24 hours, including HR statistics, ARR event statistics, max and min ST statistics of each lead, QT/QTc measurement statistics, Pacer statistics (for patients being paced), and typical ECG strips.					No change				
Dynamic minitrend	The Minitrend window is located to the left of the waveform area and shows the recent trend of a series of parameters.					The Minitrend window is located to the left of the waveform area and shows the recent trend of a series of parameters. **The Minitrend window is modified to enable users to hide, half display, or fully display the window by dragging the handle.**				
Early Warning Score (EWS)	The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), National Early Warning Score2 (NEWS2), and a user configurable Custom Score.					The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), National Early Warning Score2 (NEWS2), and a user configurable Custom Score. **The EWS window is modified to enable users to hide, half display, or fully display the window by dragging the handle.**				
Glasgow Coma Scale (GCS)	The GCS a well-established scoring system used to assess the state of consciousness based three sub-components: eye-opening response, verbal response, and limb movement.					No change				
SepsisSight	The SepsisSight feature is intended to help clinicians recognize the early signs and symptoms of Sepsis based on recommendations from the published literature (Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2016 and The Third International Consensus Definition for Sepsis and Septic Shock (Sepsis-3)).					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K192972					Subject Device				
Cardio-pulmonary resuscitation (CPR) Dashboard	Records all operations during rescue. The rescue operations recorded can be customized and include treatment (rescue drug input, rescue treatment input, start/end rescue, rescue start condition, rescue end condition).					No change				
Device integration	Support BeneLink Module to connect Anesthesia, Ventilator, Pump, TcGas Monitor Device, and Single Parameter Device. The types of the devices that can be connected are still only the five types listed above, but some types added newly approved devices.					No change				
OxyCRG Function	Support the function of oxygen cardio-respirogram (OxyCRG) when the patient type is neonate, and simultaneously provide real-time OxyCRG interface and OxyCRG review interface to display parameter trends and waveforms, and OxyCRG events.					No change				
Accessories	The accessories including ECG, SpO2, Temp, NIBP, IBP, C.O., ScvO2, ICG, BIS, CO2, AG, RM, EEG, BIS, NMT, rSO2, CCO/SvO2 accessories.					**Add new C.O. accessories**				

Table 3: Device Comparison Table – BeneVision N1

Feature	N1	N1
	Cleared in K192972	**Subject Device**
Primary display and touchscreen	5.5”, 720*1280 pixels.	No change
External display	Allows the display of mirrored or independent data when connected to an external monitor through the video connector provided by the Dock.	No change

Feature	**N1**	**N1**
	Cleared in K192972	**Subject Device**
Power supply	Two rechargeable Lithium-ion batteries (without built-in CO2 module), one rechargeable Lithium-ion battery (with built-in CO2 module), or DC-in power supply.	No change
Battery	Chargeable Lithium-ion 7.2VDC, 2500mAh.	No change
Data storage	Embedded Multi Media Card (eMMC)	No change
Speaker	Gives alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation.	No change
Alarm system	Supports Alarm Volume Escalation. The alarm lamp will light cyan, yellow, or red depending on alarm type.	No change
Communication on Interface when N1 is working as a module	Infrared communication interface. Pogo pin communication interface.	No change

Feature	N1 **Cleared in K192972**	N1 **Subject Device**
ECG	3-lead, 5-lead, 6-lead, or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, J-point auto detection, Dual channel pace detection, adjustable QRS threshold, Multi-lead ECG synchronization analysis and heart rate (HR) Supports intelligent arrhythmia alarm. Measurement range: ST: -2.0mV~+2.0mV; QT: 200~800ms; HR: 15~350bpm (neonate, pediatric), 15~300bpm (adult). Accuracy: ST: -0.8mV~+0.8mV, ±0.02mV or ±10%, whichever is greater, other range: not specified; QT: ±30ms; HR: ±1 bpm or ±1%, whichever is greater. This measurement can be used for adults, pediatrics and neonates except for the arrhythmia detection. The arrhythmia detection is intended for adult and pediatric patients only.	3-lead, 5-lead, 6-lead, or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, an interpretation of resting 12-lead ECG, J-point auto detection, Dual channel pace detection, adjustable QRS threshold, Multi-lead ECG synchronization analysis and heart rate (HR) Supports intelligent arrhythmia alarm. **Pace detection enhancement** **Expand the PVCs/min range: for adult mode is [0,300], For pediatric and neonate mode is [0,350]** Measurement range: ST: -2.0mV~+2.0mV; QT: 200~800ms; HR: 15~350bpm (neonate, pediatric), 15~300bpm(adult). Accuracy: ST: -0.8mV~+0.8mV, ±0.02mV or ±10%, whichever is greater, other range: not specified; QT: ±30ms; HR: ±1 bpm or ±1%, whichever is greater. This measurement can be used for adults, pediatrics and neonates. **Add arrhythmia detection for neonatal patients.**
Respiration rate (Resp)	Measure the respiration waveforms and respiratory rate through trans-thoracic impedance method. Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm. Accuracy: 7 to 150 rpm: ±2 rpm or ±2%, whichever is greater; 0 to 6 rpm: Not specified. This measurement can be used for adults, pediatrics and neonates.	No change

Feature	N1 Cleared in K192972	N1 Subject Device
Temperature (Temp)	Measures temperature using the thermal resistance method. Measurement range: 0 to 50°C (32 to 122°F). Accuracy: ±0.1°C or ±0.2 °F (without probe). This measurement can be used for adults, pediatrics and neonates.	No change
Pulse oxygen saturation (SpO_2)	Integrates one of the 3 kinds of SpO_2 modules: Mindray SpO_2 module board Measurement range: SpO_2:0~100 %, Accuracy: 70%~100%: ±2% ABS (Adult/pediatric); 70%~100%: ±3% ABS (neonate); 0~69%: not specified. Masimo SpO_2 module board Measurement range: 1~100 %, Accuracy: without motion 70%~100%: ±2% ABS (Adult/pediatric), 70%~100%: ±3% ABS (neonate), 1~69%: not specified; With motion 70%~100%：±3% ABS, 1~69%: not specified. Nellcor SpO_2 module board Measurement range: SpO_2:0~100 %, Accuracy: SpO_2:70%~100%：±2% ABS (Adult/pediatric); 70%~100%：±3% ABS (neonate); 0~69%: not specified. This measurement can be used for adults, pediatrics and neonates.	Integrates one of the 3 kinds of SpO_2 modules: Mindray SpO_2 module board Measurement range: SpO_2:0~100 %, Accuracy: 70%~100%: ±2% ABS(Adult/pediatric); 70%~100%: ±3% ABS(neonate); 0~69%: not specified. Masimo SpO_2 module board **Replace the Masimo SpO2 module(MS2040) in the MPM3.0 module to Masimo SpO2 module (MSX2040) (cleared in K053269)** Measurement range: 1~100 %, Accuracy: without motion 70%~100%: ±2% ABS (Adult/pediatric), 70%~100%: ±3%ABS (neonate), 1~69%: not specified; With motion 70%~100%：±3%ABS, 1~69%: not specified. **Receives and displays SIQ waveforms from the Masimo module and allows enabling and disabling FastSat.** Nellcor SpO_2 module board Measurement range: SpO_2:0~100 %, Accuracy: SpO_2:70%~100%：±2%ABS (Adult/pediatric);70%~100%：±3%ABS(neonate);0~69%: not specified. This measurement can be used for adults, pediatrics and neonates.

Feature	N1	N1
	Cleared in K192972	**Subject Device**
Pulse rate (PR)	Obtains pulse rate from SpO_2 or IBP. Measurement range: 20~254bpm (Mindray SpO_2), 25~240bpm (Masimo SpO_2), 20~300bpm (Nellcor SpO_2), 25~350bpm (IBP). Accuracy: ±3 bpm (Mindray SpO_2), ±3 bpm without motion, ±5 bpm with motion (Masimo SpO_2); 20~250bpm ±3 bpm; 251~300bpm, not specified (Nellcor SpO_2); ±1 bpm or ±1%, whichever is greater (IBP). This measurement can be used for adults, pediatrics and neonates.	No change
Non-invasive blood pressure (NIBP)	The N1 uses the oscillometric method for measuring non-invasive blood pressure (NIBP). Measurement range: Systolic: 25~290mmHg (Adult), 25~240mmHg (Pediatric), 25~140mmHg (Neonate); Diastolic: 10~250mmHg (Adult), 10~200mmHg (Pediatric), 10~115mmHg (Neonate); Mean: 15~260mmHg (Adult), 15~215mmHg (Pediatric), 15~125mmHg (Neonate); PR:30~300bpm. Accuracy: Max mean error: ±5mmHg; Max standard deviation: 8mmHg; PR: ±3 bpm or ±3%, whichever is greater. This measurement can be used for adults, pediatrics, and neonates.	The N1 uses the oscillometric method for measuring non-invasive blood pressure (NIBP). This measurement can be used for adults, pediatrics, and neonates. Measurement range: Systolic: 25~290mmHg (Adult), 25~240mmHg (Pediatric), 25~140mmHg (Neonate); Diastolic: 10~250mmHg (Adult), 10~200mmHg (Pediatric), 10~115mmHg (Neonate); Mean: 15~260mmHg (Adult), 15~215mmHg (Pediatric), 15~125mmHg (Neonate); PR:30~300bpm. Accuracy: Max mean error: ±5mmHg; Max standard deviation: 8mmHg; PR: ±3 bpm or ±3%, whichever is greater. **NIBP inflation pressure had been optimized for pediatric and neonatal patients.**

Feature	N1	N1
	Cleared in K192972	**Subject Device**
Invasive blood pressure (IBP)	The monitor can monitor up to 2 invasive blood pressures and displays the systolic, diastolic, and mean pressures and a waveform for each pressure. The IBP supports Pulse Pressure Variation (PPV) and Pulmonary Artery Wedge Pressure (PAWP) function. Measurement range: -50~300mmHg. Accuracy: ±2% or ±1mmHg, whichever is greater (without sensor). This measurement can be used for adults, pediatrics and neonates except that PAWP is not for neonates.	The monitor can monitor up to **4** invasive blood pressures and displays the systolic, diastolic, and mean pressures and a waveform for each pressure. The IBP supports Pulse Pressure Variation (PPV) and Pulmonary Artery Wedge Pressure (PAWP) function. **The monitor added stand-alone IBP module in this 510(k).** Measurement range: -50~300mmHg. Accuracy: ±2% or ±1mmHg, whichever is greater (without sensor). This measurement can be used for adults, pediatrics and neonates except that PAWP is not for neonates.

Feature	N1	N1
	Cleared in K192972	**Subject Device**
Carbon dioxide (CO2)	CO2 can be measured using a built-in Sidestream CO2 2.0 module, or it can also connect to an external Sidestream CO2 2.0 module (when used with a rack). Alternatively, third-party CO2 modules, Microstream module and Mainstream module, can be used. Type: Sidestream CO2 module Measurement range: CO2 :0~150mmHg, awRR: 0~150rpm. Accuracy: CO2: Full accuracy mode: 0~40 mmHg: ±2mmHg, 41~76 mmHg: ±5% of reading, 77~99 mmHg: ±10% of reading, 100~150mmHg: ±(3mmHg + 8% of reading), ISO accuracy mode: Add ±2mmHg to the full accuracy mode awRR: <60rpm, ±1rpm, 60~150rpm, ±2rpm. Type: Microstream CO2 module Measurement range: CO2 :0~99mmHg, awRR: 0~150rpm. Accuracy: CO2: 0~38mmHg: ±2mmHg; 39~99mmHg: ±5% of the reading+0.08% of (the reading-38). awRR: 0~70rpm: ±1rpm, 71~120rpm: ±2rpm,121~150rpm: ±3rpm. Type: Mainstream CO2 module Measurement range: CO2 :0~150mmHg; awRR: 0~150rpm. Accuracy: CO2: 0~40mmHg: ±2mmHg, 41~70mmHg: ±5% of the reading, 71~100mmHg: ±8% of the reading, 101~150mmHg: ±10% of the reading; awRR: ±1rpm.CO2 monitoring is based on calculations that come from measuring the absorption of infrared (IR) light of specific wavelengths using a photodetector. This measurement can be used for adults, pediatrics and neonates.	No change

Feature	N1	N1
	Cleared in K192972	**Subject Device**
Oxygen (O2)	Oxygen values are measured by the Sidestream CO2 (only for external Sidestream CO2 2.0 module) module using a paramagnetic method. Measurement range: O2: 0~100% Accuracy: 0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3%. This measurement can be used for adults, pediatrics and neonates.	No change
Dock, Rack and Transport Dock	The Dock is used to connect either the N1 without a Rack or the N1 docked inside a Rack, in order to extend ports such as USB, VGA, or wired network. The Rack can connect an external parameter module, such as CO2, to N1. The Transport Dock is used to provide DC voltage to N1 when N1 is used for out-of-hospital transportation on the ambulance vehicle or aircraft. The Transport Dock is fixed on the ambulance vehicle or aircraft and converts an AC input to DC output.	No change
Wireless radio module	The Wireless radio module is used for connecting to a wireless monitoring network with a central monitoring system (CMS).	No change
Helicopter and ambulance transport	ECG, RESP, Temp, SpO2, PR, NIBP, and IBP can be monitored in helicopters and ambulances.	No change
Dynamic minitrend	The Minitrend window is to the left of the waveform area and displays recent trend of parameters.	The Minitrend window is to the left of the waveform area and displays recent trend of parameters. **The Minitrend window is modified to enable users to hide, half display, or fully display the window by dragging the handle.**

Feature	N1 Cleared in K192972	N1 Subject Device
Early Warning Score (EWS)	The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), National Early Warning Score2 (NEWS2), and a user configurable Custom Score.	The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), National Early Warning Score2 (NEWS2), and a user configurable Custom Score. **The EWS window is modified to enable users to hide, half display, or fully display the window by dragging the handle.**
Glasgow Coma Scale (GCS)	The GCS a well-established scoring system used to assess the state of consciousness based three sub-components: eye-opening response, verbal response, and limb movement.	No change
SepsisSight	Not supported.	The SepsisSight feature is intended to help clinicians recognize the early signs and symptoms of Sepsis based on recommendations from the published literature (Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2016 and The Third International Consensus Definition for Sepsis and Septic Shock (Sepsis-3)).
Cardio-pulmonary resuscitation (CPR) Dashboard	Records all operations during rescue. The rescue operations recorded can be customized and include treatment (rescue drug input, rescue treatment input, start/end rescue, rescue start condition, rescue end condition).	No change
OxyCRG Function	Support the function of oxygen cardio-respirogram (OxyCRG) when the patient type is neonate, and simultaneously provide real-time OxyCRG interface and OxyCRG review interface to display parameter trends and waveforms, and OxyCRG events.	No change

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

8. PERFORMANCE DATA

To establish the substantial equivalence of the BeneVision N Series Patient Monitors, 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 complies with the FDA Special Controls Document relevant to this device "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm Guidance for Industry and FDA (10/28/2003)"

Mindray has conducted testing to ensure the subject device meets relevant consensus standards.

Biocompatibility Testing

The N Series Patient Monitors are not patient contacting. There are no new patient contacting accessories of components, therefore biocompatibility testing is not applicable.

Sterilization and Shelf Life

The BeneVision N Series Patient Monitors are non-sterile when used. All accessories have been previously cleared.

Similar to the predicate device, no shelf life is claimed for the patient monitors.

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 N Series Patient Monitors 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 N Series Patient Monitors 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.

Bench Testing

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

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

- IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 60601-2-34:2011 Medical electrical equipment - part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
- ISO 80601-2-61: 2018 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
- ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence
- AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems

9. CONCLUSION

Based on the detailed comparison of the intended use, indications for use, specifications for each of the modifications to the previously cleared BeneVision N Series Patient Monitors (K192972), the performance testing and conformance with applicable standards, the BeneVision N Series Patient Monitors (including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1) can be found substantially equivalent to the predicate devices.