July 12, 2022

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

Re: K213799
Trade/Device Name: N Series Patient Monitors
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, DSI, MLD, DRT, DXN, DSK, FLL, DQA
Dated: June 9, 2022
Received: June 10, 2022

Dear Li Lei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K213799

Device Name

BeneVision N Series Patient Monitors (including BeneVision N1, BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22)

Indications for Use *(Describe)*

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, NMT monitoring, PNP, and PNC are intended for adult and pediatric patients only. CCO using FloTrac is intended for adult 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 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):

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 (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, whereas N1 configured with WMTS technology can be used inside the hospital only. 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: Li Lei
Title: Manager Regulatory Affairs
Phone: +86 755 81885953
Fax: +86 755 26582680
E-mail: lilei.js@mindray.com

Date Prepared: December 2, 2021

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: K202405 – BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1)

4. REFERENCE DEVICES

- Philips InterlliVue MX600, MX800 patient monitors (K161531): provided as reference devices for SVT and SVCs/min High, Artifact flag of ABP shields alarms function, and combined alarm function.
- GE Carescape B850 patient monitor (K131414) is provided as reference device for SVT and SVCs/min High and SVCs/min value.
- Edwards HemoSphere Advanced Monitor (K180881) is provided as reference device for the Flotrac CCO cable.
- Philips InterlliVue MX850 patient monitors (K210906) are provided as reference devices for the aEEG module.
- Mindray BeneVision central monitoring system (K193391, including TM70 telemetry system) is provided as reference device for the WMTS module of TM70.
- Philips InterlliVue MX series patient monitors (K182979) are provided as reference devices for the Alarm Threshold.

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. CCO using FloTrac is intended for adult 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, whereas N1 configured with WMTS technology can be used inside the hospital only. 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 N12/N15/N17/N19/N22 has been modified to include support for CCO using FloTrac in adult patients. Although this feature is not present in the primary predicate devices, it is present in HemoSphere Advanced Monitor (K180881, including Pressure Cable).

The indications for use statement of the subject BeneVision N1 has been modified to include WMTS technology for use inside the hospital only.

In conclusion, the minor difference in the indications for use statements do 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, K202405). The features in grey 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 K202405					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: ET2203LM.	Mirrored display. Size: 21.5” Model: ET2203LM.		No change		No change	No change	
iView	iView is an isolated PC platform that allows the user to run 3rd party applications using a limited set of functions. The iView system is not intended to be used as a primary alarm device. 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).					No change				
Module rack	Must be connected to the main unit to provide up to 8 standard module slots.		Optional for the patient monitor, 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 K202405					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 in 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.					Provides audible alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation. * **Replace the manufacturer of the speaker.**				
Main control board	CPU module: E3827 DDR3 capacity: 2GB		CPU module: AM3358 DDR3 capacity: 1GB			CPU module: E3845 DD3 capacity: 4 GB * **Modifications for main control board. Refer to**	No change			
Alarm system	Supports alarm volume escalation. The alarm lamp will light cyan, yellow, or red depending on alarm type.					Supports alarm volume escalation. The alarm lamp will light cyan, yellow, or red depending on alarm type. **Support combined alarm monitoring, optimized auditory ALARM SIGNALS, Adjustment of Default Alarm Threshold, alarm highlight.** • **Combined alarm monitoring.** • * **Optimized auditory ALARM SIGNALS.** • * **Adjustment of Default Alarm Threshold.** • * **Alarm highlight.**				
Support T1/N1 as a Module	Support T1/N1 acting as a module.					No change				
Connect with Mindray telemetry monitors	Connect with the TM80/TM70 and the BP10 NIBP module to receive ECG, SpO_2, RESP, and NIBP waveforms and parameters.					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					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: 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 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.					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. **Adjustment of QT calculation.** **Support SVT and SVCs/min high arrhythmia alarm.** **Support SVCs/min Value** • **adult mode: 0~300** • **pediatric and neonate mode: 0~350** **Support Multi-lead ECG synchronization analysis.**				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
						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 in MPM2.0 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.				
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) 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					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
	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.									
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) 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.					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
Invasive blood pressure (IBP)	Uses the MPM (Multi Parameter Module), T1, N1 or the IBP Module to measure invasive blood pressure. The monitor can monitor up to 8 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.					Uses the MPM (Multi Parameter Module) or the IBP Module to measure invasive blood pressure. The monitor can monitor up to 8 invasive blood pressures and displays systolic, diastolic and mean pressures and a waveform for each pressure. Support Pulse Pressure Variation (PPV) and Pulmonary Artery Wedge Pressure (PAWP) function. Measurement range: -50~300mmHg, Accuracy of module: ±2% or ±1mmHg, whichever is greater This measurement can be used for adults, pediatrics and neonates except that PAWP is not for neonates. * **The Artifact flag of Arterial Blood Pressure (ABP) shields alarms Monitoring Support**				
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				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
Continuous cardiac output (FloTrac)	Not supported					**Add Continuous cardiac output (FloTrac) parameter.** **FloTrac measures a patient's hemodynamic status using a mini-invasive method based on pulse wave analysis technology.** **Measurement range:** **CCO: 1.0-20.0L/min; Reproducibility: ±6% or 0.1 L/min, whichever is greater.** **Resolution ratio: 0.1 L/min** **CCI: 0.0–20.0 L/min/m2** **SV: 0–300 mL** **SVI: 0–200 mL/m2** **SVR: 0–5000 DS/cm5** **SVRI: 0–9950 DS-m2/cm5** **SVV: 0–99%** **PPV: 0–99%** **PR:0~220bpm, Arms ≤3bpm** **Live pressure display range：-34 to 312 mmHg** **MAP/DIA/SYS display range: 0–300 mmHg** **Accuracy: ±4% or ±4 mmHg, whichever is greater, in the range of –30 mmHg to 300 mmHg** **This measurement is only indicated for adults.**				
Mixed/central venous oxygen saturation (SvO_2/$ScvO_2$)	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 mixed venous oxygen saturation (SvO_2) and central venous oxygen saturation ($ScvO_2$). This measurement can be used for adults and pediatrics.					No change				
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				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
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					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 * **Internal electronic component changes for Sidestream CO2 1.0, Sidestream CO2 2.0 modules.**				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
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 specified; awRR:2~60rpm, ±1rpm, >60rpm, not specified This measurement can be used for adults, pediatrics and neonates.					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 specified; awRR:2~60rpm, ±1rpm, >60rpm, not specified This measurement can be used for adults, pediatrics and neonates. * **Internal electronic component changes for the AG module.**				
Impedance cardiograph (ICG)	ICG measures a patient's hemodynamic status using a non-invasive method based on thoracic electrical bioimpedance (TEB) technology.					No change				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
	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.									
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: 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%;		Accuracy: 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						

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
	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;			±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;						
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).					The EEG module and EEG-1 module measure 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				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
	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.					Density Spectral Arrays (DSA) and Compressed Spectral Arrays (CSA). The aEEG module measures the electrical activity of the cortex to monitor the function of cerebral. The aEEG module can continuously monitor EEG signals from up to 4 channels. N Series patient monitors are compatible with the following 3 types of modules to measure EEG: EEG module: Frequency response: 0.5Hz ~ 50 Hz (-3 dB) Input range: 4 mVpp DC offset: ±500 mV CMRR: ≥ 100 dB @ 51 kΩ and 60 Hz Noise level: ≤ 0.5 uV rms (1Hz to 30 Hz) Differential input resistance: > 15 MΩ @ 10 Hz 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. **EEG-1 module:** **Frequency response: 0.5Hz ~ 50 Hz (-3 dB)** **Input range: 4 mVpp** **DC offset: ±500 mV** **CMRR: ≥ 100 dB @ 51 kΩ and 60 Hz** **Noise level: ≤ 0.5 uV rms (1Hz to 30 Hz)** **Differential input resistance: > 15 MΩ @ 10 Hz** **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.**				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
						aEEG module: **Frequency response: 0.5Hz ~ 50 Hz (-3 dB)** **Input range: 4 mVpp** **DC offset: ±500 mV** **CMRR: ≥ 100 dB @ 51 kΩ and 60 Hz** **Noise level: ≤ 0.5 uV rms (1Hz to 30 Hz)** **Differential input resistance: > 15 MΩ @ 10 Hz** **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.** **Added EEG-1 module.** **Added aEEG module.**				
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 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.					No change				
Device integration	Support BeneLink Module to connect Anesthesia, Ventilator, Pump, TcGas Monitor Device, and Single Paramer Device.					No change				
A-Fib overview	Not supported					* **The A-Fib overview function only collects atrial fibrillation, atrial fibrillation with rapid ventricular rate, atrial fibrillation with R-R long interval and other related events, and the A-Fib overview screen displays the A-Fib specifications.**				
Accessories	The accessories including ECG, SpO2, Temp, NIBP, IBP, C.O., ScvO2, ICG, BIS, CO2, AG, RM, EEG, BIS, NMT, rSO2,					* **Add new EEG cable**				

Feature	N22	N19	N17	N15	N12	N22	N19	N17	N15	N12
	Cleared in K202405					Subject Device				
	CCO/SvO2 accessories.									

Table 3: Device Comparison Table – BeneVision N1

Feature	N1	N1
	Cleared in K202405	**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
Power supply	Two rechargeable Lithium-ion batteries (without built-in CO_2 module), one rechargeable Lithium-ion battery (with built-in CO_2 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.	Supports alarm volume escalation. The alarm lamp will light cyan, yellow, or red depending on alarm type. Support combined alarm monitoring, optimized auditory alarm signals, Adjustment of Default Alarm Threshold, alarm highlight. **Combined alarm monitoring.** *** Optimized auditory alarm signals.** *** Adjustment of Default Alarm Threshold.** *** Alarm highlight.**

Feature	**N1**	**N1**
	Cleared in K202405	**Subject Device**
Communication on Interface when N1 is working as a module	Infrared communication interface. Pogo pin communication interface.	No change
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.	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. **Adjustment of QT calculation.** **Support SVT，SVCs/min high arrhythmia alarm.** **Support SVCs/min Value** • **adult mode :0~300** • **pediatric and neonate mode:0~350** **Support Multi-lead ECG synchronization analysis.**

Feature	**N1**	**N1**
	Cleared in K202405	**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)	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. 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.	No change

Feature	**N1**	**N1**
	Cleared in K202405	**Subject Device**
Pulse rate (PR)	Obtains pulse rate from SpO_2 or IBP. Measurement range: 20~254 bpm (Mindray 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); 20~250bpm ±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). 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.	No change

Feature	N1	N1
	Cleared in K202405	**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. 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 Artifact flag of Arterial Blood Pressure (ABP) shields alarms Monitoring Support.**

Feature	N1 Cleared in K202405	N1 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	CO_2 can be measured using the Mindray Sidestream CO_2 module or third-party CO_2 modules, Microstream module and Mainstream module. Type: Sidestream CO_2 module Measurement range: CO_2 :0~150mmHg, awRR: 0~150rpm. Accuracy: CO_2: 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. N1 can support a built-in Sidestream CO_2 2.0 module, or it can also connect to an external Sidestream CO_2 2.0 module (when used with a rack). *** Component changes for Sidestream CO_2 1.0 and 2.0 modules.** Type: Microstream CO_2 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.

Feature	N1 Cleared in K202405	N1 Subject Device
	specific wavelengths using a photodetector. This measurement can be used for adults, pediatrics and neonates.	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. CO_2 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 (O2)	Oxygen values are measured by the Sidestream CO_2 (only for external Sidestream CO_2 2.0 module) module using a paramagnetic method. Measurement range: O_2: 0~100% Accuracy:0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3%. This measurement can be used for adults, pediatrics, and neonates.	No change

Feature	**N1**	**N1**
	Cleared in K202405	**Subject Device**
Dock, Rack and Transport Dock	The Dock is used to connect either the N1 without a Rack or the N1 docked inside a Rack, to extending ports such as USB, VGA, or wired network. The Rack can connect an external parameter module, such as CO_2, 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 transfers the 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).	The Wireless radio module is used for connecting to a wireless monitoring network with a central monitoring system (CMS). **Added WMTS module**
Helicopter and ambulance transport	ECG, RESP, Temp, SpO_2, PR, NIBP, and IBP can be monitored in helicopters and ambulances.	No change
A-Fib overview	Not supported	*** The A-Fib overview function only collects atrial fibrillation, atrial fibrillation with rapid ventricular rate, atrial fibrillation with R-R long interval and other related events, and the A-Fib overview screen displays the A-Fib specifications.**

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.

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 60601-1-8:2020 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 60601-2-26:2012 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- 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 80601-2-30:2018 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34:2011 Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
- IEC 80601-2-49:2018 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55: 2018 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56: 2017 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 80601-2-61: 2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ANSI 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.
- ANSI AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms

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 (K202405), 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 device.