May 31, 2023

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

Re: K222644
Trade/Device Name: Nihon Kohden NKV-440 Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: May 4, 2023
Received: May 4, 2023

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 (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,

Ethan L. Nyberg -S

for James Lee, Ph.D.
Division 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)*
K222644

Device Name
Nihon Kohden NKV-440 Ventilator System

Indications for Use *(Describe)*
The Nihon Kohden NKV-440 Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-440 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-440 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.

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

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510(k) Summary

1. Date

May 04, 2023

2. Submitter / Manufacturing Location

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

3. Company Contact

Primary: Sheryl Higgins
Vice President of Regulatory Affairs and Quality Assurance
Email: shiggins@orange-med.com
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Secondary: Jacqueline Villanueva
Director of Quality Assurance
Email: jvillanueva@orange-med.com
Phone: (949) 502-6448 x7045

4. Common Name of Device

Critical Care Ventilator

5. Trade Name

Nihon Kohden NKV-440 Ventilator System

6. Classification Name

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

7. Predicate Device

Product:	Nihon Kohden NKV-550 Ventilator System
510k #:	K192307
Manufacturer:	Nihon Kohden OrangeMed, Inc.

8. Reference Device

Product:	Hamilton-C3
510k #:	K201306
Manufacturer:	Hamilton Medical AG

9. Description of Device

The NKV-440 is a servo-controlled ventilator that is designed to meet the gas delivery and performance requirements for neonate through adult patients. The NKV-440 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.

10. Product Intended Function

The Nihon Kohden NKV-440 Ventilator System is intended to provide continuous ventilation using medical oxygen and an internal source of 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).

11. Indication for Use (Intended Medical Indication)

The Nihon Kohden NKV-440 Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-440 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-440 is intended for use in hospitals and hospital-type facilities, as well as, for in-hospital transportation.

12. Intended Patient Population

The intended patient population includes neonate through adult patients who require invasive or non-invasive respiratory support.

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

The device does not come into direct contact with the patient. The device is considered to be externally communicating with the patient airway because it delivers air/oxygen to the patient respiratory system.

14. 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.

15. Summary of Technical Characteristics

The technological characteristics of the Nihon Kohden NKV-440 Ventilator System are substantially equivalent to the predicate device as compared and summarized in the table below.

Table 12-1 Company	Nihon Kohden OrangeMed, Inc.	Nihon Kohden OrangeMed, Inc.	Comparison
Establishment	**3014631252**	**3014631252**	
MODEL	**NKV-440**	**NKV-550**	
510(k)	**This Submission**	**K192307**	
Indications for Use	The Nihon Kohden NKV-440 Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-440 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-440 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.	Same
Clinical Conditions	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	Same
Anatomical Site	Patient airways	Patient airways	Same
Target Population	Adult, pediatric and neonatal patients	Adult, pediatric and neonatal patients	Same
Users	Trained clinicians, not lay users	Trained clinicians, not lay users	Same
Clinical 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	Same
Waveform Comparison	Comparable waveform test result	Comparable waveform test result	Similar

Table 12-1 Company	Nihon Kohden OrangeMed, Inc.	Nihon Kohden OrangeMed, Inc.	Comparison
Establishment	**3014631252**	**3014631252**	
MODEL	**NKV-440**	**NKV-550**	
510(k)	**This Submission**	**K192307**	
Design	Consists of a graphic user interface to set and monitor ventilation, breath delivery unit, breathing circuit, and cart; Controls air and oxygen deliveries by a blower and proportional valve through microprocessors	Consists of a graphic user interface to set and monitor ventilation, breath delivery unit, breathing circuit, and cart; Controls air and oxygen deliveries by proportional valves through microprocessors	Similar In the NKV-440, a built-in blower draws the room air in and controls the air delivery. In the NKV-550, an external air compressor is the air gas source, and a built-in proportional valve controls the air delivery.
Conditions of Use	Hospitals, hospital-type facilities and in-hospital transportation	Hospitals, hospital-type facilities and in-hospital transportation	Same
Chemicals Deployed to Patient	Air and oxygen	Air and oxygen	Same
Delivery method to Patient	Positive pressure	Positive pressure	Same
Energy Used for Device	AC Power and internal DC Power (Li-ion battery)	AC Power and internal DC Power (Li-ion battery)	Same Exactly same battery packs are used in both NKV-440 and NKV-550.
Control principle	time-cycled, volume-constant, pressure-controlled	time-cycled, volume-constant, pressure-controlled	Same

Table 12-1 Company	Nihon Kohden OrangeMed, Inc.	Nihon Kohden OrangeMed, Inc.	Comparison
Establishment	**3014631252**	**3014631252**	
MODEL	**NKV-440**	**NKV-550**	
510(k)	**This Submission**	**K192307**	
Specifications: Breathing Modes	**Invasive Ventilation:** A/CMV-PC A/CMV-VC A/CMV-PRVC SIMV-PC-PS SIMV-VC-PS SIMV-PRVC-PS SPONT-CPAP SPONT-PS SPONT-VS APRV **Non-Invasive Ventilation:** A/CMV-PC SIMV-PC-PS SPONT-CPAP SPONT-PS APRV CPAP **O2 Therapy**	**Invasive Ventilation:** A/CMV-PC A/CMV-VC A/CMV-PRVC SIMV-PC-PS SIMV-VC-PS SIMV-PRVC-PS SPONT-CPAP SPONT-PS SPONT-VS APRV **Non-Invasive Ventilation:** A/CMV-PC SIMV-PC-PS SPONT-CPAP SPONT-PS APRV CPAP **O2 Therapy**	Same

16. Summary of Non-Clinical Performance Data

Performance of the Nihon Kohden NKV-440 Ventilator was demonstrated by the following:

- Agency Testing to Applicable Standards
- Performance of Ventilation Modes and Control Settings
- Device/Software Functionality
- Power performance with AC power, External Battery, and Backup Battery
- Essential Performance and Worst Case VBS
- Environmental
- Waveform Comparison with Predicate
- Product Endurance/Reliability
- Biocompatibility
- Cleaning & Disinfection
- EMC and Electrical Safety
- Human Factors/Usability
- Risk Management
- Compatibility with 3rd Party Devices

Where applicable, the Nihon Kohden NKV-440 Ventilator has been tested in compliance with the following standards:

Standard	Title
AIM 7351731 Rev. 2 2017-02	Medical Electrical Equipment & System Electromagnetic Immunity Test for RFID Readers
ANSI AAMI ES 60601-1 2005+AC1;A2 (R2012)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
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. 4.1 2020-09	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 62133 Ed. 2.0 2012-12	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed Secondary cells, and for batteries made from them, for use in portable applications
IEC 62304 Ed. 1.1 2015-06	Medical device software - Software life cycle processes
IEC 62366-1 Ed. 1.0 2015-02	Medical devices — Application of usability engineering to medical devices
ISO 10993-1 Ed. 5 2018-08	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
ISO 14971 Ed. 3 2019-12	Medical devices — Application of risk management to medical devices
ISO 18562-1 Ed. 1 2017-03	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications
ISO 80601-2-12 Ed. 2 2020-02	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

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-440 Ventilator System is substantially equivalent the predicate device.