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

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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)

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

Regulation Number/Class	Product Code	Regulation description	Device Common Name
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)
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

Regulation Number/Class	Product Code	Regulation description	Device Common Name
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

- Primary Predicate: K152902 – Passport Series Patient Monitors
- Secondary Predicate: K161531 - Philips IntelliVue Patient Monitor MX800: provided as a secondary predicate for the EEG module that has been added to the subject BeneVision N Series Patient.
- Secondary Predicate: K170876 - Passport Series Patient Monitors: provided as a secondary predicate for the NMT module that has been added to the subject BeneVision N Series Patient Monitors

4. REFERENCE DEVICES

- K171292 - A7 Anesthesia System: provided as reference devices for the AG module that has been added to the subject BeneVision N Series Patient Monitors
- K131414 - CARESCAPE Monitor B850: provided as a reference device for expanding the indications for ST Segment analysis to include pediatric and neonatal patients and for the EEG module that has been added to the subject BeneVision N Series Patient Monitors.
- K130238 - Nihon Kohden AE-918P Neuro Unit: provided as a reference device for the EEG module that has been added to the subject BeneVision N Series Patient Monitors.
- K053269 - Masimo SET® Rad 8 Pulse Oximeter: provided as a reference device for the Masimo SpO2 module in MPM (Multi Parameter Module) 3.0 that has been added to the subject BeneVision N Series Patient Monitors.
- K170712 - Accutorr7/VS-900 Vital Signs Monitors: provided as reference devices for the Sidestream CO2 2.0 module that has been added to the subject BeneVision N Series Patient Monitors and for the Clinical Assistive Applications.

- K161531 - Philips IntelliVue Patient Monitor MX800 and MP2: provided as a reference device for the patient transport function, Alarm Volume Escalation and intelligent arrhythmia alarm that has been added to the subject BeneVision N Series Patient Monitors
- K082327 - INVOS 5100C Cerebral/Somatic Oximeter System: provided as a reference device for the rSO2 module that has been added to the subject BeneVision N Series Patient Monitors
- K162607 - BeneVision Central Monitoring System: provided as a reference device for the 6-Lead ECG 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

The BeneVision N Series Patient Monitors are Mindray's new generation monitoring product family with ergonomic and flexible design in platform of both software and hardware to meet the clinical needs of 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 (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), 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:

- The arrhythmia detection, RM, CCO, SvO2/ScvO2, PAWP, and NMT monitoring are intended for adult and pediatric patients only;
- C.O. monitoring is 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 (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:

- The arrhythmia detection and PAWP is intended for adult and pediatric 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 devices have been modified to include ST Segment analysis used on pediatric and neonatal patients. It also includes the following new parameters: 6-lead ECG, NMT, EEG and rSO2 and the new patient transport function. Although these features are not present in the primary predicate devices, they are present in other cleared devices and do not constitute a new intended use:

- ST Segment analysis used on pediatric and neonatal patients is present in the cleared CARESCAPE Monitor B850 (cleared in K131414).

- NMT is present in the Mindray Passport Series Monitors (Passport 12m and Passport 17m) (cleared in K170876).
- EEG is present in the Philips IntelliVue Patient Monitor MX800 (cleared in K161531) and the CARESCAPE Monitor B850 (cleared in K131414) and the Nihon Kohden AE-918P Neuro Unit (cleared in K130238)
- Patient transport is present in the Philips IntelliVue Patient Monitor MP2 (cleared in K161531)
- rSO2 is present in the INVOS 5100C Cerebral/Somatic Oximeter System (cleared in K082327).
- 6-lead ECG functionality is present in the BeneVision Central Monitoring System (cleared in K162607)

In conclusion, the minor differences of the indications for use do not change the fundamental intended use of the BeneVision N series monitors as multiparameter monitors.

Technological Comparison

The table below compares the key technological feature of the subject devices to the predicate device (the Mindray Passport Series Patient Monitors K152902). The features in grey are the features that are different from the predicate device and that are the subject of this 510(k).

Table 2: Device Comparison Table – N22/N19/N17/N15/N12

	Predicate Devices (K152902)		**Subject BeneVision Devices**				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
Integrated display and touchscreen	17” 1280*1024 pixels.	12” 800*600 pixels.	22” 1680*1050 pixels.	19” 1680*1050 pixels.	18.5” 1920*1080 pixels.	15.6” 1920*1080 pixels.	12.1” 1280*800 Pixels.
Secondary display	Independent control and display.	Mirrored display.	Independent control and display.			Mirrored display.	
iView	iView is an isolated PC platform that allows the user to run 3rd party applications using a limited set of functions.	Not supported.	iView is an isolated PC platform that allows the user to run 3rd party applications using a limited set of functions.			Not supported.	
Wireless	2.4GHz module.	2.4GHz/5GHz dual band module.	2.4GHz/5GHz dual band module.				

	Predicate Devices (K152902)		**Subject BeneVision Devices**				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
Module rack	Independent of the patient monitor, provides 8 standard module slots to extend the measurement capabilities of the system.		Must be connected to the main unit to provide at least 8 standard module slots.		Independent of the patient monitor, provides 8 standard module slots to extend the measurement capabilities of the system.		Not supported
Module communication interface	Infrared communication interface.		Infrared communication interface. **Pogo pin communication interface.**				
Power supply	Battery or AC power.	Battery or AC power.	Battery or AC power. Battery is only intended as a back-up power supply.		Battery or AC power.		
Battery	Rechargeable Lithium-Ion, 11.1 VDC, 4500 mAh.		Rechargeable Lithium-Ion, **11.3 VDC, 5600 mAh**		Rechargeable Lithium-Ion, 11.1 VDC, 4500 mAh.		
Data storage	Compact Flash.		**Solid State Hard Drive (SSD).**		**Embedded Multi Media Card (eMMC).**		
Data Recorder	Only supports internal thermal recorder.		Only supports **external** thermal recorder.		Supports internal and **external** thermal recorders. But they cannot be used at same time.		
Device integration	Use Benelink Module to integrate 3rd party devices. Allow parameter values and alarms from 3rd party devices to be displayed, stored and printed.		Use Benelink Module to integrate 3rd party devices. Allow parameter values, **waveforms** and alarms from 3rd party devices to be displayed, stored and printed.				
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation.		Same				
Alarm system	The alarm lamp is yellow, or red depending on alarm type.		The alarm lamp is **cyan**, yellow, or red depending on alarm type. **Supports Alarm Volume Escalation** Although the predicate device does not support an Alarm volume escalation functionality, the feature has been cleared in K161531.				
Support T1/N1 as a Module	Supports T1 as a module.		Supports T1/**N1** as a module.				
Supports connecting with Mindray Telemetry monitors, TM80 and BP10	No		Yes				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
ECG	3-lead, 5-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 and heart rate (HR); Arrhythmia detection is intended for adult and pediatric. ST segment analysis of Mindray algorithm is intended for adult patient. ST segment analysis of Mortara algorithm is intended for adult and pediatric patients. Supports Mindray and Mortara algorithm. Only supports ECG function from MPM 2.0 module		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 and heart rate (HR). Although the predicate device does not support a 6-lead ECG functionality, the feature has been cleared in K162607. Arrhythmia detection is intended for adult and pediatric **Supports intelligent arrhythmia alarm.** Although the predicate device does not support an intelligent arrhythmia alarm functionality, the feature has been cleared in K161531 ST segment analysis is intended for adult, **pediatric and neonate.** Although the predicate device does not support ST segment analysis used for **pediatric and neonate**, the feature has been cleared in K131414. Can be configured with either the Mindray or Mortara algorithm for ECG arrhythmia monitoring and arrhythmia detection. • MPM 3.0: supports Mindray Algorithm. • T1, MPM 2.0 and TM80: support Mindray or Mortara algorithm Supports ECG function from MPM 2.0 module **and MPM 3.0** module.				
Arrhythmia Analysis	Asystole, VFib/VTac, Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVCs, Tachy, Brady, Missed Beats, Vent. Rhythm, Pacer Not Pacing, Pacer Not Capture, Multif. PVC, Nonsus. Vtac, Pause, Irr. Rhythm, Afib.		Asystole, V-Fib/V-Tach, V-Tach, Vent Brady, Extreme Tachy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVCs/min, Tachy, Brady, Missed Beats, Vent Rhythm, Pacer Not Pacing, Pacer Not Capture, Multiform PVC, Nonsus V-Tach, Pause, Irr. Rhythm, A-Fib, Pauses/min. **Added Pauses/min;** **Changed the names of: VFib/Vtac, Vtac, Vent.Brady, Nonsus.Vtac, Vent.Rhythm, PVCs, Afib**, **and Multif.PVC**				
Respiration rate (Resp)	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. Only supports RESP function from MPM 2.0 module.		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. Supports RESP function from MPM 2.0 module **and MPM 3.0** module.				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
Temperature (Temp)	Measurement range: 0 to 50 ℃ (32 to 122 ℉) Accuracy: ±0.1 ℃ or ±0.2 ℉ (without probe). Only supports Temperature function from MPM 2.0 module.		Measurement specifications are same. Support Temperature function from MPM 2.0 module, **MPM 3.0 module and Temperature module.**				
Pulse oxygen saturation (SpO_2)	Supports Mindray SpO_2 function, Masimo SpO_2 function and Nellcor SpO_2 function from MPM 2.0 module. Supports a stand-alone Mindray or a stand-alone Masimo SpO2 module. <u>Mindray SpO_2 function</u> Measurement range: 0 to 100%; Accuracy:70 to 100%: ±2% (adult/pediatric mode); 70 to 100%: ±3% (neonate mode); 0% to 69%: Not specified. <u>Masimo SpO_2 function</u> Measurement range: 1 to 100%; Accuracy:70 to 100%: ±2% (measured without motion in adult/pediatric mode); 70 to 100%: ±3% (measured without motion in neonate mode); 70 to 100%: ±3% (measured with motion); 1% to 69%: Not specified. <u>Nellcor SpO_2 function</u> Measurement range: 0 to 100%; Accuracy:70 to 100%: ±2% (adult/pediatric); 70 to 100%: ±3% (neonate); 0% to 69%: Not specified. Note: The specifictions of the various SpO2 functions provided by each manufacturer are the same across platforms.		Supports Mindray SpO_2 function, Masimo SpO_2 function and Nellcor SpO_2 function from MPM 2.0 module. **Adds the option to use the MPM 3.0. The MPM 3.0 can be configured with either a Mindray, Masimo, or Nellcor SpO2 module.** Although the predicate device does not support Masimo SpO2 module in MPM 3.0 module, the feature has been cleared in K053269. Supports a stand-alone Mindray or a stand-alone Masimo SpO2 module. **Adds support for a stand-alone Nellcor SpO2 module.** Note: The specifications for various SpO2 functions provided by each manufacturer for the new MPM 3.0 and Nellcor stand-alone platforms are identical to those that were cleared in the primary predicate device.				

<table>
<tr><th></th><th colspan="2">Predicate Devices (K152902)</th><th colspan="5">Subject BeneVision Devices</th></tr>
<tr><th>Feature</th><th>Passport 17m</th><th>Passport 12m</th><th>N22</th><th>N19</th><th>N17</th><th>N15</th><th>N12</th></tr>
<tr><td>Pulse rate (PR)</td><td colspan="2">PR from Mindray SpO_2 Module
Measurement range: 20 to 254 bpm;
Accuracy: ±3 bpm.

PR from Masimo SpO_2 Module
Measurement range: 25 to 240 bpm;
Accuracy: ±3 bpm (measured without motion);
±5 bpm (measured with motion).

PR from Nellcor SpO_2 Module
Measurement range: 20 to 300 bpm;
Accuracy:20 to 250 bpm: ±3 bpm;
251 to 300 bpm, not specified.

PR from IBP Module
Measurement range: 25 to 350 bpm;
Accuracy: ±1 bpm or ±1%, whichever is greater.</td><td colspan="5">Same</td></tr>
<tr><td>Non-invasive blood pressure (NIBP)</td><td colspan="2">Measurement range:
<table>
<tr><th></th><th>Adult</th><th>Pediatric</th><th>Neonate</th></tr>
<tr><td>Systolic</td><td>40-270</td><td>40-200</td><td>40-135</td></tr>
<tr><td>Diastolic</td><td>10-210</td><td>10-150</td><td>10-100</td></tr>
<tr><td>Mean</td><td>20-230</td><td>20-165</td><td>20-110</td></tr>
</table>
Accuracy:
Max mean error: ±5 mmHg;
Max standard deviation: 8 mmHg.

Only supports NIBP function from MPM 2.0 module.</td><td colspan="5">Measurement range:
<table>
<tr><th></th><th>Adult</th><th>Pediatric</th><th>Neonate</th></tr>
<tr><td>Systolic</td><td>25-290</td><td>25-240</td><td>25-140</td></tr>
<tr><td>Diastolic</td><td>10-250</td><td>10-200</td><td>10-115</td></tr>
<tr><td>Mean</td><td>15-260</td><td>15-215</td><td>15-125</td></tr>
</table>
Accuracy:
Max mean error: ±5 mmHg;
Max standard deviation: 8 mmHg.

Supports NIBP function from MPM 2.0 module and MPM 3.0 module.</td></tr>
</table>

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
Invasive blood pressure (IBP)	Uses the MPM 2.0 or the stand-alone 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 PPV function. Measurement range: -50 to 300 mmHg; Accuracy: ±2% or ±1 mmHg, whichever is greater (without sensor).		Uses MPM 2.0 and **MPM 3.0** or the stand-alone IBP Module (cleared in K152902) to measure invasive blood pressure. The measurement specifications are same.				
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 is capable of storing 6 measurements. Measurement range: C.O: 0.1 to 20 L/min; TB: 23 to 43 ℃; TI: 0 to 27 ℃; Accuracy: C.O: ±5% or ±0.1 L /min, whichever is greater; TB, TI: ±0.1 ℃ (without sensor).		Same				
Continuous Cardiac output (CCO)	The CCO/SvO_2 interface module provides an interface with Edwards Vigilance II monitor (cleared in K043103) and Vigileo Monitor (cleared in K103094), which measure continuous cardiac output (CCO).		Provides an interface with Edwards Vigilance II monitor (cleared in K043103), Vigileo monitor (cleared in K103094), and **EV1000 monitor (cleared in K160552)** monitor which measure CCO.				

	Predicate Devices (K152902)		**Subject BeneVision Devices**				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
Mixed/central venous oxygen saturation (SvO_2/$ScvO_2$)	Provides an interface with monitors (Edwards Vigilance II (cleared in K043103) and Vigileo monitor (cleared in K103094)) that measure mixed venous oxygen saturation (SvO_2) and central venous oxygen saturation ($ScvO_2$).		Provides an interface with monitors (Edwards Vigilance II (cleared in K043103), Vigileo (cleared in K103094), and **EV1000 (cleared in K160552)**) that measures mixed venous oxygen saturation (SvO_2) and central venous oxygen saturation ($ScvO_2$).				
Central venous oxygen saturation (ScvO2)	Central venous oxygen saturation (ScvO2) 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.		Same				
Carbon dioxide (CO_2)	Compatible with the following 3 modules to measure carbon dioxide: • Sidestream CO_2 1.0 Module • Microstream CO_2 Module • Mainstream CO_2 Module		Compatible with the following 3 modules to measure carbon dioxide: • Sidestream CO_2 Module, 1.0 **and 2.0** • Microstream CO_2 Module • Mainstream CO_2 Module				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
	Type: Sidestream CO2Module (CO2 1.0) 0-5%: ±0.26% abs, 5-10%: ±5% of the reading, 10-13%: ±10% of the reading; ±0.3%ABS increase in error for ISO accuracy mode. AwRR measurement: range: 0 to 120rpm; accuracy: ±2rpm.		Type: Sidestream CO2 Module (CO2 2.0): Measurement range: 0~150mmHg Accuracy: 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 measurement: awRR measurement range: 0 to 150rpm; **awRR: <60rpm, ±1rpm, 60~150rpm, ±2rpm.** **The CO_2 measurement range of subject devices is wider than the predicate devices.** **The AwRR measurement range of subject devices is wider than the predicate devices. The Accuracy of AwRR is also improved.** The SideStream CO_2 1.0 module has been cleared in K152902. The SideStream CO_2 2.0 module has been cleared in K170712.				
	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.		Same				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
	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.		Same				
Oxygen (O_2)	Oxygen values are measured by 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).		Oxygen values are measured by the **Sidestream CO_2 2.0 module** or the AG module using a paramagnetic method. Measurement specifications are the same.				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
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: CO_2, HAL, ENF, ISO, SEV, DES: 0~30 %; O_2, N_2O: 0~100 %; awRR: 2~100 rpm. Accuracy: Full accuracy mode: CO_2:0%≤CO_2≤1%, ±0.1%ABS, 1%< CO_2≤5%, ±0.2% ABS, 5%< CO_2≤7%, ±0.3% ABS, 7%< CO_2≤10%, ±0.5% ABS, 10%< CO_2 not specified; N_2O: 0~20%$_{REL}$: ±2% $_{ABS}$, 20~100%$_{REL}$: ±3% $_{ABS}$; O_2 0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3%; 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 new AG module has the same measurement specifications and patient population is the same. **Includes new Gas recycling feature.** Although the predicate device does not support gas recycling feature, the feature (including the module and accessories) has been cleared in K171292.				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
Impedance cardiograph (ICG)	Measurement range: C.O.:1.4~15L/min; SV:5~250ml; HR:44~185bpm. Accuracy: HR: ±2bpm; another parameter: not specified.		Same				
Respiration mechanics	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:20 to 500 ml awRR:4~120rpm; Calculated Parameters: 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.		Same				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
	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 ±10%×reading, whichever is greater 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.		Same				
Neuromuscular transmission monitoring (NMT)	Not applicable		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 Although the predicate device does not support NMT module, the feature has been cleared in K170876, which has an identical intended use, measurement range and patient population.				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
Electroencephalograph (EEG)	Not applicable		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). Measurement range: Input range: 4mVpp DC offset voltage: ±500 mV CMRR: ≥100 dB@51 kΩ and 60Hz Differential input resistance: >15MΩ@10Hz Electrode resistance: 0 to 90 KΩ, accuracy: ±1 KΩ or 10%, whichever is the greater. Although the predicate device does not support EEG, the feature has been cleared in K161531.				
Regional oxygen saturation (rSO_2)	Not applicable		The rSO_2 module provides non-invasive 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. Although the predicate device does not support a rSO_2 module, the feature has been cleared in K082327.				
Wireless function	The Wireless radio module (ASUS) is used for connecting to a wireless monitoring network with a central monitoring system (CMS).	The Wireless radio module (Laird) is used for connecting to a wireless monitoring network with a central monitoring system (CMS).	Same as Passport 12m				
ECG 24h Summary	Not applicable		Provides the function to statistical results of heart rate changes and cardiac arrhythmia of patients within 24 hours, including HR statistics, ARR statistics, ST statistics, QT/QTc statistics and Pace statistics.				

	Predicate Devices (K152902)		Subject BeneVision Devices				
Feature	**Passport 17m**	**Passport 12m**	**N22**	**N19**	**N17**	**N15**	**N12**
EWS	Not applicable		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, cleared in the Accutorr 7), National Early Warning Score (NEWS) and Custom Scoring. Although the predicate device does not support a EWS functionality, the feature has been cleared in K170712.				
Glasgow Coma Scale (GCS)	Not applicable		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.				
SepsisSight Companion (SSC)	Not applicable		The SSC feature is intended to help clinicians recognize the early signs and symptoms of Sepsis based on recommendations from the published literature.				
Cardio-pulmonary resuscitation (CPR) Dashboard	Not applicable		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).				

Table 3: Device Comparison Table – N1

	Predicate Device (K152902)	Subject Device
Feature	**T1**	**BeneVision N1**
Primary display and touchscreen	5”, 480*272 pixels	5.5”, 720*1280 pixels.
External display	Allows the display of independent data when connected to an external monitor through the VGA connector provided by the Dock.	Allows the display of **mirrored** or independent data when connected to an external monitor through the VGA connector provided by the Dock. The mirrored function in the N1 is identical to the Passport 17m/12m mirrored function (K152902).
Power supply	One rechargeable Lithium-ion battery, or DC-in 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.

	Predicate Device (K152902)	Subject Device
Feature	**T1**	**BeneVision N1**
Battery	Chargeable Lithium-ion 7.4VDC, 2500mAh (**hard package**).	Chargeable Lithium-ion 7.56VDC, 2500mAh (**soft package**).
Data storage	Secure Digital Memory Card (SD card).	Embedded Multi Media Card (eMMC).
Communication interface when working as a module	Infrared communication interface,	Infrared communication interface. **Pogo pin communication interface.**
Speaker	Audible alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation.	Same
Alarm system	The alarm lamp is yellow or red, depending on the alarm type.	The alarm lamp is **cyan,** yellow, or red depending on alarm type. **Supports Alarm Volume Escalation** Although the predicate device does not support an Alarm volume escalation functionality, the feature has been cleared in K161531.
ECG	3-lead, 5-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 and heart rate (HR). Arrhythmia detection is intended for adult and pediatric. ST segment analysis is intended for adult patient. Support Mindray and Mortara algorithm. The ECG function comes from MPM2.0 module.	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, and heart rate (HR). Although the predicate device does not support a 6-lead ECG functionality, the feature has been cleared in K162607. Arrhythmia detection is intended for adult and pediatric. **Supports intelligent arrhythmia alarm**. Although the predicate device does not support an intelligent arrhythmia alarm functionality, the feature has been cleared in K161531. ST segment analysis is intended for adult, **pediatric and neonate.** Although the predicate device does not support ST segment analysis used for **pediatric and neonate**, the feature has been cleared in K131414. The ECG function comes from **MPM 3.0** module.

	Predicate Device (K152902)	**Subject Device**
Feature	**T1**	**BeneVision N1**
Arrhythmia Analysis	Asystole, VFib/VTac, Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVCs, Tachy, Brady, Missed Beats, Vent. Rhythm, Pacer Not Pacing, Pacer Not Capture, Multif. PVC, Nonsus. Vtac, Pause, Irr. Rhythm, Afib.	Asystole, V-Fib/V-Tach, V-Tach, Vent Brady, Extreme Tachy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVCs/min, Tachy, Brady, Missed Beats, Vent Rhythm, Pacer Not Pacing, Pacer Not Capture, Multiform PVC, Nonsus V-Tach, Pause, Irr. Rhythm, A-Fib, Pauses/min **Added: Pauses/min;** **Changed the name of: VFib/Vtac, Vtac, Vent.Brady, Nonsus.Vtac, Vent.Rhythm, PVCs, Afib, and Multif.PVC.**
Respiration rate (Resp)	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. The RESP function comes from MPM2.0 module.	Measurement specifications are the same. The RESP function comes from **MPM 3.0** module.
Temperature (Temp)	Measurement range: 0 to 50 ℃ (32 to 122 ℉); Accuracy: ±0.1 ℃ or ±0.2 ℉ (without probe). The TEMP function comes from MPM 2.0 module.	Measurement specifications are same. The TEMP function comes from **MPM 3.0** module.

	Predicate Device (K152902)	**Subject Device**
Feature	**T1**	**BeneVision N1**
Pulse oxygen saturation (SpO_2)	Mindray SpO_2 function Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric mode) 70 to 100%: ±3% (neonate mode) 0% to 69%: Not specified. Masimo SpO_2 function Measurement range: 1 to 100% Accuracy:70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified. Nellcor SpO_2 function Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified. The Mindray SpO_2 function, Masimo SpO2 function and Nellcor SpO_2 function come from MPM 2.0 module.	Measurement specifications are same. The Mindray SpO_2 function, Masimo SpO_2 function and Nellcor SpO_2 function come from **MPM 3.0** module. Although the predicate device does not support Masimo SpO2 module in MPM 3.0 module, the feature has been cleared in K053269.
Pulse rate (PR)	PR from Mindray SpO_2 Module Measurement range: 20 to 254 bpm Accuracy: ±3 bpm. PR from Masimo SpO_2 Module Measurement range: 25 to 240 bpm Accuracy: ±3 bpm (measured without motion) ±5 bpm (measured with motion). PR from Nellcor SpO_2 Module Measurement range: 20 to 300 bpm Accuracy:20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified. PR from IBP Module Measurement range: 25 to 350 bpm Accuracy: ±1 bpm or ±1%, whichever is greater.	Same

<table>
<tr><th></th><th>Predicate Device (K152902)</th><th>Subject Device</th></tr>
<tr><th>Feature</th><th>T1</th><th>BeneVision N1</th></tr>
<tr><td>Non-invasive blood pressure (NIBP)</td><td>Measurement range:
<table>
<tr><th></th><th>Adult</th><th>Pediatric</th><th>Neonate</th></tr>
<tr><td>Systolic</td><td>40-270</td><td>40-200</td><td>40-135</td></tr>
<tr><td>Diastolic</td><td>10-210</td><td>10-150</td><td>10-100</td></tr>
<tr><td>Mean</td><td>20-230</td><td>20-165</td><td>20-110</td></tr>
</table>
Accuracy:
Max mean error: ±5 mmHg.
Max standard deviation: 8 mmHg.
The NIBP function comes from MPM 2.0 module.</td><td>Measurement range:
<table>
<tr><th></th><th>Adult</th><th>Pediatric</th><th>Neonate</th></tr>
<tr><td>Systolic</td><td>25-290</td><td>25-240</td><td>25-140</td></tr>
<tr><td>Diastolic</td><td>10-250</td><td>10-200</td><td>10-115</td></tr>
<tr><td>Mean</td><td>15-260</td><td>15-215</td><td>15-125</td></tr>
</table>
Accuracy:
Max mean error: ±5 mmHg.
Max standard deviation: 8 mmHg.
The NIBP function comes from MPM 3.0 module.</td></tr>
<tr><td>Invasive blood pressure (IBP)</td><td>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).

The IBP function comes from MPM 2.0 module.</td><td>Measurement specifications are the same.

The IBP function comes from MPM 3.0 module.</td></tr>
<tr><td>Carbon dioxide (CO_2)</td><td>Is compatible with the following 3 modules to measure carbon dioxide:
• Sidestream CO_2 1.0 Module
• Microstream CO_2 Module
• Mainstream CO_2 Module</td><td>Is compatible with the following 3 modules to measure carbon dioxide:
• Sidestream CO_2 Module, 1.0 and 2.0
• Microstream CO_2 Module
• Mainstream CO_2 Module</td></tr>
</table>

	Predicate Device (K152902)	Subject Device
Feature	**T1**	**BeneVision N1**
	Type: Sidestream CO2 (CO2 1.0) Module 0-5%: ±0.26% abs; 5-10%: ±5% of the reading; 10-13%: ±10% of the reading; ±0.3%ABS increase in error for ISO accuracy mode. AwRR measurement: range: 0 to 120rpm; accuracy: ±2rpm.	Type: Sidestream CO2 Module (CO2 2.0) Measurement range: 0~150mmHg Accuracy: 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 measurement: awRR measurement range: 0 to 150rpm; **awRR: <60rpm, accuracy: ±1rpm;** **60~150rpm, accuracy: ±2rpm.** **The CO_2 measurement range of subject devices is wider than the predicate devices** **The AwRR measurement range of subject devices is wider than the predicate devices. The Accuracy of AwRR is also improved.** The SideStream CO_2 1.0 module has been cleared in K152902. The SideStream CO_2 2.0 module has been cleared in K170712.
	Type: Microstream CO2 Module Measurement range: CO_2: 0~99mmHg, awRR: 0~150rpm. Accuracy: CO_2: 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.	Same

	Predicate Device (K152902)	Subject Device
Feature	**T1**	**BeneVision N1**
	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.	Same
Oxygen (O_2)	Not Applicable	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%.
Wireless radio Module	The Wireless radio module (Laird) is used for connecting to a wireless monitoring network with a central monitoring system (CMS).	Same
Helicopter and ambulance transport	Not Applicable	Only ECG, RESP, Temp, SpO_2, PR, NIBP, and IBP can be used in helicopters and ambulances. CO_2 and O_2 cannot be used in helicopters or ambulances. Although the predicate device does not support a Helicopter and ambulance transport functionality, the feature has been cleared in K161531.
EWS	Not Applicable	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, cleared in the Accutorr 7), National Early Warning Score (NEWS) and Custom Scoring. Although the predicate device does not support a EWS functionality, the feature has been cleared in K170712.
Glasgow Coma Scale (GCS)	Not Applicable	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.

	Predicate Device (K152902)	Subject Device
Feature	**T1**	**BeneVision N1**
Cardio-pulmonary resuscitation (CPR) Dashboard	Not Applicable	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).

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.

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.
- IEC 62133:2012 (Second Edition) Secondary cell and batteries containing alkaline or other non-acid electrolytes

Bench Testing

To establish the substantial equivalence of the BeneVision 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 60601-1-6: 2010, AMD1:2013 Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance- collateral standard: usability
- IEC 60601-1-8:2006 + Am1:2012 Medical electrical equipment - part 1-8: general requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-12:2014 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
- IEC 60601-2-10:2012 Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- 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 80601-2-30:2013 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, including essential performance, of invasive blood pressure monitoring equipment
- IEC 60601-2-49:2011 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55: 2011 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56: 2009 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: 2011 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- EN 1789:2014 Medical vehicles and their equipment - Road ambulances
- EN 13718-1:2008 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
- AAMI / ANSI EC57:2012 Testing and reporting performance results of cardiac rhythm and st-segment measurement algorithms
- MIL-STD-810G:2008 Department of defense test method standard – environmental engineering considerations and laboratory tests
- MIL-STD-461F:2007 Department of interface standard – requirements for the control of electromagnetic interference characteristic of subsystems and equipment
- IEC 60068-2-27:2008 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
- IEC 60068-2-64: 2008 Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance
- IEC 60068-2-6: 2008 Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal)
- IEC 60068-2-29:1993 Basic environmental testing procedures -- part 2: tests - test eb and guidance: bump

- IEC 61000-4-3: 2006+A1:2007+A2:2010 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- IEC 60529:2013 Degrees of protection provided by enclosures (IP Code)

Clinical Data

Mindray provided the results of clinical testing to demonstrate that the Mindray and Nellcor SpO2 modules meet relevant consensus standards.

9. CONCLUSION

Based on the detailed comparison of specifications for each of the modifications to the previously cleared Passport Series devices (K152902), 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.