



June 5, 2025

Nihon Kohden Digital Health Solutions, LLC
Arthur Webb
Director Software Quality
14 Bunsen
Irvine, California 92618

Re: K242750

Trade/Device Name: Central Station
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: May 2, 2025
Received: May 2, 2025

Dear Arthur Webb:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. Shih -S

Jennifer 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

Indications for Use

Submission Number (if known)

K242750

Device Name

Central Station

Indications for Use (Describe)

Central Station is a network device, intended to display, record and print monitored physiological data from Nihon Kohden bedside monitors, telemetry receiver and/or transmitters.

Central Station does not perform any data processing on the data received from the Nihon Kohden compatible devices. When Central Station is connected with the Nihon Kohden bedside monitors and telemetry receivers/transmitters the Central Station can:

- Admit and discharge patients on the Nihon Kohden network.
- Display and manage compatible devices' real-time patient clinical data, vital signs, alarms and waveforms.
- Review and trend data calculated by connected Nihon Kohden devices.
- Store and transfer historical clinical data for the connected systems.
- Print patient data.

Central Station 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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510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance

21 CFR §807.92.

SUBMITTER:

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Preparation date: May 02, 2025

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Device:

Device Name: Central Station
Device Common Name: System, Network and Communication, Physiological Monitor
Proprietary Name: Central Station
Marketing Names: Central Station
Regulation Medical Specialty: Cardiovascular
Classification Panel: Cardiovascular
Regulation Number: 870.2300
Device Class: II
Submission Type: 510(k)
Product Code: MSX
Subsequent Product Codes: DRQ, MHX, MWI
Premarket Review: Office of Cardiovascular Devices (OHT2),
Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A)
Submission Basis: New Device
Previous 510(k) submissions: None
Submission Date: May 02, 2025

Predicate device:

Device Trade Name: CNS – 2101 Central Monitor
510(k) Number: K223567

Nihon Kohden Digital Health
Solutions
Proprietary and Confidential

DEVICE DESCRIPTION

Central Station is software only product that is installed on a Commercial Off the Shelf (COTS) Computer.

Central Station displays waveforms data and numerical data from a connected bedside monitor, vital sign telemeter, or multiple patient receiver unit on the screen.

Central Station is a network device, intended to provide remote patient monitoring to medical personnel.

Central Station displays a list of measured values and a trend graph. Numerical data and various waveforms are color-coded for each parameter. Central Station also has the function of displaying an alarm.

Alarm indication in Central Station is displayed as a result of a judgment by the bedside monitor, vital sign telemeter, or multiple patient receiver units connected to the Central Station. Central Station itself does not have the function to perform alarm indication judgment.

INDICATIONS FOR USE/INTENDED USE

Central Station is a network device, intended to display, record and print monitored physiological data from Nihon Kohden bedside monitors, telemetry receiver and/or transmitters.

Central Station does not perform any data processing on the data received from the Nihon Kohden compatible devices. When Central Station is connected with the Nihon Kohden bedside monitors and telemetry receivers/transmitters the Central Station can:

- Admit and discharge patients on the Nihon Kohden network.
- Display and manage compatible devices' real-time patient clinical data, vital signs, alarms and waveforms.
- Review and trend data calculated by connected Nihon Kohden devices.
- Store and transfer historical clinical data for the connected systems.
- Print patient data.

Central Station is intended for use in professional medical facilities by trained medical personnel.

SUBMISSION SCOPE

Nihon Kohden Digital Health Solutions (NKDHS) is requesting market clearance for the Central Station. The Central Station communicates with other NK devices on the NK network (NET-9).

Comparison of Technological Characteristics with the Predicate Device

Central Station has the same intended use/ indication for use, and technological Characteristics, as the predicate CNS-2101 Central Monitor. Both the predicate as well as subject device intended to display, record, and print monitored physiological data from Nihon Kohden bedside monitors, telemetry receiver and/or transmitters.

COMPARISON TABLE

The table below contains a detailed comparison of the Central Station to the Predicate Device (K223567).

Characteristics	Central Station (Proposed Device)	CNS-2101 Central Monitor (Predicate Device: K223567) Info on predicate	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	<p><u>Primary Product Codes:</u> MSX - System, network and communication, physiological monitors</p> <p><u>Subsequent Product Codes:</u></p> <p>MHX- Monitor, physiological, patient (with arrhythmia detection or alarms)</p> <p>DRQ- Amplifier and signal conditioner, transducer signal</p> <p>MWI Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)</p>	<p><u>Primary Product Codes:</u> MSX - System, network and communication, physiological monitors</p> <p><u>Subsequent Product Codes:</u></p> <p>MHX- Monitor, physiological, patient (with arrhythmia detection or alarms)</p> <p>DRQ- Amplifier and signal conditioner, transducer signal</p> <p>MWI Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)</p>	<p>Both devices share the same MSX primary code and performance specifications.</p> <p>The subsequent (secondary) product codes are related to the type of the devices the CNS can connect to. The NK systems were cleared with the additional secondary codes.</p>

Characteristics	Central Station (Proposed Device)	CNS-2101 Central Monitor (Predicate Device: K223567) Info on predicate	Comparison
Indications for Use	<p>Central Station is a network device, intended to display, record and print monitored physiological data from Nihon Kohden bedside monitors, telemetry receiver and/or transmitters.</p> <p>Central Station does not perform any data processing on the data received from the Nihon Kohden compatible devices. When Central Station is connected with the Nihon Kohden bedside monitors and telemetry receivers/transmitters the Central Station can:</p> <ul style="list-style-type: none"> • Admit and discharge patients on the Nihon Kohden network. • Display and manage compatible devices' real-time patient clinical data, vital signs, alarms and waveforms. • Review and trend data calculated by connected Nihon Kohden devices. • Store and transfer historical clinical data for the connected systems. • Print patient data. <p>Central Station is intended for use in professional medical facilities by trained medical personnel.</p>	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. <p>The CNS-2101 is intended for use in professional medical facilities by trained medical personnel.</p>	Same Intended use but the indications for uses has some minor editorial
Hardware			
Display	1,920× 1,080 resolution 23.8-inch color TFT type LCD	1,920× 1,080 resolution 23.8-inch color TFT type LCD	Same
Operation System	Microsoft Windows 10 IoT (Embedded)	Microsoft Windows 10 IoT (Embedded)	Same.
Storage media	512GB (Solid State Drive)	480 GB SSD (Solid State Drive)	Substantial Equivalence.

Characteristics	Central Station (Proposed Device)	CNS-2101 Central Monitor (Predicate Device: K223567) Info on predicate	Comparison
Audio	Built-in speakers	Built-in speakers	Same
Operation Methods			
Touchscreen	Yes	Yes	Same
Keyboard	Yes	Yes	Same
Mouse	Yes	Yes	Same
Installation method	Stand / Wall mount	Stand / Wall mount	Same
Power source	AC Power Supply	AC Power Supply	Same
Power interruption support	No	Yes- Internal battery (3-minute backup)	The CNS-2101 has an internal battery. Central Station supports an external Uninterruptible power supply battery. The difference does not raise questions of safety and effectiveness of the subject device.
Network	Yes	Yes (NK Network)	Same
Compatible monitoring systems	NK Bedside Monitors (MHX): BSM: 1700, 3000, 6000, G9, G5, G7 Vital Signs Monitor (MWI): SVM-7200 NK Telemetry (MHX/DRG): GZ-120/130/140 Multiple Patient Receiver and Transmitters (DRG): ORG-9700/9100 (DRT): ZS-940, ZM-520/521/530/531 Central Monitor (MHX): CNS-6201/6801/2101	NK Bedside Monitors (MHX): BSM: 1700, 3000, 6000, G9, G5, G7 Vital Signs Monitor (MWI): SVM-7200 NK Telemetry (MHX/DRG): GZ-120/130/140 Multiple Patient Receiver and Transmitters (DRG): ORG-9700/9100 (DRT): ZS-940, ZM-520/521/530/531 Central Monitor (MHX): CNS- 6201 and 6801	Same- The CNS communicates with other monitoring stems within the manufacturers 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	NET-9/LS-NET communication	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

Characteristics	Central Station (Proposed Device)	CNS-2101 Central Monitor (Predicate Device: K223567) Info on predicate	Comparison
Patient Admit/Discharge			
Patient Admit/Discharge/ Transfer	Following functions are supported <ul style="list-style-type: none"> • Admit, Discharge, Pause, and Transfer functions • Patient transfer within one central station • Patient transfer between central stations • Entering patient information (Manual, Auto) 	Following functions are supported <ul style="list-style-type: none"> • Admit, Discharge, Pause, and Transfer functions • Patient transfer within one central station • Patient transfer between central stations • Entering patient information (Manual, Auto) 	Same
Review window			
Review windows	<ul style="list-style-type: none"> • Trend window • Tabular Trend window • Full Disclosure window • Expanded Waveform window • Arrhythmia Recall window • ST Recall window • Event List window • Alarm Events window • ECG 12 Lead Analysis window • Hemodynamics List window • SpO2 Trend window 	<ul style="list-style-type: none"> • Trend window • Tabular Trend window • Full Disclosure window • Expanded Waveform window • Arrhythmia Recall window • ST Recall window • Event List window • Alarm Events window • ECG 12 Lead Analysis window • Hemodynamics List window • SpO2 Trend window 	Same - Both devices can connect and display monitored parameters. The viewable data points are similar on each of the monitoring system.
Review history	<ul style="list-style-type: none"> • Trendgraph data: 120 hours • Tabular trend data: 120 hours • Full disclosure and expanded waveform data: 120 hours • Arrhythmia recall data: 1,500 files • Event list data: 10,000 files • Alarm events data: 120 files • ECG 12 lead analysis data: 200 files • ST recall data: 120 files • Hemodynamics list data: 256 files • SpO₂ trendgraph data: 120 hours 	<ul style="list-style-type: none"> • Trendgraph data: 120 hours • Tabular trend data: 120 hours • Full disclosure and expanded waveform data: 120 hours • Arrhythmia recall data: 1,500 files • Event list data: 10,000 files • Alarm events data: 120 files • ECG 12 lead analysis data: 200 files • ST recall data: 120 files • Hemodynamics list data: 256 files • SpO₂ trendgraph data: 120 hours 	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			
Setting Alarm Priorities	Bedside Monitor: No Telemetry system and transmitter: Yes	Bedside Monitor: No Telemetry system and transmitter: Yes	Same
Printing and Recording			

Characteristics	Central Station (Proposed Device)	CNS-2101 Central Monitor (Predicate Device: K223567) Info on predicate	Comparison
Print	Patient information (Hospital Name, Bed name, Patient name) Recording start time or file creation date and time 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 <ul style="list-style-type: none"> • Trend window • Tabular Trend window • Full Disclosure window • Expanded Waveform window • Arrhythmia Recall window • ST Recall window • Event List window • Alarm Events window • ECG 12 Lead Analysis window • Hemodynamics List window • SpO2 Trend window 	Patient information (Hospital Name, Bed name, Patient name) Recording start time or file creation date and time 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 <ul style="list-style-type: none"> • Trend window • Tabular Trend window • Full Disclosure window • Expanded Waveform window • Arrhythmia Recall window • ST Recall window • Event List window • Alarm Events window • ECG 12 Lead Analysis window • Hemodynamics List window • SpO2 Trend window 	Same - Both devices are capable of printing to an external network printer.
Recording	No	Patient information (Hospital Name, Bed name, Patient name) Recording start time or file creation date and time 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) Recording duration, Recording speed (25 or 50 mm/s), Numeric data, Waveforms (up to 16 channels), Sensitivity, Lead Waveform Printing	CNS-2101 is capable of printing on a thermal printer when the parameters fall outside the limits.
ECG Features			
ECG Functions Display	Yes	Yes	Same
HR Display	Yes	Yes	
ST Alarm Page settings	Upper Limit: OFF, -1.99 to 2.00 mV Lower Limit: OFF, -2.00 to 1.99 mV	Upper Limit: OFF, -1.99 to 2.00 mV Lower Limit: OFF, -2.00 to 1.99 mV	
ST segment analysis Display	Yes	Yes	

Characteristics	Central Station (Proposed Device)	CNS-2101 Central Monitor (Predicate Device: K223567) Info on predicate	Comparison
Arrhythmia detection Display	Yes	Yes	
Arrhythmia analysis Setting	Yes	Yes	
QTc/QRSD display	Spot check and continuous When connected to BSM-1700, G5 and G7	Spot check and continuous When connected to BSM-1700, G5 and G7	
QRS detection Display	Yes	Yes	
Pace pulse rejection (Display)	Yes	Yes	

Summary of Nonclinical/Bench Studies

Software

The software documentation was prepared following the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (released June 14, 2023), specifically for an Enhanced Documentation Level. The rationale for choosing this documentation level is detailed in the Documentation Level document.

Verification testing was conducted at the system integration level to confirm that the device software fulfills its requirements and that safety and

security risk mitigations, where applicable, were effective. Additionally, system-level testing was carried out to show that the software addresses user needs. All unit, integration, and system-level tests successfully met the test protocols.

Cybersecurity information has been provided in line with the FDA's "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" guidance document, dated September 27, 2023.

The CENTRAL STATION has been designed and verified through a risk analysis that considers the risks associated with interoperability, the anticipated users, reasonably foreseeable misuse, and reasonably foreseeable combinations of events that can result in a hazardous situation. Our Interoperability-related risk management activities are included in Cybersecurity Risk Management activities.

Conclusion:

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