Nihon Kohden OrangeMed, Inc.
Sheryl Higgins
V.P. of Regulatory Affairs & Quality Assurance
1800 E. Wilshire Avenue
Santa Ana, California 92705

Re: K231778
Trade/Device Name: Nihon Kohden NKV-550 Series Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: February 6, 2024
Received: February 6, 2024

Dear Sheryl Higgins:

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.

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,

John S. Bender -S

Digitally signed by John S. Bender -S
Date: 2024.03.01 10:47:10 -05'00'

for Ethan Nyberg
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K231778

Device Name
Nihon Kohden NKV-550 Series Ventilator System

Indications for Use *(Describe)*
The Nihon Kohden NKV-550 Series Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-550 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-550 is intended for use in hospitals and hospital-type facilities, as well as, for in-hospital transportation.

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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Section 5 - 510(k) Summary

Submission Date

February 29, 2024

Submitter / Manufacturing Location

Nihon Kohden OrangeMed, LLC
1800 E. Wilshire Avenue
Santa Ana, CA 92705
USA

Phone: (949) 502-6448

Company Contact

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Establishment Registration Number

3014631252 - Nihon Kohden OrangeMed, LLC

Common Name of Device

Critical Care Ventilator

Trade Name

Nihon Kohden NKV-550 Series Ventilator System

Classification Name

Product Code: CBK – Ventilator, Continuous, Facility Use
Regulation Number: 21 CFR 868.5895 – Continuous ventilator
Device Class: II
Review Panel: Anesthesiology

A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

Primary Predicate Device

Trade Name:	Nihon Kohden NKV-550 Series Ventilator System
510k #:	K192307
Product Code:	CBK
Manufacturer:	Nihon Kohden OrangeMed, LLC
Establishment Reg. #:	3014631252

Secondary Predicate Device

Trade Name:	Hamilton-G5
510k #:	K193228
Product Code:	CBK
Manufacturer:	Hamilton Medical AG
Establishment Reg. #:	3001421318

Device Description

The Nihon Kohden NKV-550 Series Ventilator System consists of a graphic user interface (GUI) and a breath delivery unit (BDU). The GUI allows clinicians to set ventilator control parameters such as tidal volume and inspiratory pressure, to set alarm limits such as high inspiratory pressure alarm, to view monitored numeric values, to view waveform and loops, and to operate various features through the apps.

The BDU contains a microprocessor that receives inputs from the electronic system and controls the pneumatic system for breath delivery to the patient. It also provides various alarms, a safety valve, and other design features to maximize patient safety.

Product Intended Function

The Nihon Kohden NKV-550 Series Ventilator System is intended to provide continuous ventilation using medical oxygen and external sources of compressed medical air to deliver oxygen concentrations of 21% to 100%. Ventilatory support is intended to be delivered invasively or non-invasively to patients who require Assisted/Control Mandatory Ventilation (A/CMV), Synchronized Intermittent Mandatory Ventilation (SIMV) or Spontaneous Ventilation (SPONT).

Indication For Use (Intended Medical Indication)

The Nihon Kohden NKV-550 Series Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-550 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-550 is intended for use in hospitals and hospital-type facilities, as well as, for in-hospital transportation.

Summary of Technical Characteristics

The Nihon Kohden NKV-550 Series Ventilator System technological characteristics with the addition of Adaptive Ventilation Mode (AVM) and Adaptive Trigger (A_{TRIG}) /Adaptive Cycle (A_{CYCLE}) are substantially equivalent as compared to the predicate device and the reference device as summarized in the table below.

Table 7-1 Characteristic	**Nihon Kohden NKV-550 Series Ventilator System (Modified Device)**	**Nihon Kohden NKV-550 Series Ventilator System (Primary Predicate Device – k192307)**	**Hamilton G5 (Secondary Predicated Device – k193228)**	**Comparison**
Indication for Use	The Nihon Kohden NKV-550 Series Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-550 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-550 is intended for use in hospitals and hospital-type facilities, as well as for in-hospital transportation.	The Nihon Kohden NKV-550 Series Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-550 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-550 is intended for use in hospitals and hospital-type facilities, as well as for in-hospital transportation.	The Hamilton-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where health care professionals provide patient care	Same
Environment of Use	Hospitals, hospital-type facilities and in-hospital transportation for patients who need ventilation therapy	Hospitals, hospital-type facilities and in-hospital transportation for patients who need ventilation therapy	Hospital and institutional environment where health care professionals provide patient care	Same
Anatomical Site	Patient airways	Patient airways	Patient airways	Same
Target Population	Adult, pediatric and neonatal patients	Adult, pediatric and neonatal patients	Adult, pediatric, and neonatal patients	Same
Performance	Met ISO 80601-2-12 requirements on essential performance of critical care ventilator	Met ISO 80601-2-12 requirements on essential performance of critical care ventilator	Met ISO 80601-2-12 requirements on essential performance of critical care ventilator	Same

Table 7-1 Characteristic	Nihon Kohden NKV-550 Series Ventilator System (Modified Device)	Nihon Kohden NKV-550 Series Ventilator System (Primary Predicate Device – k192307)	Hamilton G5 (Secondary Predicated Device – k193228)	Comparison
Design	Consists of a graphic user interface to set and monitor ventilation, breath delivery unit, breathing circuit; Controls air and oxygen deliveries by proportional valves through microprocessors	Consists of a graphic user interface to set and monitor ventilation, breath delivery unit, breathing circuit; Controls air and oxygen deliveries by proportional valves through microprocessors	Consists of a graphic user interface to set and monitor ventilation, breath delivery unit, breathing circuit; Controls air and oxygen deliveries by proportional valves through microprocessors	Same
Chemicals Delivered to Patient	Medical Air and Oxygen	Medical Air and Oxygen	Medical Air and Oxygen	Same
Delivery method to Patient	Positive pressure	Positive pressure	Positive pressure	Same
Energy Used for Device	AC Power and DC Power (battery)	AC Power and DC Power (battery)	AC Power and DC Power (battery)	Same
Control principle	time-cycled, volume-constant, pressure-controlled	time-cycled, volume-constant, pressure-controlled	time-cycled, volume-constant, pressure-controlled	Same
Therapy Types	Invasive, Non-invasive, O2 Therapy	Invasive, Non-invasive, O2 Therapy	Invasive, Non-invasive, O2 Therapy	Same

The differences between the modified Nihon Kohden NKV-550 Ventilator System and the predicate device (k192307) are as follows:

1. The subject device adds a breath mode, Adaptive Ventilation Mode (AVM), as well as Adaptive Trigger (A_{TRIG})/Adaptive Cycle (A_{CYCLE}). These are software-only features that do not require any new hardware.

The differences between the modified Nihon Kohden NKV-550 Ventilator System and the secondary predicate device (k193228) are described in section 12 – Substantial Equivalent Discussion.

In conjunction with AVM and Adaptive Trigger (A_{TRIG})/Adaptive Cycle (A_{CYCLE}), this 510(k) brings FDA up-to-date on non-significant changes implemented since the last 510(k) clearance. Therefore, the following modifications are included:

1. Mechanical Hardware changes
2. Software Revision History changes
3. Labeling changes

Device modifications were made in compliance with Design Control procedures.

Summary of Non-Clinical Performance Data

Performance of the Nihon Kohden NKV-550 Series Ventilator System was demonstrated by the following testing performed in compliance with Design Controls:

- Software Verification
- Device Functionality Testing
- Human Factors/Usability Testing
- Bench Test Comparison with Reference Device
- Risk Management
- Regression

Additional biocompatibility testing was not required since no material changes were made to the gas path of the ventilator.

Summary of Clinical Performance Data

Not Applicable – Clinical performance data was not required to demonstrate substantial equivalence.

Conclusion

The evaluation and testing performed in compliance with Design Controls demonstrates that the Nihon Kohden NKV-550 Series Ventilator System is as safe and as effective as its primary and secondary predicate devices.