July 31, 2023

Nihon Kohden Corporation
% Sandra Gadeyne
Sr. Director, Quality and Regulatory Affairs
Nihon Kohden America
15353 Barranca Pkwy
Irvine, California 92618

Re: K223567
Trade/Device Name: CNS-2101 Central Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, MHX, DRQ, MWI
Dated: November 29, 2022
Received: November 29, 2022

Dear Sandra Gadeyne:

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,

Shruti N. Mistry -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*
K223567

Device Name
CNS-2101 Central Monitor

Indications for Use *(Describe)*
The CNS-2101 central monitor is a networked multi-patient monitoring system, that is intended to display, record and print monitored physiological data from Nihon Kohden bedside monitors, telemetry receiver and/or transmitters.
The CNS-2101 does not perform any data processing on the data received from the Nihon Kohden compatible devices.
When the CNS-2101 is to connect with the Nihon Kohden bedside monitors and telemetry receivers/transmitters the CNS-2101 can:
• Admit and discharge patients on the Nihon Kohden network.
• Display and manage compatible devices' real-time patient clinical data.
• Mimic the alarms of connected devices when a measured parameter falls outside a preset limits or when an arrhythmia is detected.
• Review and trend data calculated by connected Nihon Kohden devices.
• Store and transfer historical clinical data for the connected systems.
• Print patient data.
The CNS-2101 is intended for use in professional medical facilities by trained medical personnel.

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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# 1. 510(K) SUMMARY GENERAL PROVISIONS

**Table 1 Administrative Information**

| | |
|---|---|
| **Sponsor** | Nihon Kohden Corporation<br>1-31-4 Nishiochiai, Shinjuku-Ku<br>Tokyo, Japan 161-8560 |
| **Initial Importer** | Nihon Kohden America<br>15353 Barranca Parkway<br>Irvine, CA |
| **Company Representative/U.S. Agent** | Sandra Gadeyne, MBA, ASQ-CQA<br>Sr. Director, Quality Assurance and Regulatory Assurance<br>15353 Barranca Parkway<br>Irvine, CA<br>Office Phone: (949) 268-7708<br>Mobile Phone: (949) 356-3401<br>Email: Sandra_Gadeyne@nihonkohden.com |
| **Official Correspondent/Primary Contact** | Hiroko Hagiwara<br>General Manager, Clinical Development and Regulatory Affairs Division, NIHON KOHDEN CORPORATION<br>Office Phone: +81-3-5996-8156<br>Mobile Phone: +81-70-5541-9661<br>Email: Hiroko_Hagiwara@mb2.nkc.co.jp |

**Table 2 Submission Information**

| | |
|---|---|
| **Submission Type** | Traditional 510(k) |
| **Common Device Name** | System, Network and Communication, Physiological Monitor |
| **Regulation Medical Specialty** | Cardiovascular |
| **Classification Panel** | Cardiovascular |
| **Product Codes** | MSX |
| **Premarket Review** | Cardiovascular Devices (OHT2)<br>Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A) |
| **Regulation Number** | 870.2300 |
| **Classification** | Class II |
| **Decision Type** | 510(k) |
| **Proprietary Name** | CNS-2101 Central Monitor |
| **Marketing Names** | CNS-2101, CNS-2101 Central Monitoring System |
| **Submission Basis** | New Device; |
| **Previous 510(k) Submissions** | None |
| **Predicates** | BeneVision Central Monitoring System (K193391) |
| **Date Prepared** | November 29, 2022 |

# 2. PRODUCT DESCRIPTIONS

The CNS-2101 central monitor is a central monitoring device designed to support medical personnel to provide medical care to multiple patients at the same time. It acquires vital sign data from multiple

monitoring devices such as bedside monitors and displays the acquired data such as ECG and pulse rate on the screen as well as informing alarms.

The CNS-2101 can communicate with other devices through a network connection. The CNS-2101 can acquire vital sign data directly from multiple monitoring devices (e.g., bedside monitors) connected to Nihon Kohen Monitoring device network or using multiple patient receivers and transmitters, or by a combination of both methods. The parameters to monitor on the central monitor can be changed as necessary by selecting a monitoring device such as a bedside monitor or transmitter and changing the parameter settings for that device.

The CNS-2101 is designed to be installed in a location outside the patient environment such as a nurse's station for central monitoring.

## 3. INDICATIONS FOR USE/INTENDED USE

The CNS-2101 central monitor is a networked multi-patient monitoring system, that is intended to display, record and print monitored physiological data from the Nihon Kohden bedside monitors, telemetry receiver and/or transmitters.

The CNS-2101 does not perform any data processing on the data received from the Nihon Kohden compatible devices. When the CNS-2101 is to connect with the Nihon Kohden bedside monitors and telemetry receivers/transmitters, the CNS-2101 can:

- Admit and discharge patients on the Nihon Kohden network.
- Display and manage compatible devices' real-time patient clinical data.
- Mimic the alarms of connected devices when a measured parameter falls outside a preset limit or when an arrhythmia is detected.
- Review and trend data calculated by connected Nihon Kohden devices.
- Store and transfer historical clinical data for the connected systems.
- Print patient data.

The CNS-2101 is intended for use in professional medical facilities by trained medical personnel.

## 4. SUBMISSION SCOPE

Nihon Kohden (NK) is requesting market clearance for the CNS-2101 and accessories. The accessories include software licenses, peripheral devices and networking materials. The CNS-2101 communicates with other NK devices on the NK network (NET-9). The previously cleared devices compatible with the CNS-2101 are provided in Table 3.

**Table 3 NK Compatible Devices**

| Device name | Product code | 510(k) number | Clearance date |
|---|---|---|---|
| Life Scope® BSM-1700 Series Bedside Monitor | MHX | K220976 | July 21, 2022 |
| Life Scope® BSM-6000 Bedside Monitoring System | MHX | K213316 | Dec 29, 2021 |
| Life Scope® BSM-3000 Bedside Monitor | MHX | K213316 | Dec 29, 2021 |
| Life Scope® CSM-1901 Bedside Monitoring System | MHX | K213316 | Dec 29, 2021 |
| Life Scope® G5 Bedside Monitoring System | MHX | K203435 | July 16, 2021 |
| Life Scope® G7 Bedside Monitoring System | MHX | K203435 | July 16, 2021 |
| Nihon Kohden CNS-6200 Series CNS Mode1-6201/6801 | MHX | K102376 | Dec. 7, 2010 |

| Device name | Product code | 510(k) number | Clearance date |
|---|---|---|---|
| Nihon Kohden SVM-7200 series Vital Signs Monitor | MWI | K190468 | May 28, 2019 |
| Nihon Kohden Vital Sign Telemeter GZ-140P | MHX/DRG | K163459 | Apr. 4, 2017 |
| Nihon Kohden Vital Sign Telemeter, GZ-120P/GZ-130P | MHX/DRG | K153707 | Sept. 2, 2016 |
| Transmitter ZS-940PA Series, ZM 520/521/530/531 | DRT | K043517 | Feb. 3, 2005 |
| Multiple Patient Receiver, Model ORG-9700/9100A | DRG | K071058 | June 29, 2007 |

# 5. COMPARISON WITH THE PREDICATE DEVICE

## 5.1 Subject Device Information

Table 4 provides the regulations that the CNS-2101 is the subject device. with the product code MSX

**Table 4 Regulatory Information on CNS-2101**

| Regulation No | Product code | Device classification | Classification |
|---|---|---|---|
| § 870.2300 | MSX | System, Network and Communication, Physiological Monitors | Class II (performance standards) |

## 5.2 Predicate Device Information

Table 5 lists the basic information about the predicate device including 510(k) number, device trade name, 510(k) holder, and clearance date. Regulatory information used for comparison is provided in Table 6.

**Table 5 Predicate Device General Information**

| 510(k) product | 510(k) holder | Clearance date |
|---|---|---|
| BeneVision Central Monitoring System (K193391) | Shenzhen Mindray Bio-medical Electronics Co., LTD. | 22 April, 2020 |

**Table 6 Predicate Device Regulatory Information**

| Regulation No | Product code | Device classification | Classification |
|---|---|---|---|
| §870.2300 | MSX | System, Network and Communication, Physiological Monitors | Class II (performance standards) |

## 5.3 Comparison Table

**Table 7 Comparison Table of CNS-2101 Central Monitor and its Predicate**

| Characteristics | CNS-2101 Central Monitor (Proposed device) | BeneVision Central Monitoring System (Predicate Device: K193391) | Comparison |
|---|---|---|---|
| **Regulation items** | | | |
| Classification Panel | Cardiovascular | Cardiovascular | Same |
| Device Name | System, Network And Communication, Physiological Monitors | System, Network And Communication, Physiological Monitors | Same |
| Regulatory Class | Class II (performance standards) | Class II (performance standards) | Same |
| Regulatory Number | 21CFR 870.2300- Cardiac monitor (including cardiotachometer and rate alarm) | 21CFR 870.2300 -Cardiac monitor (including cardiotachometer and rate alarm) | Same |
| Product Code | Primary Product Codes:<br>MSX - System, network and communication, physiological monitors<br><br>Subsequent Product Codes:<br>MHX- Monitor, physiological, patient (with arrhythmia detection or alarms)<br>DRQ- Amplifier and signal conditioner, transducer signal<br>MWI- Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) | Primary Product Codes:<br>MSX - System, network and communication, physiological monitors<br><br>Subsequent Product Codes:<br>DRQ- amplifier and signal conditioner, transducer signal<br>MHX- monitor, physiological, patient (with arrhythmia detection or alarms)<br>DRT- monitor, cardiac (incl. cardiotachometer & rate alarm)<br>DXN- system, measurement, blood pressure, non-invasive<br>DQA- Oximeter<br>DSB- Impedance plethysmograph | Both devices share the same MSX primary code and performance specifications.<br><br>The subsequent (secondary) product codes are related to the type of the devices the CNS-2101 can connect to. The NK systems were cleared with the additional secondary codes. |

| Characteristics | CNS-2101 Central Monitor (Proposed device) | BeneVision Central Monitoring System (Predicate Device: K193391) | Comparison |
|---|---|---|---|
| Indications for use | The CNS-2101 central monitor is a networked multi-patient monitoring system, that is intended to display, record and print monitored physiological data from Nihon Kohden bedside monitors, telemetry receiver and/or transmitters. The CNS-2101 does not perform any data processing on the data received from the Nihon Kohden compatible devices. When the CNS-2101 is to connect with the Nihon Kohden bedside monitors and telemetry receivers/transmitters the CNS-2101 can:<br>• Admit and discharge patients on the Nihon Kohden network.<br>• Display and manage compatible devices' real-time patient clinical data.<br>• Mimic the alarms of connected devices when a measured parameter falls outside a preset limits or when an arrhythmia is detected.<br>• Review and trend data calculated by connected Nihon Kohden devices.<br>• Store and transfer historical clinical data for the connected systems.<br>• Print patient data.<br>The CNS-2101 is intended for use in professional medical facilities by trained medical personnel. | The indications for use of the BeneVision Central Monitoring System include:<br>• Real time viewing of patient clinical data and alarms<br>• Storage and historical review of patient clinical data and alarms<br>• Printing of real time and historical patient data<br>• Configuration of local settings as well as synchronizing settings across the network to a remote device<br>• Transfer of patient clinical data and settings between several CentralStations<br>The BeneVision Central Monitoring System is a networked patient monitoring system intended for use in a fixed location, installed in professional healthcare facilities to provide clinicians remote patient monitoring. The network connections between the various devices can be any combination of Ethernet (Wired), Wireless WIFI (WLAN), and Wireless WMTS. The BeneVision Central Monitoring System supports one or more Mindray<br>compatible physiological monitors and will display, store, print, and transfer information received from the compatible monitors; The BeneVision Central Monitoring System supports bi-directional configuration of the compatible monitors. No data processing is done by the BeneVision Central Monitoring System for data received from compatible monitors. | Same - Both devices are compatible with their commercial monitoring devices. The BeneVision includes additional devices; the NK's systems are cleared under a separate 510(k) and is equivalent in terms of functions. |

| Characteristics | CNS-2101 Central Monitor (Proposed device) | BeneVision Central Monitoring System (Predicate Device: K193391) | Comparison |
|---|---|---|---|
| | | The telemetry monitoring systems are designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The BeneVision Central Monitoring System supports Telemetry Systems: TMS-6016, Telepack-608, TMS60, TM80, and TM70.<br>• The TMS-6016 transmitter is intended for use on Adult and Pediatric patients to monitor ECG and SpO2 physiological data.<br>• The Panorama Telepack-608 transmitter is intended for use on Adult patients to monitor ECG and SpO2 physiological data.<br>• The TMS60 transmitter is intended for use on Adult and Pediatric patients over three years old to monitor ECG, SpO2, NIBP and Resp physiological data. The physiological data can be reviewed locally on the display of the transmitter.<br>• The CentralStation will support ECG, Heart Rate, SpO2, NIBP, Resp, Pulse Rate, Arrhythmia analysis, QT monitoring, and<br>• ST Segment Analysis for the TMS60.<br>• The TM80/TM70 telemetry monitor is intended for use on Adult and Pediatric patients over three years old to monitor ECG, SpO2, NIBP and Resp physiological data. The physiological data can be analyzed, alarmed, stored, reviewed locally on the display of the monitor, and the CentralStation can configure and display the physiological parameters from the TM80/TM70.<br>The BeneVision Central Monitoring System is intended for use in professional healthcare facilities under the direct supervision of a licensed healthcare practitioner. | |

| Characteristics | CNS-2101 Central Monitor (Proposed device) | BeneVision Central Monitoring System (Predicate Device: K193391) | Comparison |
|---|---|---|---|
| **Hardware** | | | |
| Display | 1,920× 1,080 resolution<br>23.8-inch color TFT type LCD | 1920 x 1080 resolution,<br>19” 16:9 widescreen<br>LCD display, 21.5” and 23” | The BeneVision offers 2 sizes; the CNS-2101 is offered as 1 size that is equivalent to the BeneVisions larger size and is an LCD screen. The difference is minor. |
| Operation system | Microsoft Windows 10 IoT<br>(Embedded) | Microsoft Windows 7 Professional<br>Embedded SP1<br>Microsoft Windows 10 | Both devices support the current version of Windows 10. MS is no longer supporting Window 7. The difference does not affect their substantial equivalence. |
| Storage media | 480 GB SSD (Solid State Drive) | 500 GB Hard Disk Drive | Both devices have storage capacity. The difference does not affect their substantial equivalence. |
| Monitor design | PC Integrated main unit and display<br>Into 1 device | PC unit and display are separated | The CNS-2101 has an integrated design. Both devices are compliant with IEC 60601-1:2005+A1:2012. The difference does not affect their substantial equivalence. |
| USB ports | 5 | 2 | The CNS-2101 has an integrated design. Both devices are compliant with IEC 60601-1:2005+A1:2012. The difference does not affect their substantial equivalence. |
| USB lockout | Yes | Unknown | The additional USB port lockout is a cybersecurity enhancement and does not affect the performance of the device. |
| Audio | Built-in speakers | Built-in speakers | Same |
| **Operation Methods** | | | |
| Touchscreen | Yes | Yes | Same |
| Keyboard | Yes | Yes | Same |
| Mouse | Yes | Yes | Same |
| Thermal array recorder compatible | Yes-Nihon Kohden WS-140P Recorder Unit | Yes-Mindray thermal array module product | Same - Both devices use thermal recorders. |

| Characteristics | CNS-2101 Central Monitor (Proposed device) | BeneVision Central Monitoring System (Predicate Device: K193391) | Comparison |
|---|---|---|---|
| Installation method | Stand / Wall mount | Stand only | The CNS-2101 can be wall mounted or be free standing on a desk. The BeneVision is only offered as a free standing device. The difference does not affect their substantial equivalence. |
| Power source | AC Power Supplied | AC Power Supplied | Same |
| Power interruption support | Yes- Internal battery (3-minute backup) | Yes- UPS | Both devices have a battery backup system. |
| Network | Yes (NK Network) | Yes | Same |
| Compatible monitoring systems | NK Bedside Monitors (MHX):<br>BSM: 1700, 3000, 6000, G9, G5, G7<br>Vital Signs Monitor (MWI): SVM-7200<br>NK Telemetry (MHX/DRG): GZ-120/130/140<br>Multiple Patient Receiver and Transmitters<br>(DRG): ORG-9700/9100<br>(DRT): ZS-940, ZM-520/521/530/531<br>Central Monitor (MHX): CNS- 6201 and 6801 | Supports the following telemetry systems that included its premarket notification scope:<br>− TMS-6016 (K162607)<br>− TMS60 (K162607)<br>− Telepack-608 (K162607)<br>− TM80(K162607)<br>− TM70(K193391) | Same - The CNS-2101 communicates with other monitoring systems within the manufacturer's product portfolio. |
| Extended display | Yes | Yes | Same |
| Max connections are supported for one central station | Up to 32 | Up to 32 | Same |
| Communication protocol (and compatible monitors) | NET-9/LS-NET communication | CMS+ protocol<br>ELAN protocol<br>MD2 protocol | Same - Both devices use a communication protocol to communicate between devices on the network. |
| Output to EMR | Yes | Yes | Same |
| Serial data output capable | Yes | Yes | Same |
| **Display** | | | |
| Wave display | Yes | Yes | Same |
| Numeric display | Yes | Yes | Same |

| | | | |
|---|---|---|---|
| **Patient Admit/Discharge** | | | |
| Patient admit/discharge/transfer | Following functions are supported<br>• Admit, discharge, pause, and transfer functions<br>• Patient transfer within one central station<br>• Patient transfer between central stations<br>• Entering patient information (Manual, Auto) | Following functions are supported<br>• Admit, discharge, pause, and transfer functions<br>• Patient transfer within one central<br>• Patient transfer between central stations<br>• Entering patient information (Manual, Auto) | Same |
| **Review window** | | | |
| Review windows | • Trend window<br>• Tabular Trend window<br>• Full Disclosure window<br>• Expanded Waveform window<br>• Arrhythmia Recall window<br>• ST Recall window<br>• Event List window<br>• Alarm Events window<br>• ECG 12 Lead Analysis window<br>• Hemodynamics List window<br>• SpO2 Trend window | • Minitrend<br>• Trend review<br>• Full disclosure<br>• C.O. review<br>• NIBP review<br>• Event review<br>• OxyCRG review<br>• Historic review<br>• 12-lead Review<br>• ST review | Same - Both devices can connect and display monitored parameters. The viewable data points are similar on each of the monitoring system. |
| Review history | • Trendgraph data: 120 hours<br>• Tabular trend data: 120 hours<br>• Full disclosure and expanded waveform data: 120 hours<br>• Arrhythmia recall data: 1,500 files<br>• Event list data: 10,000 files<br>• Alarm events data: 120 files<br>• ECG 12 lead analysis data: 200 files<br>• ST recall data: 120 files<br>• Hemodynamics list data: 256 files<br>• $SpO_2$ trendgraph data: 120 hours | • Dynamic short trend: 8 hours<br>• Trend review: 240 hours<br>• Wave review: 240 hours of full-disclosure waveforms and compressed waveforms<br>• NIBP review: Most recent 3000 NIBP measurements<br>• Event review: 3000 events<br>• 12-lead review: 720 12-lead analysis results, 12 analysis waveforms for each analysis result<br>• ST review: Most recent 240 hours of ST segments<br>• Cardiac output review: 720 measurements | Same - Both devices provide review history data on the central monitor system each of the system can store data. The differences do not affect their substantial equivalence. |
| **Alarm** | | | |
| Compliance standard | IEC 60601-1-8: 2012 | IEC 60601-1-8: 2012 | Same |
| Setting alarm priorities | Bedside monitor: No<br>Telemetry system and transmitter: Yes | Yes (For telemetry system) | Same |

| | | | |
|---|---|---|---|
| **Silence Alarm** | **Yes** | **Yes** | **Same** |
| **Printing and Recording** | | | |
| Print | Patient information (Hospital Name, Bed name, Patient name)<br>Recording start time or file creation date and time<br>Recording type (Multiple Waveform, Expanded Waveform, Trend, Tabular Trend, Full Disclosure, Arrhythmia Recall, ST Recall, Event List, Alarm Event, ECG 12 Lead Analysis, Hemodynamics List) and Review window parameters<br>• Trend window<br>• Tabular Trend window<br>• Full Disclosure window<br>• Expanded Waveform window<br>• Arrhythmia Recall window<br>• ST Recall window<br>• Event List window<br>• Alarm Events window<br>• ECG 12 Lead Analysis window<br>• Hemodynamics List window<br>• SpO2 Trend window | Patient information, real-time waveform, real-time alarm, Alarm Settings, Multilead ECG Report, CSA Report, waveform review, Arrhythmia Statistic Result, Trend Review, C.O. measurement, events, 12-lead Review, ST review, QT View Report, drug calculations, hemodynamics calculations, oxygenation calculations, ventilation calculations, renal calculations, ICG hemodynamic parameter, CCO hemodynamic parameter, SvO2/ScvO2 oxygenation parameters | Same - Both devices are capable of printing to an external network printer. |
| Recording | Patient information (Hospital name, Bed name, Patient name)<br>Recording start time or file creation date and time<br>Recording type (Multiple Waveform, Expanded Waveform, Trend, Tabular Trend, Full Disclosure, Arrhythmia Recall, ST Recall, Event List, Alarm Event, ECG 12 Lead Analysis, Hemodynamics List)<br><br>Recording duration, Recording speed (25 or 50 mm/s), Numeric data, Waveforms (up to 16 channels), Sensitivity, Lead Waveform Printing | Patient information, real-time waveform, real-time alarm, waveform review, C.O. measurement, events, 12-lead Review, ST review, drug calculation, hemodynamics calculations, oxygenation calculations, ventilation calculations, renal calculations, ICG hemodynamic parameter, CCO hemodynamic parameter, SvO2/ScvO2 oxygenation parameters | Same - Both devices are capable of printing on a thermal printer when the parameters fall outside the limits. |
| **ECG features** | | | |
| ECG functions display | Yes | Yes | This item does not affect the substantial equivalence at the |
| HR display | Yes | Yes | |

| | | | |
|---|---|---|---|
| ST alarm page settings | Upper Limit: OFF, −1.99 to 2.00 mV<br>Lower Limit: OFF, −2.00 to 1.99 mV | Range: -2.0 to 2.0 mV | point that the central monitor itself does not perform vital sign measurements or data processing. |
| ST segment analysis display | Yes | Yes | |
| Arrhythmia detection display | Yes | Yes | |
| Arrhythmia analysis setting | Yes | Yes | |
| QTc/QRSd display | Spot check and continuous<br>When connected to BSM-1700, G5 and G7 | Yes | |
| QRS Detection display | Yes | Yes | |
| Pace pulse rejection (Display) | Yes | Yes | |

# 6. PERFORMANCE DATA

## 6.1 Summary of Non-Clinical Performance Testing

NK conducted non-clinical verification and validation testing for the CNS-2101. These tests were performed on the CNS-2101 according to the international and FDA-recognized consensus standards listed below. All function in the CNS-2101 have been validated by the FDA-recognized consensus standards, therefore, the validity of the results can be ensured.

**Table 8 Applied Standards and Guidance List for CNS-2101**

| Recognition number | **D**escription |
|---|---|
| Standard | |
| 5-125 | ISO 14971 :2019 Medical devices - Application of risk management to medical devices |
| 13-79 | IEC 62304:2006/A1:2015 Medical device software -Software life cycle processes |
| 19-4 | ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010 /(R)2012 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance |
| 19-8 | IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests |
| 5-76 | IEC 60601-1-8: 2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| 3-126 | IEC 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment |
| 5-114 | ANSI/AAMI/IEC 62366-1:2015, Medical devices –Part 1: Application of usability engineering to medical devices. |
| Guidance | |
| | “General Principles of Software Validation” Document issued on: January 11, 2002 |
| | “Content of Premarket Submissions for Software Contained in Medical Devices.” Document Issued on May 11, 2005 |
| | Draft Guidance “Content of Premarket Submissions for Device Software Functions” Document Issued on November 4, 2021 |
| | “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” Document Issued on October 2, 2014. |
| | Draft Guidance “Cybersecurity in Medical devices: Quality System Considerations and Contents of Premarket Submissions.” Document Issued on April 8, 2022. |
| | “Postmarket Management of Cybersecurity in Medical Devices” Document Issued on December 28, 2016 |
| | “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” Document issued on September 6, 2017 |
| | “Off-The-Shelf Software Use in Medical Devices” Document Issued on September 27, 2019. |
| | “Electromagnetic Compatibility (EMC) of Medical Devices” Document issued on June 6, 2022. |
| | “Applying Human Factors and Usability Engineering to Medical Devices” Document issued on: February 3, 2016 |

The functionality and technical characteristics of the CNS-2101 have been verified and validated by testing based on the above FDA-recognized standards and FDA guidance.

## 6.2 Substantial Equivalence Discussion

The comparison of the CNS-2101 central monitor to its predicate device (BeneVision / K193391) and the discussion of the key aspects are presented in the following sections.

### 6.2.1 Discussion for Intended Use/Indications for Use

The predicate and subject devices share the following general functions.

- Real-time viewing of measured patient clinical data.
- Receiving alarm indications and generating an alarm including vital sign alarm, arrhythmia alarm and technical alarm.
- Review and trend application data calculated by connected monitoring devices.
- Configuration settings for connected monitoring devices.
- Connections to other systems not associated with active patient monitoring, such as information systems.
- Storage and Historical review of patient clinical data and alarms.
- Printing of real time and historical patient data.

The design verification and validation procedure confirmed for the operation of the software and hardware of the device is in accordance to the design specifications.
Therefore, based on the above, Nihon Kohden believes that the CNS-2101 central monitor is substantially equivalent to the predicate device.

### 6.2.2 Discussion for Technological Difference

This section provides description for two minor technical differences between the CNS-2101 and the BeneVision.

The following two minor hardware differences between the CNS-2101 and the BeneVision are not considered significant.

- The CNS-2101 PC main unit and display are integrated into one unit.
- The CNS-2101 operates on AC power, but has a built-in sub-battery for use in the event of a sudden loss of power, such as a power interruption.

Electrical safety and Electromagnetic compatibility tests etc. were conducted in consideration of the CNS-2101's built-in battery of the CNS-2101. It was concluded that their hardware differences do not raise concerns about the effectiveness and safety of the CNS-2101 as compared to the predicate device.

### 6.2.3 Submission Scope (Presence or Absence of Monitoring Device)

In contrast to the predicate device, the CNS-2101 does not include a vital sign measuring device in the scope of its premarket notification. The CNS-2101 is a networked device that receives and displays vital signs measured by the Nihon Kohden 510(k)-cleared vital signs monitoring devices through the network. Tests conducted within the software development cycle demonstrate that communication between the CNS-2101 and the Nihon Kohden 510(k)-cleared monitoring devices is robust and stable enough to exchange accurate physiological data in real time. Therefore, this difference in the scope of submission does not affect its effectiveness and safety as compared to the predicate device.

## 6.3 CONCLUSION

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety, and electromagnetic compatibility, software verification, and validation demonstrate that the CNS-2101 does not raise concerns regarding its safety and effectiveness compared to its predicate device and operates in accordance with claimed indications for use.