



May 7, 2020

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

Re: K192972

Trade/Device Name: Patient Monitor

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: April 7, 2020

Received: April 8, 2020

Dear Yanhong Bai:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

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

Enclosure

Indications for Use

510(k) Number (if known)

K192972

Device Name

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

Indications for Use (Describe)

BeneVision N12/N15/N17/N19/N22

The BeneVision N12/N15/N17/N19/N22 patient monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, 5-lead, 6-lead or 12-lead selectable, Arrhythmia Detection, ST Segment Analysis, QT Analysis, and Heart Rate (HR)), Respiration Rate (Resp), Temperature (Temp), Pulse Oxygen Saturation (SpO₂), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Pulmonary Artery Wedge Pressure (PAWP), Cardiac Output (C.O.), Continuous Cardiac Output (CCO), Mixed/Central Venous Oxygen Saturation (SvO₂/ScvO₂), Carbon Dioxide (CO₂), Oxygen (O₂), Anesthetic Gas (AG), Impedance Cardiograph (ICG), Bispectral Index (BIS), Respiration Mechanics (RM), Neuromuscular Transmission Monitoring (NMT), Electroencephalograph (EEG), and Regional Oxygen Saturation (rSO₂). The system also provides an interpretation of resting 12-lead ECG.

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

- The arrhythmia detection, BIS, 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.

(Continue on next page for N1 Indications for Use)

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Number (if known): K192972

Indications for Use (con't)

BeneVision N1 Patient Monitor:

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

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

- 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.

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Mindray BeneVision N Series Monitors is provided below.

1. SUBMITTER

Applicant: SHENZHEN MINDRAY BIO-MEDICAL
ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South
High-tech Industrial Park, Nanshan
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680

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

Date Prepared: October 22, 2019

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 cardiometer and rate alarm) | Monitor, cardiac (incl. cardiometer & 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 cardiometer 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

- Predicate: K182075 – BeneVision N Series Patient Monitors (Including BeneVision N12, BeneVision N15, BeneVision N17, BeneVision N19, BeneVision N22, BeneVision N1)

4. REFERENCE DEVICES

- K190011 - Passport 12m, Passport 17m, T1: provided as a provided as reference devices for the BIS module that has been added to the subject BeneVision N Series Patient Monitors.
- K163381 - Hemosphere Monitor: provided as a reference device in support the device integration functionality and PPV parameters.

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 (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:

- The arrhythmia detection, BIS, 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 BeneVision N12/N15/N17/N19/N22 has been modified to include the BIS parameter used on adult and pediatric patients. Although this feature is not present in the primary predicate devices, it is present in other cleared multiparameter patient monitors such as the Passport series Patient Monitors (K190011, Passport 12m, Passport 17m, T1). The inclusion of BIS in the indications for use does not constitute a new fundamental intended use.

The indications for use statement of the subject BeneVision N1 has not been changed.

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

Technological Comparison

The tables below compare the key technological feature of the subject devices to the predicate device (N series Patient Monitors, K182075). The features in gray 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 K182075 | | | | | 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:18.5"; Model: ET1919LM; | Mirrored display. Size:18.5"; Model: ET1919LM; | | No change | | Independent control and display. Size: 21.5"; Model:2203L | Mirrored display. Size: 21.5"; Model: 2203L; | |
| 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: 4GB Model of CPU: J1900 Windows 7 | | | Not supported. | | Change the PC platform Capacity of RAM: 8GB Model of CPU: N4200 Windows 10 | | | 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 monitors, adding 8 standard module slots to extend the measurement capabilities of the system. | | Not supported. | No change | | | | |
| Power supply | One rechargeable Lithium-ion battery or AC power supply. | | | | | No change | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|---------------------------|---|-----|--|-----|-----|---|-----|--|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Battery | Chargeable Lithium-Ion, 11.3 VDC, 5600 mAh. | | Chargeable Lithium-Ion, 11.1 VDC, 4500 mAh. | | | Chargeable Lithium-Ion, 10.8 VDC , 5600 mAh. | | Chargeable Lithium-Ion, 10.95 VDC , 4500 mAh. | | |
| Data storage | Solid State Hard Drive (SDD) | | Embedded Multi Media Card (eMMC). | | | No change | | | | |
| Data recorder | Supports the thermal recorder module, needs to be plugged into the SMR. | | Supports the thermal recorder module and the built-in thermal recorder, but they cannot work at the same time. | | | No change | | | | |
| Speaker | Provides audible alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation. | | | | | No change | | | | |
| Alarm system | Supports alarm volume escalation. The alarm lamp will light cyan, yellow, or red depending on alarm type. | | | | | No change | | | | |
| Support T1/N1 as a Module | Support T1/N1 acting as a module. | | | | | No change | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|---------|---|-----|-----|-----|-----|-----------------------|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| ECG | <p>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.</p> <ul style="list-style-type: none"> • MPM 3.0, N1: supports Mindray Algorithm. • T1, MPM 2.0, and TM80: support Mindray or Mortara algorithm <p>Supports intelligent arrhythmia alarms HR Measurement range: 15~350 bpm (neonate, pediatric), 15~300 bpm (adult); Accuracy: ± 1 bpm or $\pm 1\%$, whichever is greater. ST Measurement range: $-2.0\text{mV}\sim+2.0\text{mV}$; Accuracy: $-0.8\text{mV}\sim+0.8\text{mV}$, $\pm 0.02\text{mV}$ or $\pm 10\%$, whichever is greater, other range: not specified. QT Measurement range: 200~800ms; Accuracy: $\pm 30\text{ms}$. This measurement can be used for adults, pediatrics, and neonates, except that:</p> <ol style="list-style-type: none"> 1. The arrhythmia detection of MPM 3.0 is intended for adult and pediatric patients only; 2. The arrhythmia detection and ST segment analysis of Mortara algorithm in T1, MPM 2.0, and TM80 (T1 is cleared in K190011, MPM 2.0 is cleared in K152902, and TM80 is cleared in K183238) are intended for adult and pediatric patients only; 3. The arrhythmia detection of Mindray algorithm in T1, MPM 2.0, and TM80 is intended for adult and pediatric patients only; 4. The ST Segment analysis of Mindray algorithm in T1, MPM 2.0, and TM80 is intended for adult patients only. | | | | | No change | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|---|--|-----|-----|-----|-----|----------------|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | 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 $\pm 2\%$, 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: $\pm 0.1^\circ\text{C}$ or $\pm 0.2^\circ\text{F}$ (without probe). This measurement can be used for adults, pediatrics and neonates. | | | | | No change | | | | |
| Pulse oxygen saturation (SpO ₂) | Uses the MPM (Multi Parameter Module), T1, N1 or the SpO ₂ Module to measure Pulse oxygen saturation. N Series patient monitors are compatible with the following 3 types of modules to measure oxygen saturation: Mindray SpO ₂ module Measurement range: 0~100 % Accuracy: 70%~100%: $\pm 2\%$ ABS (Adult/pediatric); 70%~100%: $\pm 3\%$ ABS (neonate); 0~69%: not specified. Masimo SpO ₂ module Measurement range: 1~100 %, Accuracy: without motion 70%~100%: $\pm 2\%$ ABS (Adult/pediatric), 70%~100%: $\pm 3\%$ ABS (neonate), 1~69%: not specified; With motion 70%~100%: $\pm 3\%$ ABS, 1~69%: not specified. Nellcor SpO ₂ module Measurement range: 0~100 %, Accuracy: 70%~100% : $\pm 2\%$ ABS (Adult/pediatric); 70%~100% : $\pm 3\%$ ABS (neonate); 0~69%: not specified. 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 K182075 | | | | | Subject Device | | | | |
| Pulse rate (PR) | <p>Pulse rate may be obtained from all sources of SpO₂, or the IBP module.</p> <p>Measurement range: 20~254 bpm (Mindray SpO₂), 25~240 bpm (Masimo SpO₂), 20~300 bpm (Nellcor SpO₂), 25~350 bpm (IBP).</p> <p>Accuracy: ±3 bpm (Mindray SpO₂), ±3 bpm without motion, ±5 bpm with motion (Masimo SpO₂); 20~250 bpm ±3 bpm; 251~300 bpm, not specified (Nellcor SpO₂); ±1 bpm or ±1%, whichever is greater (IBP).</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | | | | | No change | | | | |
| Non-invasive blood pressure (NIBP) | <p>Uses the MPM (Multi Parameter Module), T1 or N1 to measure NIBP. The MPM uses the oscillometric method for measuring non-invasive blood pressure (NIBP).</p> <p>Measurement range:</p> <p>Systolic: 25~290 mmHg (Adult), 25~240 mmHg (Pediatric), 25~140 mmHg (Neonate).</p> <p>Diastolic: 10~250 mmHg (Adult), 10~200 mmHg (Pediatric), 10~115 mmHg (Neonate).</p> <p>Mean: 15~260 mmHg (Adult), 15~215 mmHg (Pediatric), 15~125 mmHg (Neonate).</p> <p>PR: 30~300bpm.</p> <p>Accuracy:</p> <p>NIBP: Max mean error: ±5mmHg; Max standard deviation: 8mmHg.</p> <p>PR: ±3 bpm or ±3%, whichever is greater.</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | | | | | No change | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|---------------------------------|---|-----|-----|-----|-----|---|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Invasive blood pressure (IBP) | <p>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.</p> <p>The IBP supports Pulse Pressure Variation (PPV) and Pulmonary Artery Wedge Pressure (PAWP) function.</p> <p>Measurement range: -50~300mmHg,</p> <p>Accuracy of module: $\pm 2\%$ or $\pm 1\text{mmHg}$, whichever is greater (without sensor)</p> <p>This measurement can be used for adults, pediatrics and neonates except that PAWP is not for neonates.</p> | | | | | No change | | | | |
| Cardiac output (C.O.) | <p>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.</p> <p>Measurement range:</p> <p>C.O. : 0.1~20 L/min.</p> <p>TB: 23~43°C, TI: 0~27°C.</p> <p>Accuracy:</p> <p>C.O.: $\pm 5\%$ or $\pm 0.1\text{L/min}$, whichever is greater.</p> <p>TB, TI: $\pm 0.1^\circ\text{C}$ (without sensor).</p> <p>This measurement can be used for adults.</p> | | | | | No change | | | | |
| Continuous cardiac output (CCO) | <p>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) which measures continuous cardiac output (CCO).</p> <p>This measurement can be used for adults and pediatrics.</p> | | | | | <p>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).</p> <p>This measurement can be used for adults and pediatrics.</p> | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|---|---|-----|-----|-----|-----|---|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Mixed/central venous oxygen saturation (SvO ₂ /ScvO ₂) | <p>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) which measures mixed venous oxygen saturation (SvO₂) and central venous oxygen saturation (ScvO₂).</p> <p>This measurement can be used for adults and pediatrics.</p> | | | | | <p>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 (SvO₂) and central venous oxygen saturation (ScvO₂).</p> <p>This measurement can be used for adults and pediatrics.</p> | | | | |
| Central venous oxygen saturation (ScvO ₂) | <p>Central venous oxygen saturation (ScvO₂) is measured using spectrophotometry.</p> <p>Measurement range: 0 to 99%</p> <p>Accuracy: 50% to 80%: ±3%, Other ranges: Not specified.</p> <p>This measurement can be used for adults and pediatrics.</p> | | | | | <p>No change</p> | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|-----------------------------------|--|-----|-----|-----|-----|----------------|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Carbon dioxide (CO ₂) | <p>CO2 can be measured using the Mindray Sidestream CO2 module, Mindray AG module or third-party CO2 modules, Microstream module and Mainstream module.</p> <p>Type: Sidestream CO2 module.</p> <p>Measurement range: CO2: 0~150mmHg, awRR: 0~150rpm.</p> <p>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),</p> <p>ISO accuracy mode: Add ±2mmHg to the full accuracy mode.</p> <p>awRR: <60rpm, ±1rpm, 60~150rpm, ±2rpm</p> <p>Type: Microstream CO2 module</p> <p>Measurement range: CO2: 0~99mmHg, awRR: 0~150rpm</p> <p>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.</p> <p>Type: Mainstream CO2 module.</p> <p>Measurement range: CO2: 0~150mmHg; awRR: 0~150rpm.</p> <p>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</p> <p>AG module:</p> <p>Measurement range: 0~30%;</p> <p>Accuracy: Full accuracy mode: 0%≤CO2≤1%, ±0.1%ABS, 1%< CO2≤5%, ±0.2% ABS, 5%< CO2≤7%, ±0.3% ABS, 7%< CO2≤10%, ±0.5% ABS, 10%< CO2 not specified,</p> <p>ISO mode: Add ±0.3% ABS.</p> <p>CO2 monitoring is based on calculations that come from measuring the absorption of infrared (IR) light of specific wavelengths using a photodetector.</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | | | | | No change | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|--------------------------|---|-----|-----|-----|-----|----------------|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Oxygen (O ₂) | <p>Oxygen values are measured by the Sidestream CO₂ module or the AG module using a paramagnetic method.</p> <p>Measurement range: 0~100% (CO₂ and AG),</p> <p>Accuracy: 0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3% (CO₂ and AG).</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | | | | | No change | | | | |
| Anesthetic gas (AG) | <p>The AG module analyzes gas samples from the patient and calculates CO₂, O₂, N₂O, and AA waveforms and related numerics that include airway respiratory rate and MAC (minimum alveolar concentration).</p> <p>Measurement range:</p> <p>HAL, ENF, ISO, SEV, DES: 0~30 %,</p> <p>N₂O: 0~100 %;</p> <p>awRR: 2~100 rpm</p> <p>Accuracy:</p> <p>Full accuracy mode:</p> <p>N₂O: 0~20%_{REL}: ±2%_{ABS}, 20~100%_{REL}: ±3%_{ABS};</p> <p>HAL, ENF, ISO: 0~1%_{REL}: ±0.15%_{ABS}, 1~5%_{REL}: ±0.2%_{ABS}, >5%_{REL}, not specified;</p> <p>SEV: 0~1%_{REL}: ±0.15%_{ABS}, 1~5%_{REL}: ±0.2%_{ABS}, 5~8%_{REL}: ±0.4%_{ABS}, >8%_{REL}, not specified;</p> <p>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;</p> <p>awRR: 2~60rpm, ±1rpm, >60rpm, not specified</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | | | | | No change | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|-----------------------------|---|-----|-----|-----------|-----|---|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Impedance cardiograph (ICG) | ICG measures a patient's hemodynamic status using a non-invasive method based on thoracic electrical bioimpedance (TEB) technology. Measurement range: C.O.: 1.4~15L/min; SV: 5~250ml; HR: 44~185bpm. Accuracy: HR: ± 2 bpm; other parameter: not specified. This measurement can be used for adults. | | | | | No change | | | | |
| Bispectral index (BIS) | Not supported | | | | | 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. | | | | |
| Respiration mechanics (RM) | The RM module measures respiration mechanics for adult and pediatric patients. | | | | | No change | | | | |
| | Measurement range: | | | Accuracy: | | | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 | |
|---------|--|-----|-----|-----|-----|---|-----|-----|-----|-----|--|
| | Cleared in K182075 | | | | | Subject Device | | | | | |
| | <p>FLOW: Adult/Pediatric: $\pm(2\sim 120)$L/min; Infant: $\pm(0.5$ to 30) L/min PAW:-20~120 cmH₂O; MVe/MVi: Adult/Pediatric: 2~60L/min; Infant: 0.5 to 15 L/min TVe/TVi: Adult/Pediatric: 100~1500ml; Infant: 0.5 to 15 L/min Calculated Parameters: awRR:4~120rpm; I:E:4:1~1:8; FEV1.0: 0~100%; Pmean:0~120 cmH₂O; PEEP:0~120 cmH₂O; PEF:2~120L/min; PIF:2~120L/min; PIP: 0~120 cmH₂O; Pplat:0~120 cmH₂O; Compl: 0~200ml/ cmH₂O; RSBI:0~4095rpm/L;</p> | | | | | <p>FLOW: Adult/Pediatric: 1.2L/min or $\pm 10\%$ of reading, whichever is greater; Infant: 0.5 L/min or $\pm 10\%$ of the reading, whichever is greater PAW: $\pm 3\%$ of reading; MVe/MVi: $\pm 10\%$ of reading; TVe/TVi: Adult/Pediatric: ± 15ml or $\pm 10\%$ of reading, whichever is greater; Infant: ± 6 ml or $\pm 10\% \times$reading, whichever is greater Calculated Parameters: awRR:4~99rpm: ± 1rpm, 100~120rpm, ± 2rpm; I:E: not specified; FEV1.0: not specified; Pmean: $\pm 10\%$; PEEP: not specified; PEF: $\pm 10\%$; PIF: $\pm 10\%$; PIP: $\pm 10\%$; Pplat: not specified; Compl: not specified; RSBI: not specified;</p> | | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|---|--|-----|-----|-----|-----|----------------|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Neuromuscular transmission monitoring (NMT) | <p>NMT evaluates muscle relaxation of patients under a neuromuscular block by measuring the strength of muscle reaction after electrically stimulating the dedicated motor nerve.</p> <p>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%</p> <p>This measurement can be used for adults and pediatrics.</p> | | | | | No change | | | | |
| Electroencephalograph (EEG) | <p>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).</p> <p>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</p> <p>This measurement is intended to be used for adults, pediatrics and neonates.</p> | | | | | No change | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|--|---|-----|-----|-----|-----|---|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Regional oxygen saturation (rSO ₂) | <p>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.</p> <p>Measurement range: rSO₂: 15~95.</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | | | | | No change | | | | |
| ECG 24h Summary | <p>Provides an option to view a summary of a patient's ECG statistics from the previous 24 hours, including HR statistics, ARR event statistics, max and min ST statistics of each lead, QT/QTc measurement statistics, Pacer statistics (for patients being paced), and typical ECG strips.</p> | | | | | No change | | | | |
| Early Warning Score (EWS) | <p>The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS) and a user configurable Custom Score.</p> | | | | | <p>The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), National Early Warning Score2 (NEWS2), and a user configurable Custom Score.</p> <p>Refer to Section 12.3.6</p> | | | | |
| Glasgow Coma Scale (GCS) | <p>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.</p> | | | | | <p>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.</p> | | | | |
| SepsisSight | <p>The SepsisSight feature is intended to help clinicians recognize the early signs and symptoms of Sepsis based on recommendations from the published literature (Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012 and and The Third International Consensus Definition for Sepsis and Septic Shock (Sepsis-3)).</p> | | | | | <p>The SepsisSight feature is intended to help clinicians recognize the early signs and symptoms of Sepsis based on recommendations from the published literature (Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2016 and and The Third International Consensus Definition for Sepsis and Septic Shock (Sepsis-3))².</p> | | | | |

| Feature | N22 | N19 | N17 | N15 | N12 | N22 | N19 | N17 | N15 | N12 |
|--|--|-----|-----|-----|-----|---|-----|-----|-----|-----|
| | Cleared in K182075 | | | | | Subject Device | | | | |
| Cardio-pulmonary resuscitation (CPR) Dashboard | Records all operations during rescue. The rescue operations recorded can be customized and include treatment (rescue drug input, rescue treatment input, start/end rescue, rescue start condition, rescue end condition). | | | | | No change | | | | |
| Device integration | Support BeneLink Module to connect Anesthesia, Ventilator, Pump, TcGas Monitor Device, and Single Parameter Device. | | | | | Support BeneLink Module to connect Anesthesia, Ventilator, Pump, TcGas Monitor Device, and Single Parameter Device. The types of the devices that can be connected are still only the five types listed above, but some types added newly approved devices. | | | | |
| OxyCRG Function | Support the function of oxygen cardio-respirogram (OxyCRG) when the patient type is neonate, and simultaneously provide real-time OxyCRG interface and OxyCRG review interface to display parameter trends and waveforms | | | | | Support the function of oxygen cardio-respirogram (OxyCRG) when the patient type is neonate, and simultaneously provide real-time OxyCRG interface and OxyCRG review interface to display parameter trends and waveforms, and OxyCRG events. | | | | |
| Security of Patient Information | Support Mindray proprietary encryption algorithm (XOR algorithm) | | | | | Support AES128 encryption algorithm | | | | |
| Accessories | The accessories including ECG, SpO2, Temp, NIBP, IBP, C.O., ScvO2, ICG, CO2, AG, RM, EEG, BIS, NMT, rSO2, CCO/SvO2 accessories. | | | | | Add new ECG, Temp, C.O., and IBP accessories | | | | |

Table 3: Device Comparison Table – N1

| Feature | N1 | N1 |
|---------------------------------|------------------------|----------------|
| | Cleared in K182075 | Subject Device |
| Primary display and touchscreen | 5.5", 720*1280 pixels. | No change |

| Feature | N1 | N1 |
|---|---|---|
| | Cleared in K182075 | Subject Device |
| 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 CO2 module), one rechargeable Lithium-ion battery (with built-in CO2 module), or DC-in power supply. | No change |
| Battery | Chargeable Lithium-ion 7.56VDC, 2500mAh. | Chargeable Lithium-ion 7.2VDC, 2500mAh. |
| Data storage | Embedded Multi Media Card (eMMC) | No change |
| Speaker | Gives alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation. | No change |
| Alarm system | Supports Alarm Volume Escalation. The alarm lamp will light cyan, yellow, or red depending on alarm type. | No change |
| Communication on Interface when N1 is working as a module | Infrared communication interface. Pogo pin communication interface. | No change |

| Feature | N1 | N1 |
|-------------------------|---|----------------|
| | Cleared in K182075 | Subject Device |
| ECG | <p>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.</p> <p>Measurement range: ST: -2.0mV~+2.0mV; QT: 200~800ms; HR: 15~350bpm (neonate, pediatric), 15~300bpm (adult).</p> <p>Accuracy: ST: -0.8mV~+0.8mV, $\pm 0.02\text{mV}$ or $\pm 10\%$, whichever is greater, other range: not specified; QT: $\pm 30\text{ms}$; HR: $\pm 1\text{ bpm}$ or $\pm 1\%$, whichever is greater.</p> <p>This measurement can be used for adults, pediatrics and neonates except for the arrhythmia detection. The arrhythmia detection is intended for adult and pediatric patients only.</p> | No change |
| Respiration rate (Resp) | <p>Measure the respiration waveforms and respiratory rate through trans-thoracic impedance method.</p> <p>Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm.</p> <p>Accuracy: 7 to 150 rpm: $\pm 2\text{ rpm}$ or $\pm 2\%$, whichever is greater; 0 to 6 rpm: Not specified.</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | No change |
| Temperature (Temp) | <p>Measures temperature using the thermal resistance method.</p> <p>Measurement range: 0 to 50°C (32 to 122°F).</p> <p>Accuracy: $\pm 0.1^\circ\text{C}$ or $\pm 0.2^\circ\text{F}$ (without probe).</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | No change |

| Feature | N1 | N1 |
|---|---|----------------|
| | Cleared in K182075 | Subject Device |
| Pulse oxygen saturation (SpO ₂) | <p>Integrates one of the 3 kinds of SpO₂ modules:</p> <p>Mindray SpO₂ module board Measurement range: SpO₂:0~100 %, Accuracy: 70%~100%: ±2% ABS (Adult/pediatric); 70%~100%: ±3% ABS (neonate); 0~69%: not specified.</p> <p>Masimo SpO₂ module board Measurement range: 1~100 %, Accuracy: without motion 70%~100%: ±2% ABS (Adult/pediatric), 70%~100%: ±3% ABS (neonate), 1~69%: not specified; With motion 70%~100%: ±3% ABS, 1~69%: not specified.</p> <p>Nellcor SpO₂ module board Measurement range: SpO₂:0~100 %, Accuracy: SpO₂:70%~100%: ±2% ABS (Adult/pediatric); 70%~100% : ±3% ABS (neonate); 0~69%: not specified.</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | No change |
| Pulse rate (PR) | <p>Obtains pulse rate from SpO₂ or IBP.</p> <p>Measurement range: 20~254bpm (Mindray SpO₂), 25~240bpm (Masimo SpO₂), 20~300bpm (Nellcor SpO₂), 25~350bpm (IBP).</p> <p>Accuracy: ±3 bpm (Mindray SpO₂), ±3 bpm without motion, ±5 bpm with motion (Masimo SpO₂); 20~250bpm ±3 bpm; 251~300bpm, not specified (Nellcor SpO₂); ±1 bpm or ±1%, whichever is greater (IBP).</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | No change |

| Feature | N1 | N1 |
|------------------------------------|--|----------------|
| | Cleared in K182075 | Subject Device |
| Non-invasive blood pressure (NIBP) | <p>The N1 uses the oscillometric method for measuring non-invasive blood pressure (NIBP).</p> <p>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 $\pm 3\%$, whichever is greater. This measurement can be used for adults, pediatrics, and neonates.</p> | No change |
| Invasive blood pressure (IBP) | <p>The monitor can monitor up to 2 invasive blood pressures and displays the systolic, diastolic, and mean pressures and a waveform for each pressure.</p> <p>The IBP supports Pulse Pressure Variation (PPV) and Pulmonary Artery Wedge Pressure (PAWP) function.</p> <p>Measurement range: -50~300mmHg.</p> <p>Accuracy: $\pm 2\%$ or ± 1mmHg, whichever is greater (without sensor).</p> <p>This measurement can be used for adults, pediatrics and neonates except that PAWP is not for neonates.</p> | No change |

| Feature | N1 | N1 |
|----------------------|---|----------------|
| | Cleared in K182075 | Subject Device |
| Carbon dioxide (CO2) | <p>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.</p> <p>Type: Sidestream CO2 module</p> <p>Measurement range:</p> <p>CO2 :0~150mmHg, awRR: 0~150rpm.</p> <p>Accuracy:</p> <p>CO2: Full accuracy mode: 0~40 mmHg: ± 2mmHg, 41~76 mmHg: $\pm 5\%$ of reading, 77~99 mmHg: $\pm 10\%$ of reading, 100~150mmHg: $\pm (3$mmHg + 8% of reading), ISO accuracy mode: Add ± 2mmHg to the full accuracy mode</p> <p>awRR: < 60rpm, ± 1rpm, 60~150rpm, ± 2rpm.</p> <p>Type: Microstream CO2 module</p> <p>Measurement range:</p> <p>CO2 :0~99mmHg, awRR: 0~150rpm.</p> <p>Accuracy:</p> <p>CO2: 0~38mmHg: ± 2mmHg; 39~99mmHg: $\pm 5\%$ of the reading+0.08% of (the reading-38).</p> <p>awRR: 0~70rpm: ± 1rpm, 71~120rpm: ± 2rpm, 121~150rpm: ± 3rpm.</p> <p>Type: Mainstream CO2 module</p> <p>Measurement range: CO2 :0~150mmHg; awRR: 0~150rpm.</p> <p>Accuracy:</p> <p>CO2: 0~40mmHg: ± 2mmHg, 41~70mmHg: $\pm 5\%$ of the reading, 71~100mmHg: $\pm 8\%$ of the reading, 101~150mmHg: $\pm 10\%$ of the reading;</p> <p>awRR: ± 1rpm.</p> <p>CO2 monitoring is based on calculations that come from measuring the absorption of infrared (IR) light of specific wavelengths using a photodetector</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | No change |

| Feature | N1 | N1 |
|------------------------------------|---|--|
| | Cleared in K182075 | Subject Device |
| Oxygen (O2) | <p>Oxygen values are measured by the Sidestream CO2 (only for external Sidestream CO2 2.0 module) module using a paramagnetic method.</p> <p>Measurement range: O2: 0~100%</p> <p>Accuracy: 0~25%, ±1%; 26~80%, ±2%; 81~100%, ±3%.</p> <p>This measurement can be used for adults, pediatrics and neonates.</p> | No change |
| Dock, Rack and Transport Dock | <p>The Dock is used to connect either the N1 without a Rack or the N1 docked inside a Rack, in order to extend ports such as USB, VGA, or wired network.</p> <p>The Rack can connect an external parameter module, such as CO2, to N1.</p> <p>The Transport Dock is used to provide DC voltage to N1 when N1 is used for out-of-hospital transportation on the ambulance vehicle or aircraft. The Transport Dock is fixed on the ambulance vehicle or aircraft and converts an AC input to DC output.</p> | No change |
| Wireless radio module | The Wireless radio module is used for connecting to a wireless monitoring network with a central monitoring system (CMS). | No change |
| Helicopter and ambulance transport | ECG, RESP, Temp, SpO2, PR, NIBP, and IBP can be monitored in helicopters and ambulances. | No change |
| Early Warning Score (EWS) | The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS) and a user configurable Custom Score. | The EWS is a set of early warning scores that are intended to assist clinicians in recognizing the early signs of deterioration in patients based on vital signs and clinical observations. The three types of EWS provided are Modified Early Warning Score (MEWS), National Early Warning Score (NEWS), National Early Warning Score2 (NEWS2) , and a user configurable Custom Score. |
| Glasgow Coma Scale (GCS) | The GCS a well-established scoring system used to assess the state of consciousness based three sub-components: eye-opening response, verbal response, and limb movement. | No change |

| Feature | N1 | N1 |
|--|--|---|
| | Cleared in K182075 | Subject Device |
| Cardio-pulmonary resuscitation (CPR) Dashboard | Records all operations during rescue. The rescue operations recorded can be customized and include treatment (rescue drug input, rescue treatment input, start/end rescue, rescue start condition, rescue end condition). | No change |
| OxyCRG Function | Support the function of oxygen cardio-respirogram (OxyCRG) when the patient type is neonate, and simultaneously provide real-time OxyCRG interface and OxyCRG review interface to display parameter trends and waveforms | Support the function of oxygen cardio-respirogram (OxyCRG) when the patient type is neonate, and simultaneously provide real-time OxyCRG interface and OxyCRG review interface to display parameter trends and waveforms, and OxyCRG events. |
| Security of Patient Information | Support Mindray proprietary encryption algorithm (XOR algorithm) | Support AES128 encryption algorithm |
| Accessories | The accessories including ECG, SpO2, Temp, NIBP, IBP, C.O., ScvO2, ICG, CO2, AG, RM, EEG, BIS, NMT, rSO2, CCO/SvO2 accessories. | Add new ECG, Temp, C.O., and IBP accessories |

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 or 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 62133-2:2017 Secondary cell and batteries containing alkaline or other non-acid electrolytes – safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: lithium systems.

Bench Testing

To establish the substantial equivalence of the BeneVision N Series Patient Monitors, Mindray conducted functional and system level testing to validate the performance of the devices. The

results of the bench testing show that the subject device meets its accuracy specification and is substantially equivalent to the predicate device.

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

- IEC 60601-2-26:2012 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

9. CONCLUSION

Based on the detailed comparison of specifications for each of the modifications to the previously cleared BeneVision N Series Patient Monitors (K182075), 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.