January 10, 2020

Nihon Kohden OrangeMed, Inc.
Sheryl Higgins
V.P. of RA/QA
1800 E. Wilshire Avenue
Santa Ana, California 92705

Re: K192307
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: December 9, 2019
Received: December 12, 2019

Dear Ms. 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,

James J. Lee Ph.D.
Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192307

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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510(k) Summary

Submission Date

January 09, 2020

Submitter / Manufacturing Location

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

Company Contact

Sheryl Higgins – V.P. of Regulatory Affairs and Quality Assurance
Email: shiggins@orange-med.com
Phone: (949) 502-6448 x7012

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
Device Class: II
Review Panel: Anesthesiology

Predicate Device

Product:	Nihon Kohden NKV-550 Series Ventilator System
510k #:	k181695
Manufacturer:	Nihon Kohden OrangeMed, Inc.
Establishment Reg. #:	3014631252

Reference Device

Drager Medical AG & Co KG - Evita Infinity V500 (k093633)

Maquet Critical Care AB - Servo U (k151814)

Puritan Bennett 980 Ventilator System (k162738)

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.

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.

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).

Summary of Technical Characteristics with the Predicate Device

The Nihon Kohden NKV-550 Series Ventilator System technological characteristics are substantially equivalent as compared to the predicate device and are summarized in the table below.

Table 7-1 Characteristic	**Nihon Kohden NKV-550 Series Ventilator System (Proposed Device)**	**Nihon Kohden NKV-550 Series Ventilator System (Predicate Device – k181695)**	**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.	Same

Table 7-1 Characteristic	Nihon Kohden NKV-550 Series Ventilator System (Proposed Device)	Nihon Kohden NKV-550 Series Ventilator System (Predicate Device – k181695)	Comparison
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	Same
Anatomical Site	Patient airways	Patient airways	Same
Target Population	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	Same
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	Same
Chemicals Delivered to Patient	Medical Air and Oxygen	Medical Air and Oxygen	Same
Delivery method to Patient	Positive pressure	Positive pressure	Same
Energy Used for Device	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	Same
Therapy Types	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 (k181695) are as follows:

1. Update.
2. Device/manufacturing improvements such as (a) More efficient cooling of the electronics module, (b) Revised sealing method between Monitor Arm (MNT5513P) and Top Housing (HSG5504M), (c) Improved IO board bracket, and (d) Additional EEPROM for secondary storage location for data.
3. Replace the Exhalation Flow Sensor (SEN5505P) any time the sensor fails calibration or after 5 cycles of cleaning and disinfection, whichever occurs first.
4. Compatible accessories.

Device modifications were made in compliance Design Control procedures.

Summary of Technical Characteristics with the Reference Device

The Drager V500 and Servo U are used as reference devices for the proposed Nihon Kohden NKV-550 Series Ventilator System as both the reference devices and the proposed device are critical care ventilators.

Table 7-2 Characteristic	Nihon Kohden NKV-550 Series Ventilator System (Proposed Device)	Draeger Medical AG & Co. KG - Drager V500 (Reference Device K093633)	Maquet Critical Care AB - Servo U (Reference Device K151814)	Puritan Bennett 980 Series Ventilator System (Reference Device K162738)	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 Evita V500 ventilation unit of the Infinity Acute Care System is intended for the ventilation of adult, pediatric and neonatal patients. Evita V500 offers mandatory ventilation modes and ventilation modes for spontaneous breathing support and airway monitoring. The Evita V500 ventilation unit is used with Infinity C Series Draeger Medical Cockpits. The Evita V500 ventilation unit is intended for use in different medical care areas. Evita V500 is intended for stationary use in hospitals and medical rooms or for patient transportation within the hospital.	The SERVO-U ventilator system is: *intended for respiratory support, monitoring and treatment of neonatal, pediatric and adult patients *to be used only by healthcare providers *to be used only in professional healthcare facilities and for transport within these facilities	The Puritan Bennett 980 Series Ventilator System is designed for use on patient population sizes from Neonatal (NICU) through Adult who require respiratory support or mechanical ventilation and weigh a minimum of 0.3kg (0.66lb). It is suitable for service in hospital (institutions) and intra-hospital transport to provide continuous positive pressure ventilatory support using medical oxygen and compressed medical air from either an internal air compressor or external air sources to deliver oxygen concentrations of 21% to 100%. Ventilatory support can be delivered invasively or non-invasively to patients who require the following types of ventilator support - Positive Pressure Ventilation, delivered invasively (via endotracheal tube or tracheotomy tube) or non-invasively (via mask or nasal prongs) - Assist/Control, SIMV, or Spontaneous modes of ventilation	Same

Table 7-2 Characteristic	Nihon Kohden NKV-550 Series Ventilator System (Proposed Device)	Draeger Medical AG & Co. KG - Drager V500 (Reference Device K093633)	Maquet Critical Care AB - Servo U (Reference Device K151814)	Puritan Bennett 980 Series Ventilator System (Reference Device K162738)	Comparison
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	Professional healthcare facilities and for transport within these facilities	It is suitable for service in hospital (institutions) and intra-hospital transport	Same
Anatomical Site	Patient airways	Patient airways	Patient airways	Patient airways	Same
Target Population	Adult, pediatric and neonatal patients	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	Met ISO 80601-2-12 requirements on essential performance of critical care ventilator	Same
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	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	Substantially Equivalent
Delivered to Patient	Medical Air and Oxygen	Medical Air and Oxygen	Medical Air and Oxygen	Medical Air and Oxygen	Same
Delivery method to Patient	Positive pressure	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)	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	time-cycled, volume-constant, pressure-controlled	Same

Table 7-2 Characteristic	Nihon Kohden NKV-550 Series Ventilator System (Proposed Device)	Draeger Medical AG & Co. KG - Drager V500 (Reference Device K093633)	Maquet Critical Care AB - Servo U (Reference Device K151814)	Puritan Bennett 980 Series Ventilator System (Reference Device K162738)	Comparison
Therapy Types	Invasive, Non-invasive, O2 Therapy	Intubated, Non-invasive, O2 Therapy	Invasive and Non-invasive	Invasive and Non-invasive	Substantially Equivalent

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
- Electrical Safety & EMC Testing
- Device Functionality Testing
- Performance of Therapy Types and Ventilation Modes
- Environmental
- Cleaning & Disinfection
- Risk Management
- Accessory Compatibility
- 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 modified Nihon Kohden NKV-550 Series Ventilator System is substantially equivalent to the legally marketed predicate device identified herein.