July 29, 2022

Nihon Kohden Digital Health Solutions, Inc.
Maria Pronina
Regulatory Affairs Manager
14 Bunsen
Irvine, California 92618

Re: K220989
Trade/Device Name: Next Generation NetKonnect
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
Dated: March 31, 2022
Received: April 4, 2022

Dear Maria Pronina:

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

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

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

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*

Device Name
Next Generation NetKonnect

Indications for Use *(Describe)*

Next Generation NetKonnect is intended to interface the Nihon Kohden monitoring network with networked client PCs to annunciate and display patient monitoring information to healthcare providers. The device is intended for use in near real-time monitoring of routing patient status and alarm events. Next Generation NetKonnect supplements the primary patient monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and event related information including vital signs values and waveforms. The system is intended for use on any patients as determined by qualified medical personnel within a hospital or clinical environment.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K220989

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|---|---|
| **Submitted by:** | Nihon Kohden Digital Health Solutions, Inc.<br>14 Bunsen<br>Irvine, CA 92618 |
| **Establishment Registration Number:** | 2032233 |
| **Contact Person:** | Maria Pronina<br>Regulatory Affairs Manager<br>Phone: 949.591.9596<br>E-mail: maria_pronina@nihonkohden.com |
| **Date Summary Prepared:** | March 31, 2022 |
| **Reason for Premarket Notification:** | Device Modification |
| **Trade Name:** | Next Generation NetKonnect |
| **Common Name:** | Patient Physiological Monitor Network |
| **Regulation Name:** | Patient Physiological Monitor with Arrhythmia detector and alarm (including ST-segment measurement and alarm) |
| **Regulation Number:** | 21 CFR 870.1025 |
| **Product Code:** | MHX |
| **Regulatory Class:** | II |
| **Panel:** | Cardiovascular |

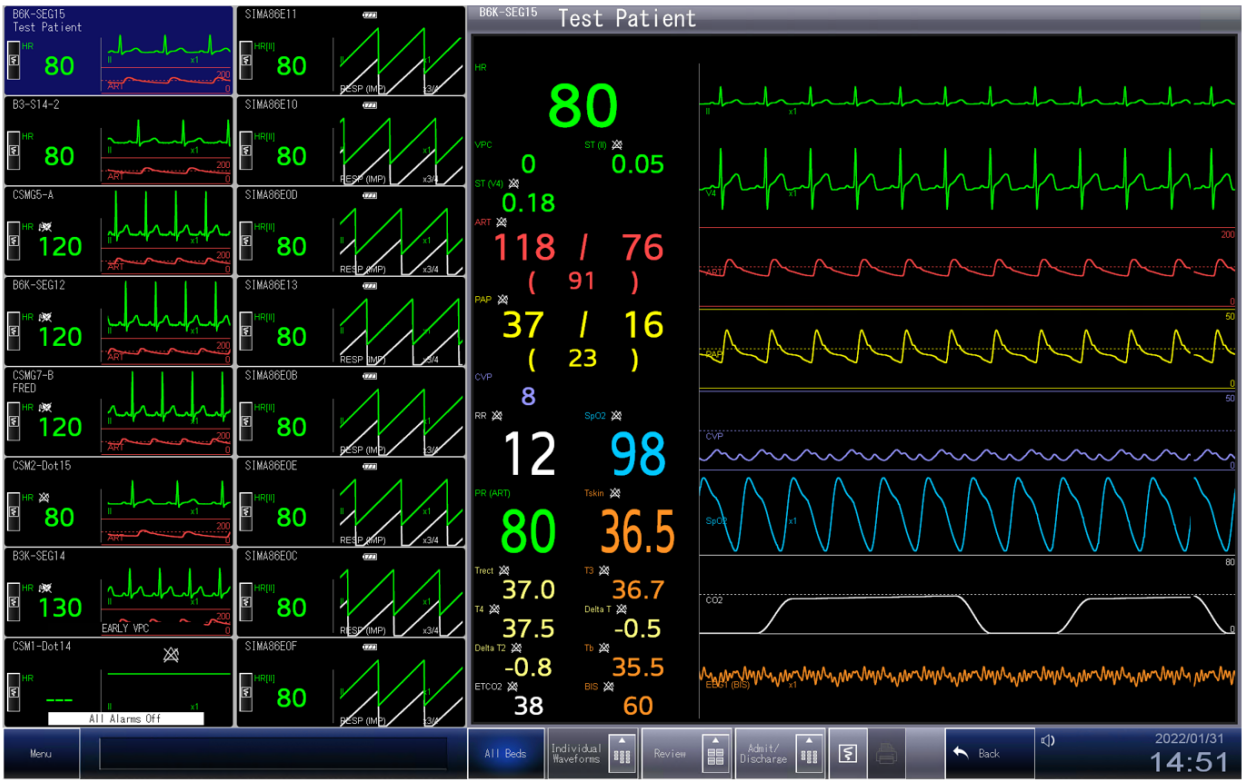
**Predicate Device:** NetKonnect Remote Network Extension (K112637)
Nihon Kohden America received clearance for the NetKonnect (K112637). Ownership of K112637 was transferred to Nihon Kohden Digital Health Solutions (formerly NKUS Lab).

**Device Description:**

*Physical Description*

NGNK is a software product that runs on Microsoft Windows architecture. NGNK will communicate with Nihon Kohden devices by a network connection and through the Gateway. The NGNK is intended to interface the Nihon Kohden monitoring network to annunciate and display patient monitoring information to healthcare providers. The device is intended for use in near real-time monitoring of patient status and alarm events. NGNK supplements the primary patient monitoring system by providing remote monitoring capability, including vital signs, alarms and waveforms.

**Picture 1: All Beds screen**




*Principles of Operation*

The NGNK receives the data from the Gateway to provide remote monitoring of single or multiple patients. Remote monitoring function includes waveform, vital signs and alarms. When the system is started, it runs automatically and detects each of the Nihon Kohden devices on

the patient monitoring network and establishes a vital signs and patient status communication with each one.

Modified Design Features

The primary objective of NGNK is to update the User Interface due to advancements in technologies and match current on-market products for a consistent experience. The modified feature included an update of User Interface consistent with current technology and common user experience.

**Intended Use:**

Next Generation NetKonnect is intended to interface the Nihon Kohden monitoring network with networked client PCs to annunciate and display patient monitoring information to healthcare providers. The device is intended for use in near real-time monitoring of routing patient status and alarm events. Next Generation NetKonnect supplements the primary patient monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and event related information including vital signs values and waveforms. The system is intended for use on any patients as determined by qualified medical personnel within a hospital or clinical environment.

**Technological comparison to predicate device:**

The Next Generation NetKonnect device is technologically equivalent to NetKonnect Remote Network Extension (K112637). Any differences are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness.

**Summary of Substantial Equivalence:**

| Features | Predicate device NetKonnect (K112637) | Subject device Next Generation NetKonnect |
|---|---|---|
| Manufacturer | Nihon Kohden America, Inc. | Nihon Konden Digital Health Solutions, Inc. (NKDHS) Ownership of K112637 was transferred from Nihon Kohden America to Nihon Kohden Digital Health Solutions (formerly NKUS Lab) |
| Classification Name | Arrhythmia detector and alarm (including ST-segment measurement and alarm) | **SAME** |
| Product code | MHX | **SAME** |
| Regulation Number | 21 CFR 870.1025 | **SAME** |
| Class | II | **SAME** |

| | | |
|---|---|---|
| Indications for use | The NetKonnect Remote Network Extension is intended to interface the Nihon Kohden monitoring network with networked client PCs to annunciate and display patient monitoring information to healthcare providers. The device is intended for use in real-time monitoring of routine patient status and alarm events. NetKonnect Remote Network Extension supplements the primary patient monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and event related information including vital signs values and waveforms.<br>The system is intended for use by qualified medical personnel within a hospital or clinical environment. The stimulator is available for use on any patient as determined by the qualified medical personnel. | **SAME** |
| Alarm Notification | Alarm notification is a secondary notification system and does not replace the primary alarm notification at the bedside monitor | **SAME** |
| Description of Communication requirements | Receives and forwards waveform data using Nihon Kohden's proprietary "NET9" protocol language. | **SAME** |
| | Receives and forwards numerical data using Nihon | **SAME** |

| | | |
|---|---|---|
| | Kohden's proprietary "NET9" protocol language. | |
| | Receives and forwards alarm notification to other Nihon Kohden cleared devices such as Central Nurse station using proprietary "NET9" protocol language.<br>When used with PC or Portable device, no alarm notification is available | **Substantially equivalent:** NGNK does not forward alarm notification. This difference does not affect the device from performing in a manner in which it is intended to operate from the predicate device "NetKonnect" |
| Communication Design | Real Time monitoring | **SAME** |
| OS requirements | Micorsoft windows that support Win32 service processes | **Substantially equivalent:** NGNK now supports current standard 64 bit Windows archetures |
| Target Population | NetKonnect does not affect the target population of the cleared monitoring devices that the patients are connected to. The device is available for use by medical personnel on all patient populations. | **SAME** |
| User Interface | User interface is similar to the connected FDA cleared devices Nihon Kohden bedside monitoring and primary central monitoring systems. | **Substantially equivalent:** Updates in the user interface to be consistent with current user interfaces on connected FDA cleared devices Nihon Kohden bedside monitoring and primary central monitoring systems |
| Oerational Requirements | Software Product. No hardware installed with this product. | **SAME** |
| | Runs on any PC with Microsoft .NET Framework environment. | **Substantially equivalent** - NGNK has been updated to be a Windows application due to changes in the PC environment. |
| Performance Specification | NetKonnect can download and display the following patient history information, | **SAME** |

| | | |
|---|---|---|
| | which is stored in Storage Device such as the Nihon Kohden Central Monitoring Devices. The total number of these events depends on the storage device.<br>Trend Data (Graphical, Tabular, NIBP)<br>Hemodynamics lists<br>Arrhythmia recall<br>ST recall<br>Full disclosure<br>ECG 12 lead analysis | |
| | NetKonnect does not perform arrhythmia detection and makes no determination or generation of alarm conditions. All display elements are generated based on the data from the bedside monitors or central monitor. | **SAME** |

**Summary of Non-Clinical Testing:**
The required testing of the Next Generation NetKonnect was performed in accordance with the requirements of the design control guidelines and established quality assurance processes to demonstrate substantial equivalence of the subject device to the predicate device. The software testing demonstrated that the software version meets it design requirements.

**Summary of Clinical Testing:**
No clinical testing was required or performed since substantial equivalence of the device was supported by the non-clinical testing.

**Conclusion:**
Based on the design and results of testing, it can be concluded that the subject device - Next Generation NetKonnect - is as safe, as effective, and performs as well as or better than the predicate. The Next Generation NetKonnect is substantially equivalent to the predicate device.