



December 7, 2018

Nihon Kohden OrangeMed, Inc.
Sheryl Higgins
Director of RA/QA
1800 E. Wilshire Ave.
Santa Ana, California 92705

Re: K181695

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: November 6, 2018
Received: November 7, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

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

Date

December 07, 2018

Submitter / Manufacturing Location

Nihon Kohden OrangeMed, Inc.

1800 E. Wilshire Avenue

Santa Ana, CA 92705

USA

Company Contact

Sheryl Higgins - Director of Regulatory Affairs and Quality Assurance

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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:	Evita Infinity® V500
510k #:	k093633
Manufacturer:	Draegerwerk AG & Co. KGaA
Establishment Reg. #:	9611500

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.

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

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.

Technical Characteristic	Nihon Kohden NKV-550 Series Ventilator System	Draeger Evita V500 Ventilation Unit* (Predicate Device – k093633)	Comparison
Indication for Use	The Nihon Kohden NKV-550 Series Ventilator System is intended to provide continuous <u>ventilation for adult, pediatric and neonatal patients</u> who require invasive or noninvasive respiratory support. The NKV-550 offers <u>mandatory and spontaneous ventilation modes as well as respiratory monitoring</u> . The NKV-550 is intended for <u>use in hospitals and hospital-type facilities, as well as for in-hospital transportation</u> .	The Evita V500 ventilation unit of the Infinity Acute Care System is intended for the <u>ventilation of adult, pediatric and neonatal patients</u> . Evita V500 offers <u>mandatory ventilation modes and ventilation modes for spontaneous breathing support and airway monitoring</u> . 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 <u>use in hospitals and medical rooms or for patient transportation within the hospital</u> .	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	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
Waveform Comparison	Comparable waveform test result	Comparable waveform test result	Substantially equivalent
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	Substantially equivalent
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

Technical Characteristic	Nihon Kohden NKV-550 Series Ventilator System	Draeger Evita V500 Ventilation Unit* (Predicate Device – k093633)	Comparison
Therapy Types	Invasive, Non-invasive, O2 Therapy	Intubated, Non-invasive, O2 Therapy	Same

*Information from manufacturer's "Instructions for use Infinity Acute Care System – Evita Infinity V500 SW 2.n" (Ed: 3 – 2010-08)

Summary of Non-Clinical Performance Data

Performance of the Nihon Kohden NKV-550 Series Ventilator System was demonstrated by the following:

- Software Verification
- Electrical Safety & EMC Testing
- Agency Testing to Applicable Standards
- Device Functionality Testing
- Performance of Therapy Types and Ventilation Modes
- Product Endurance
- Power Performance
- Environmental
- Cleaning & Disinfection
- Gas Path Biocompatibility
- Human Factors/Usability Testing
- Risk Management
- Waveform Comparison with Predicate
- Accessory Compatibility

Where applicable, the Nihon Kohden NKV-550 Series Ventilator System has been tested in compliance with the following standards:

Standard	Testing
ISO 80601-2-12 2011/04/15 Ed: 1; CORR 1: 2011/10/15	Medical Electrical Equipment - Part 2-12: Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators
ANSI AAMI ES60601-1 2005+AC1;A2 (R2012)	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2 2014/02/25 Ed: 4	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-1-6 2013/10/28 Ed: 3.1	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
IEC 60601-1-8 2012/11/28 Ed: 2.1	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 2012/12/06 Ed: 2.0	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
ISO 80601-2-55 2011/12/15 Ed: 1	Medical Electrical Equipment – Part 2-55: Particular Requirements for The Basic Safety and Essential Performance of Respiratory Gas Monitor
ISO 10993-1 2009/10/15 Ed: 4; TC 1 2010	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
ISO 18562-1 to 3 2017/03 Ed: 1	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications

Summary of Clinical Performance Data

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

Conclusion

The evaluation and testing performed demonstrates that the Nihon Kohden NKV-550 Series Ventilator System is as safe and as effective as the predicate device.