July 1, 2022

Nihon Kohden OrangeMed, Inc.
Jacqueline Villanueva
Quality Engineering Manager
1800 E. Wilshire Avenue
Santa Ana, California 92705

Re: K213521
Trade/Device Name: Nihon Kohden NKV-330 Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: MNT
Dated: June 1, 2022
Received: June 3, 2022

Dear Jacqueline Villanueva:

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,

Brandon Blakely, Ph.D.
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

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)*
K213521/S002

Device Name
Nihon Kohden NKV-330 Ventilator System

Indications for Use *(Describe)*
The Nihon Kohden NKV-330 Ventilator is intended to provide ventilation and oxygen concentration for patients who are breathing spontaneously but need partial ventilation support due to respiratory failure or chronic respiratory insufficiency. It is intended for children weighing 12.5 kg or greater to adult patients. It offers noninvasive ventilation, invasive ventilation, and respiratory monitoring. The NKV-330 is intended for use in hospitals, hospital-type facilities, and in-hospital transportation by qualified and trained users under the directions of a physician.

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

1. Date

July 1, 2022

2. Submitter / Manufacturing Location

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

3. Company Contact

Jacqueline Villanueva – Quality Assurance Director

Email: jvillanueva@orange-med.com

Phone: (949) 502-6448 x7045

4. Common Name of Device

Assist Ventilator

5. Trade Name

Nihon Kohden NKV-330 Ventilator System

6. Classification Name

Product Code:	MNT Ventilator, Continuous, Minimal Ventilatory Support, Facility Use
Regulation Number:	21 CFR 868:5895
Device Class:	II
Review Panel:	Anesthesiology

7. Predicate Device

Predicate Device

Product:	V60 Ventilator with PPV and Auto-Trak + Software Options
510k #:	k102985
Manufacturer:	Respironics California, LLC

Reference Device

Product:	NKV-550 Series Ventilator System
510k #:	k181695
Manufacturer:	Nihon Kohden OrangeMed, Inc.

8. Description of Device

The NKV-330 is a servo-controlled ventilator that is designed to meet the gas delivery and performance requirements for pediatric through adult patients. The NKV-330 design is comprised of two major components, a Breath Delivery Unit (BDU) and a Graphic User Interface (GUI). The GUI allows clinicians to set ventilator control parameters such as PEEP and inspiratory pressure, to set alarm limits such as high inspiratory pressure alarm, to view monitored numeric values, and to view waveforms. The BDU assembly contains a blower and the electronics required to perform breath delivery. Ambient air is taken into the blower and mixed with oxygen which is flow rate controlled by a proportional valve. The mixed gas is provided to the patient. The microprocessor controls the blower and the proportional valve to deliver the pressure and oxygen concentration which are set by the user. It also provides various alarms and other design features to maximize patient safety.

9. Product Intended Function

The Nihon Kohden NKV-330 Ventilator is an assist ventilator intended to support adult and pediatric patients who are breathing spontaneously and require a tidal volume of 100mL or more with an oxygen concentration of 21 to 100%. It is also intended for intubated patients meeting the same selection criteria as the noninvasive applications.

10. Indication for Use (Intended Medical Indication)

The Nihon Kohden NKV-330 Ventilator is intended to provide ventilation and oxygen concentration for patients who are breathing spontaneously but need partial ventilation support due to respiratory failure or chronic respiratory insufficiency. It is intended for children weighing 12.5 kg or greater to adult patients. It offers noninvasive ventilation, invasive ventilation, and respiratory monitoring. The NKV-330 is intended for use in hospitals, hospital-type facilities, and in-hospital transportation by qualified and trained users under the directions of a physician.

11. Intended Patient Population

Adult and pediatric patients that are breathing spontaneously but need partial ventilation support through invasive or non-invasive ventilation.

12. Intended Part of the Body or Type of Tissue Applied to or Interacted with

The device is intended for use with a breathing circuit attached to a patient interface for noninvasive ventilation or patients that are under invasive ventilation and meet the selection criteria for noninvasive application. For noninvasive ventilation, the part of the body or type of tissue applied to or interacted with would include a facial or nasal mask, or nasal cannula, applied to the mouth and/or nose. For invasive ventilation, the part of the body or type of tissue applied to or interacted with would include an endotracheal tube inserted through the mouth or the nose or a tracheostomy tube inserted into the trachea.

13. Intended Environment of Use (Use Environment)

The device is intended for use in hospitals and hospital-type facilities, which provide respiratory care for patients requiring respiratory support.

The device may be used for intra-hospital transport within a hospital or hospital-type facility. The device is not intended for transport between hospitals or hospital-type facilities, therefore is not a transport ventilator as defined by ISO 80601-2-12 Section 201.1.1.

The device is not to be used in the presence of flammable anesthetics and MRI applications.

14. Accessories

The NKV-330 is designed to be used with ventilator support accessories, such as, filters and breathing circuits. Optional accessories have been tested to be compatible with the NKV-330.

Accessory	Description	Manufacturer	Model # Tested for System Compatibility
Respiratory Gas Humidifier	F&P MR850 Respiratory Humidifier	Fisher Paykel	MR850
Heated Single Limb Breathing Circuit	Fisher & Paykel Single Limb Adult Circuit Kit with Chamber	Fisher Paykel	RT219
	Fisher & Paykel Single Limb Adult Circuit Kit with Chamber	Fisher Paykel	RT202
Breathing Circuit Bacterial Filter	F&P Inspiratory/ Expiratory Filter	Fisher Paykel	RT019
Nasal Cannula	Teleflex Comfort Flow Plus Cannula	Teleflex	2412-13 (S) 2412-12 (M) 2412-11 (L)
NIV face mask	6700 Series Non-vented Full Face Mask	Hans Rudolph	113550 (L), 113551 (M), 113552 (S), 113553 (XS), 113554 (Petite)
NIV face mask	Respironics PerforMax Pediatric SE Total Face Mask	Philips	1119026 (XS)
NIV Face Mask Set	NPPV Cap-ONE Mask Set	Nihon Kohden OrangeMed	MSK3313P (L), MSK3314P (M), MSK3315P (S), MSK3316P (XS)
SPO2 Monitor	Nihon Kohden SpO2 Monitor Kit	Nihon Kohden Corp.	JL-500P1
SPO2 Sensor	Nihon Kohden Finger Probe	Nihon Kohden Corp.	TL-201T
SPO2 Sensor	Nihon Kohden Multi-site Probe	Nihon Kohden Corp.	TL-220T
CO2 Monitor	Nihon Kohden CO2 Monitor Kit	Nihon Kohden Corp.	TG-980P
CO2 Airway Adapter	Nihon Kohden CO2 Airway Adapter	Nihon Kohden Corp.	YG-211T
On Airway Flow Sensor	EnviteC SpiroQuant H	EnviteC	TF-330Z (E07-00-0001)
Exhalation Port	Exhalation Port	Nihon Kohden OrangeMed	EXH3301P

15. Summary of Technical Characteristics

The technological characteristics of the Nihon Kohden NKV-330 Ventilator System are substantially equivalent to the predicate device as compared and summarized in the table below.

*Reference for predicate device information: "Respironics V60 Ventilator User Manual" (1047358 Rev C) and Philips V60 Ventilator Specification (Oct 2016).

Technical Characteristic	**Nihon Kohden NKV-330 Ventilator System**	**Philips/Respironics V60 Ventilator* (Predicate Device – k102985)**	**Comparison**
Indication for Use	The Nihon Kohden NKV-330 Ventilator is intended to provide ventilation and oxygen concentration for **patients who are breathing spontaneously** but need partial ventilation support due to respiratory failure or chronic respiratory insufficiency. It is intended for children weighing 12.5 kg or greater to adult patients. **It offers noninvasive ventilation, invasive ventilation,** and respiratory monitoring. The NKV-330 is intended for **use in hospitals, hospital-type facilities, and in-hospital transportation by qualified and trained users under the directions of a physician.**	The Respironics V60 Ventilator is an assist ventilator and is intended to augment patient breathing. It is intended for **spontaneously breathing individuals** who require mechanical ventilation: patients with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea in **a hospital or other institutional settings under the direction of a physician**. The ventilator is intended to support pediatric patients weighing 20 kg (44 lb) or greater to adult patients. It is also intended **for intubated patients meeting the same selection criteria as the noninvasive applications.** The ventilator is intended to be used by qualified medical professionals, such as physicians, nurses, and respiratory therapists. The ventilator is intended to be used only with various combinations of Respironics-recommended patient circuits, interfaces (masks), humidifiers, and other accessories	Substantially equivalent Both ventilators are intended for patients who have spontaneous breathes. Both ventilators can be used for invasive ventilation (i.e., through intubation) and noninvasive ventilation. The minimum patient weights in both ventilators (12.5 kg for the NKV-330 and 20 kg for the V60) are within the same subpopulation of "Children" under the FDA definition for Pediatrics.

Technical Characteristic	Nihon Kohden NKV-330 Ventilator System	Philips/Respironics V60 Ventilator* (Predicate Device – k102985)	Comparison
Intended Environment of use	Intra-hospital transport within a hospital or hospital-type facility. The device is not intended for transport between hospitals or hospital-type facilities, therefore is not a transport ventilator as defined by ISO 80601-2-12 Section 201.1.1.	In a hospital or other institutional settings under the direction of a physician. In other section than intended use from the V60 manual, there is a description to use the ventilator during intra-hospital transport	Same
Anatomical Site	Patient face and airways	Patient face and airways	Same
Target Population	Adult and pediatric patients	Adult and pediatric patients	Same
Waveform Comparison	Comparable waveform test result	Comparable waveform test result	Substantially equivalent
Design	Consists of a graphic user interface to set ventilation and to monitor ventilation and SpO2 and CO2, breath delivery unit, breathing circuit, and cart; Controls oxygen delivery through a proportional valve and controls air delivery through an internal blower	Consists of a graphic user interface to set ventilation and to monitor ventilation, breath delivery unit, breathing circuit, and cart; Controls oxygen delivery through a proportional valve and controls air delivery through an internal blower	Substantially equivalent The NKV-330 has optional SpO2 and CO2 monitors, for the users who desire to use these monitors for added safety. The reference device, NKV-550 Series Ventilator System (K181695), contains the same optional SpO2 and CO2 monitors.
Chemicals Deployed to Patient	Ambient air and oxygen	Ambient air and oxygen	Same
Delivery method to Patient	Positive pressure	Positive pressure	Same
Energy Used for Device	AC Power, a backup battery DC Power (Ni-Mh battery), and a main battery (Li-ion battery)	AC Power, and optional internal DC Power (Li-ion battery)	Substantially equivalent The NKV-330 contains two batteries for added safety. The V60 has one battery.
Control principle	Time-cycled, volume-target, pressure-controlled	Time-cycled, volume-target, pressure-controlled	Same

Technical Characteristic	Nihon Kohden NKV-330 Ventilator System	Philips/Respironics V60 Ventilator* (Predicate Device – k102985)	Comparison
Modes and Controls Settings	**PCV mode**	**PCV mode**	Substantially equivalent
	PRVC mode (Volume Target) -Max Pressure for PRVC -Min Pressure for PRVC	**AVAPS mode** (Volume Target) Max Pressure for AVAPS Min Pressure for AVAPS	Substantially equivalent
	S/T mode (Spontaneous PS / Timed PCV) -IPAP -EPAP/CPAP	**S/T mode** (Spontaneous PS / Timed PCV) -IPAP -EPAP	For trigger, both the NKV-330 and the V60 use flow shape method for triggering. The NKV-330 provides conventional flow trigger in addition.
	Spont/PS mode (PS set to zero is CPAP) Inspiratory Time or I:E Pressure Release (pressure relief during the active part of exhalation only for CPAP) Trigger; flow trigger or advanced trigger (Flow shape method for trigger) Cycling off; peak flow %	**CPAP mode** Inspiratory Time (i-Time) C-Flex (pressure relief during the active part of exhalation only for CPAP) Trigger; auto-track trigger (flow shape method for trigger) Cycling off; Auto-Track (flow shape method)	NKV-330 uses a peak flow % for cycling off. V60 uses Auto-Track by flow shape method.
	PPV mode Max E (PPV) Max R (PPV) Max P (PPV) Max VT (PPV) O2 concentration (FiO2) Ramp up time Resp Rate (frequency) Slope (rise time) Min/Max Ti	**PPV mode** Max E (PPV) Max R (PPV) Max P (PPV) Max V (PPV) O2 concentration (FiO2) Ramp time Resp Rate (frequency) Rise Time	NKV-330 has additional settings for limiting Min and Max inspiratory time (Ti).
	O2 Therapy Mode Flow (1-60 L/min) Circuit Obstruction Alarm (automatic)	-	Substantially equivalent to reference device, NKV-550 Series Ventilator System (K181695).** O2 therapy mode delivers only a constant flow at FiO2 that is set by the user.

*Reference manufacturer's user manual "Respironics V60 Ventilator User Manual" (1047358 Rev C) and Philips V60 Ventilator Specification (Oct 2016)

** The O2 Therapy operation, applicable settings, monitors, and alarms are the same between proposed device, NKV-330 Series Ventilator System, and reference device, NKV-550 Series Ventilator System. NKV-330 added a Circuit Obstruction alarm. Ventilator performance during O2 Therapy comparison testing was completed and demonstrated substantial equivalence between proposed and reference device.

16. Summary of Non-Clinical Performance Data

Performance of the Nihon Kohden NKV-330 Ventilator was demonstrated by the following:

- Software Verification
- Electrical Safety & EMC Testing
- Agency Testing to Applicable Standards
- Performance of Ventilation Modes and Control Settings
- Device Functionality
- Power performance with AC Mains power or Reserve battery power
- Endurance/Reliability
- Essential Performance and Worst Case VBS
- Environmental
- Cleaning & Disinfection
- Biocompatibility
- Waveform Comparison with Predicate
- Human Factors/Usability
- Risk Management
- Accessory Compatibility

Where applicable, the Nihon Kohden NKV-330 Ventilator has been tested in compliance with the following standards:

Standard	Title
ANSI AAMI ES 60601-1 2005+AC1;A2 (R2012)	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1 Ed. 3.1 2012-08	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2 Ed. 4.0 2014-02	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-1-6 Ed. 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
IEC 60601-1-8 Ed 2.1 2012-11	Medical Elec. Equip. - Part 1-8: General Req. for Basic Safety & Essential Perf. – Collateral Standard: General Req., Tests & Guidance for Alarm Systems in Medical Elec. Equip. & Medical Elec. Systems
IEC 60601-1-9 Ed. 1.1 2013-06	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
IEC 60601-2-49 Ed. 2.0 2011-02	Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC 62133-2 Ed. 1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
IEC 62366 Ed. 1.1 2014-01	Medical devices — Application of usability engineering to medical devices — Amendment 1

Standard	Title
ISO 80601-2-12 Ed. 1 2011-04	Medical Electrical Equipment - Part 2-12: Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators
ISO 80601-2-55 Ed. 2 2018-02	Medical Electrical Equipment – Part 2-55: Particular Requirements for The Basic Safety and Essential Performance of Respiratory Gas Monitor
ISO 80601-2-61 Ed. 2 2017-12	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
FDA Biocompatibility Guidance 2016-06	Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff
ISO 10993-1 Ed. 5 2018-08	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
ISO 18562-1 Ed. 1 2017-03	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications
ISO 14971 Ed. 3 2019-12	Medical devices — Application of risk management to medical devices

17. Summary of Animal Performance Data

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

18. Summary of Clinical Performance Data

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

19. Conclusion

The evaluation and testing performed demonstrates that the Nihon Kohden NKV-330 Ventilator is as safe and effective as the predicate device.