



May 15, 2025

MEKICS Co., Ltd.  
% Paul Dryden  
Consultant  
ProMedic Consulting LLC  
131 Bay Point Dr. NE  
St. Petersburg, Florida 33704

Re: K242931  
Trade/Device Name: Hft750u  
Regulation Number: 21 CFR 868.5895  
Regulation Name: Continuous Ventilator  
Regulatory Class: Class II  
Product Code: MNT  
Dated: April 14, 2025  
Received: April 15, 2025

Dear Paul Dryden:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.

Assistant Director

DHT1C: Division of Anesthesia,

Respiratory, and Sleep Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K242931

Device Name

HFT750U

### Indications for Use (Describe)

The HFT750U 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.

The device provides heated and humidified gas to the patient.

The device is intended for pediatric patients weighing 12.5 kg or greater to adult patients in non-invasive respiratory therapy. Patients with their upper airways bypassed are included.

The High Flow mode has a flow range from 1 to 60 lpm.

The HFT750U is intended for use in hospitals, hospital-type facilities, and in hospital transportation by qualified and trained users under the directions of a physician.

It is not intended for life support.

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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**Date Prepared:** 13-May-2025**Sponsor:**MEKICS Co. Ltd  
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+82-70-7119-253**Sponsor Contact:** Sang-Hag Lee – Regulatory Affairs Team Lead**Submission Contact:** Paul Dryden  
Promedic Consulting LLC**Proprietary or Trade Name:** HFT750U  
**Common/Usual Name:** Continuous Ventilator  
**Classification Name:** Continuous Ventilator  
**CFR:** 868.5895  
**Product Classification:** MNT**Primary Predicate Device:** Nihon Kohden NKV-330 - K213521  
**Classification Name:** Continuous ventilator  
**CFR:** 868.5895  
**Product Classification:** MNT**Secondary Predicate Device:** Fisher and Paykel – Airvo 3 NIV – K233643  
**Classification Name:** Continuous ventilator  
**CFR:** 868.5895  
**Product Classification:** MNT**Device Description:**

This HFT750U is a Continuous Ventilator, intended to provide the patient with a high flow of gas that contains a constant amount of oxygen in a non-invasive method, thereby assisting or regulating the patient's respiration use in a hospital or medical institutions.

It can be used by the upper airways bypassed patients. Equipped with various alarm and safety functions, High flow (HF), the Continuous Positive Airflow Pressure (CPAP) and Bilevel Positive Airway Pressure (bilevel) modes regulate the patient's respiration, but for correct diagnosis it should be used together with clinical information.

**Principle of Operation:**

HFT750U system consists of the Oxygen gas supply system, the gas control system and humidifier system.

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| Item                     | Description                                                              |
|--------------------------|--------------------------------------------------------------------------|
| Oxygen gas supply system | It controls the amount of oxygen supplied to the patient by proportional |

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|                    |                                                                                                                                                                              |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    | valve.                                                                                                                                                                       |
|                    | It helps patients breathing or treat patients with hypoxic respiratory failure by required amount of oxygen.                                                                 |
| Humidifier system  | The humidity is controlled to be sufficiently in accordance with the humidity level by user set and, humidification is maintained to not higher than the saturated humidity. |
|                    | The warm humidified air is supplied to the upper airway of the patient in high flow, CPAP and bilevel mode.                                                                  |
|                    | Enhance the patient's pulmonary compliance and conductance.                                                                                                                  |
| Gas control system | It supplies the correct flow rate or pressure to the patient by blower control.                                                                                              |
|                    | The flow rate is controlled in 1 L/min and is supplied up to 60 L/min.                                                                                                       |

**Indications for Use:**

The HFT750U 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.

The device provides heated and humidified gas to the patient.

The device is intended for pediatric patients weighing 12.5 kg or greater to adult patients in non-invasive respiratory therapy. Patients with their upper airways bypassed are included.

The High Flow mode has a flow range from 1 to 60 lpm.

The HFT750U is intended for use in hospitals, hospital-type facilities, and in hospital transportation by qualified and trained users under the directions of a physician.

It is not intended for life support.

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**Comparison of Subject vs. Predicates**

|                            | Primary Predicate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Secondary Predicate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Subject device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Comparison                                                                                                                                                                                                                              |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>K#</b>                  | K213521                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | K233643                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | K242931                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                         |
| <b>Manufacturer</b>        | Nihon Kohden – NKV-330                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | F&P Airvo3 NIV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | MEKICS HFT750U                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                         |
| <b>Product Code</b>        | MNT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | MNT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | MNT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                         |
| <b>Classification</b>      | 21CFR858.5895                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 21CFR858.5895                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 21CFR858.5895                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                         |
| <b>Indications for Use</b> | <p>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.</p> <p>It is intended for children weighing 12.5 kg or greater to adult patients. It offers noninvasive ventilation, invasive ventilation, and respiratory monitoring.</p> <p>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.</p> | <p>F&amp;P Airvo 3 NIV (PT311US)<br/>When used in NIV mode:<br/>The Airvo 3 NIV provides non-invasive ventilator support for non-ventilator dependent, spontaneously breathing adult patients (66 lb/30 kg and above) with respiratory insufficiency. It is intended to be used in hospitals. It is not intended for life support.</p> <p>When used in High Flow mode:<br/>The Airvo 3 NIV is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals. It adds heat and moisture to the flow of air, or blended air/medical oxygen mixture, and assures the user of the air/oxygen mixture using an integrated oxygen analyzer and visual display. The flow may be from 2 to 70 L/min depending on the patient interface. The Airvo 3 NIV provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients with or without bypassed upper airways in hospitals.</p> <p>The Airvo 3 NIV provides high flow gases with simultaneous oxygen</p> | <p>The HFT750U 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.</p> <p>The device provides heated and humidified gas to the patient.</p> <p>The device is intended for pediatric patients weighing 12.5 kg or greater to adult patients in non-invasive respiratory therapy. Patients with their upper airways bypassed are included.</p> <p>The High Flow mode has a flow range from 1 to 60 lpm.</p> <p>The HFT750U is intended for use in hospitals, hospital-type facilities, and in hospital transportation by qualified and trained users under the directions of a physician.</p> <p>It is not intended for life support.</p> | <p>Similar<br/>The primary predicate patient population is the same as well as environments of use.</p> <p>The secondary predicate includes integrated heated humidifier and High Flow mode as well as the same environment of use.</p> |

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|                                          | Primary Predicate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Secondary Predicate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Subject device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Comparison                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>delivery through nasal cannula interfaces to augment the breathing of spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting. The Airvo 3 NIV is not intended to provide total ventilatory requirements and is not intended for use during field transport.</p> <p>AirSpiral NIV tube and chamber kit (900PT573):<br/> For use with noninvasive ventilator support for non-ventilator dependent, spontaneously breathing adult patients (66 lbs./30 kg and above) with respiratory insufficiency. It is intended to be used in hospitals. It is not intended for life support.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                           |
| <b>Fundamental scientific technology</b> | <p>This device uses outside air and a high pressure oxygen source or oxygen cylinder. Outside air which is taken in by the blower and oxygen which has a flow rate controlled by the proportional control valve are mixed in the mixing chamber and supplied to the patient. The microprocessor controls the blower and the proportional control valve to deliver the pressure and oxygen concentration which are set by the user.</p> <p>The gas delivered from the ventilator is supplied to the patient through the patient breathing circuit, flow sensor, and patient interface.</p> | <p>The Airvo 3 NIV design makes uses a centrifugal blower with a low inertia impeller to control the pressure based on the device setting as well as pressure and flow sensor measurements. The Airvo 3 NIV has three modes of NIV therapy: Bi-Level S/T, Bi-Level PCV and CPAP.</p>                                                                                                                                                                                                                                                                                                                                                         | <p>This device uses outside air and a high pressure oxygen source or oxygen cylinder. Outside air which is taken in by the blower and oxygen which has a flow rate controlled by the proportional control valve are mixed in the mixing chamber and supplied to the patient. The microprocessor controls the blower and the proportional control valve to deliver the pressure and oxygen concentration which are set by the user.</p> <p>The warmed and humidified gas delivered from the ventilator is supplied to the patient through the patient breathing circuit, flow sensor, and patient interface.</p> | <p>HFT750U operates with an integrated humidifier and provides the heated and humidified gas delivered to the patient similar to the secondary predicate.</p> <p>The technology of a blower to generate positive pressure, plus connection to an oxygen source with similar accessories and sensor is similar to both the predicates.</p> |
| <b>Oxygen Input Sources</b>              | High pressure oxygen source or oxygen cylinder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | High-Pressure Oxygen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | High pressure oxygen source or oxygen cylinder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Similar                                                                                                                                                                                                                                                                                                                                   |

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|                            | Primary Predicate                                                                                                                                                                                                                                                                                                                                | Secondary Predicate                              | Subject device                                                                                                                                                                                                                                                                                                                                     | Comparison                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                            |                                                                                                                                                                                                                                                                                                                                                  | Low-Pressure Oxygen (LPO)                        |                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Humidity Source</b>     | Optional use of an external Heated Humidifier                                                                                                                                                                                                                                                                                                    | Integrated heated humidifier                     | Integrated heated humidifier                                                                                                                                                                                                                                                                                                                       | Similar to the secondary predicate both comply with ISO 80601-2-74<br>HFT750U operates with an integrated humidifier and displays temperature related to humidifier.                                                                                                                                                                                                                                                                              |
| <b>Parameters measured</b> | FI-PEAK (Peak Inspiratory Flow)<br>PIP (Peak Inspiratory Pressure)<br>PEEP (Positive End Expiratory Pressure)<br>RR TOT (Total Respiratory Rate)<br><br>VTI (Inspiratory Tidal Volume)<br><br>VT (Expiratory Tidal Volume)<br><br><br><br><br><br><br>O2 Gas Usage<br>Flow Rate<br>FiO2<br>SpO2<br>PR (Pulse rate)<br>PI (Pulse-amplitude index) | Many measured parameters. List is not available. | Flow (Peak Inspiratory Flow)<br>PIP(Peak Inspiratory Pressure)<br>PEEP(Positive End Expiratory Pressure)<br>RR (Respiration rate)<br><br>Vti(Inspiratory Tidal Volume)<br><br>V delivery or Vt est (Expiratory Tidal Volume)<br><br><br><br><br><br><br>O2 Gas Usage<br>Flow Rate<br>FiO2<br>SpO2<br>PR (Pulse rate)<br>PI (Pulse-amplitude index) | HFT750U measures similar parameters to both the predicates.<br><br><br><br><br><br><br>Similar<br><br><br>Although both represent expiratory tidal volume, they are labeled separately as <i>V delivery</i> in Volume guarantee mode (a controlled value) and <i>Vt est</i> in non-VG mode (an estimated value) due to their different clinical implications.<br><br>Any differences of measured parameters do not raise different risk concerns. |
|                            | FE-PEAK (Peak Expiratory Flow)                                                                                                                                                                                                                                                                                                                   | Many measured parameters. List is                | FE-PEAK (Peak Expiratory Flow)                                                                                                                                                                                                                                                                                                                     | Ventilation parameters                                                                                                                                                                                                                                                                                                                                                                                                                            |

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|                                 | <b>Primary Predicate</b>                                                                                                                                                                                                                                                                                                                                                                                           | <b>Secondary Predicate</b>                                          | <b>Subject device</b>                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Comparison</b>                                                                                                                                                                |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                 | MVI (Total Inspiratory Minute Volume)<br>MVI SPONT (Spontaneous Inspiratory Minute Volume)<br>MV (Total Expiratory Minute Volume)<br>MV SPONT (Spontaneous Expiratory Minute Volume)<br>RR SPONT (Spontaneous Respiratory Rate)<br>TI/TTOT (Inspiratory duty cycle)<br>I:E ratio (I:E)<br>TI (Inspiratory Time)<br>TE (Expiratory Time)<br>Pt. Trig (Spontaneous breathing ratio)<br>Leak % (Leakage volume ratio) | not available.                                                      | MVI (Total Inspiratory Minute Volume)<br>MVI SPONT (Spontaneous Inspiratory Minute Volume)<br>MV (Total Expiratory Minute Volume)<br>MV SPONT (Spontaneous Expiratory Minute Volume)<br>RR SPONT (Spontaneous Respiratory Rate)<br>TI/TTOT (Inspiratory duty cycle)<br>I:E ratio (I:E)<br>TI (Inspiratory Time)<br>TE (Expiratory Time)<br>Pt. Trig (Spontaneous breathing ratio)<br>Leak ratio (Leakage volume ratio) | are similar to the predicate.                                                                                                                                                    |
|                                 | Not provided or calculated                                                                                                                                                                                                                                                                                                                                                                                         | Not provided or calculated                                          | S/F ratio (SpO2/FiO2 ratio)<br>ROX (Respiratory rate-Oxygenation)                                                                                                                                                                                                                                                                                                                                                      | These are indexes which are generated from the similar measured parameters and displayed. They are for display to the clinician only. They do not raise different risk concerns. |
|                                 | External Humidifier includes many measured parameters<br>Airway Temperature<br>Chamber Temperature<br>Heat plate Temperature                                                                                                                                                                                                                                                                                       | Airway Temperature<br>Chamber Temperature<br>Heat plate Temperature | Airway Temperature<br>Chamber Temperature<br>Heat plate Temperature                                                                                                                                                                                                                                                                                                                                                    | Similar to the secondary predicate with integrated humidifier                                                                                                                    |
|                                 | CO2 (I)<br>CO2 (E)<br>RR (Respiration Rate) (CO2).                                                                                                                                                                                                                                                                                                                                                                 | Not available                                                       | Not available                                                                                                                                                                                                                                                                                                                                                                                                          | HFT750U does not support an optional EtCO2 monitor or its measurement.                                                                                                           |
| <b>Intra-hospital transport</b> | Transit-operable                                                                                                                                                                                                                                                                                                                                                                                                   | In hospital transport                                               | Transit-operable                                                                                                                                                                                                                                                                                                                                                                                                       | Similar                                                                                                                                                                          |
| <b>Patient Interface</b>        | Face mask or nasal mask, nasal cannula                                                                                                                                                                                                                                                                                                                                                                             | Face mask or nasal mask, nasal cannula                              | Face mask or nasal mask, nasal cannula                                                                                                                                                                                                                                                                                                                                                                                 | Similar                                                                                                                                                                          |
| <b>Cleaning</b>                 | External surface cleaning                                                                                                                                                                                                                                                                                                                                                                                          | External surface cleaning                                           | External surface cleaning                                                                                                                                                                                                                                                                                                                                                                                              | Similar                                                                                                                                                                          |

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|                                    | <b>Primary Predicate</b>                                                                                                                                                                 | <b>Secondary Predicate</b>                                                                                                                                                                                                    | <b>Subject device</b>                                                                                                                                                                                                                                                               | <b>Comparison</b>                                                                                          |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| <b>Patient use</b>                 | Adult and pediatric >12.5 kg patients that are breathing spontaneously but need partial ventilation support through invasive or non-invasive ventilation.                                | NIV – adults – 60 lbs. / 30 kg<br><br>High Flow - spontaneously breathing infant, child, adolescent and adult patients                                                                                                        | Adult and pediatric >12.5 kg patients that are breathing spontaneously but need partial ventilation support through non-invasive ventilation.                                                                                                                                       | HFT750U does not provide invasive ventilation like the predicate but is similar to the secondary predicate |
| <b>Specifications</b>              | <b><u>S/T mode (Spontaneous PS/Timed PCV)</u></b><br>- IPAP<br>- EPAP/CPAP                                                                                                               | <b><u>Bi-level S/T</u></b>                                                                                                                                                                                                    | <b><u>S/T mode (Spontaneous PS/Timed PCV)</u></b><br>- IPAP<br>- EPAP                                                                                                                                                                                                               | Similar                                                                                                    |
|                                    | <b><u>PRVC</u></b><br>- V <sub>t</sub><br>- EPAP                                                                                                                                         | <b><u>Information not available</u></b>                                                                                                                                                                                       | <b><u>S/T mode (Volume Guarantee)</u></b><br>- V delivery<br>- EPAP                                                                                                                                                                                                                 | Similar                                                                                                    |
|                                    | <b><u>Spont/PS mode</u></b> (PS set to zero is CPAP)<br>- Inspiratory Time or I:E<br>- Pressure Release<br>- Trigger: flow trigger or advanced trigger<br>- Cycling off<br>- Peak flow % | <b><u>PVC / CPAP</u></b><br><b>IPAP Range</b> - 4-30cm/H <sub>2</sub> O<br><b>EPAP Range</b> - 4-25cm/H <sub>2</sub> O<br><b>CPAP Range</b> - 4-25cm/H <sub>2</sub> O<br><br><b><u>Alarms</u></b><br>Visual and audible alarm | <b><u>CPAP Mode</u></b><br><b>IPAP Range</b> - 4-40cm/H <sub>2</sub> O<br><b>EPAP Range</b> - 4-20cm/H <sub>2</sub> O<br><b>CPAP Range</b> - 4-20cm/H <sub>2</sub> O<br><br><b><u>Alarms</u></b><br>Visual and audible alarm<br>- Pressure Release<br>- Flow trigger<br>- Rise Time | Similar                                                                                                    |
|                                    | <b><u>O2 Therapy Mode</u></b><br>- Flow (1 – 60 L/min)<br>- Circuit Obstruction Alarm                                                                                                    | <b><u>HF Mode</u></b><br>- Flow (2 – 70 L/min)<br>- Circuit Obstruction Alarm                                                                                                                                                 | <b><u>HF Mode</u></b><br>- Flow (1 – 60 L/min)<br>- Circuit Obstruction Alarm                                                                                                                                                                                                       | Similar                                                                                                    |
| <b>Operating temperature range</b> | 5 °C to 40 °C                                                                                                                                                                            | Not listed                                                                                                                                                                                                                    | 5 °C to 40 °C                                                                                                                                                                                                                                                                       | Similar                                                                                                    |
| <b>Optional SpO2</b>               | Connects to external cleared pulse oximeter                                                                                                                                              | Connects to external cleared pulse oximeter                                                                                                                                                                                   | Connects to external cleared pulse oximeter                                                                                                                                                                                                                                         | Similar                                                                                                    |
| <b>Performance standards</b>       | ISO 80601-2-12 Ed.1 2011-04<br>ISO 80601-2-55 Ed.2 2018-02<br>ISO 80601-2-61 Ed.2 2017-12                                                                                                | ISO 80601-2-12 Ed.3 2023-11<br>ISO 80601-2-55 Ed.2 2018-02<br>ISO 80601-2-61 Ed.2 2018-02<br>ISO 80601-2-74 Ed.2 2021-07<br>ISO 80601-2-90 Ed.1 2021-08                                                                       | ISO 80601-2-12 Ed.3 2023-11<br>ISO 80601-2-55 Ed.2 2018-02<br>ISO 80601-2-61 Ed.2 2018-02<br>ISO 80601-2-74 Ed.2 2021-07<br>ISO 80601-2-90 Ed.1 2021-08                                                                                                                             | HFT750U complies to ISO 80601-2-90 and ISO 80601-2-74 for humidification                                   |
| <b>Electrical Safety and EMC</b>   | ANSI AAMI ES 60601-1:2005+AC1;A2(R2021)<br>IEC 60601-1 Ed.3.1 2012-08<br>IEC 60601-1-2 Ed.4.0 2014-02                                                                                    | IEC 60601-1 Ed.3.2 2020-08<br>IEC 60601-1-2 Ed.4.1 2020-09<br>IEC 60601-1-6 Ed.3.1 2013-10<br>IEC 60601-1-8 Ed. 2012                                                                                                          | IEC 60601-1 Ed.3.2 2020-08<br>IEC 60601-1-2 Ed.4.1 2020-09<br>IEC 60601-1-6 Ed.3.1 2013-10<br>IEC 60601-1-8 ed. 2012                                                                                                                                                                | Similar                                                                                                    |

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|                                  | <b>Primary Predicate</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Secondary Predicate</b>                                                                                                                                                                                                                                                                                                                                                                         | <b>Subject device</b>                                                                                                                                                                                                                                                                                                                                                                              | <b>Comparison</b>   |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
|                                  | IEC 60601-1-6 Ed.3.1 2013-10<br>IEC 60601-1-9 Ed.2.1 2012-11<br>IEC 60601-2-49 Ed.2.0 2011-02<br>IEC 62133-2 Ed.1.0 2011-02<br>IEC 62366 Ed.1.1 2014-01                                                                                                                                                                                                                                                                                                                                                   | IEC 62133-2 Ed.1 2021-07<br>IEC 62366-1 Ed.1 2015-02                                                                                                                                                                                                                                                                                                                                               | IEC 62133-2 Ed.1 2021-07<br>IEC 62366-1 Ed.1 2015-02                                                                                                                                                                                                                                                                                                                                               |                     |
| <b>Bench Testing</b>             | Software Verification<br>Electrical Safety & EMC Testing<br>Agency Testing to Applicable Standards<br>Performance of Ventilation Modes and Control Settings<br>Device Functionality<br>Power performance with AC Mains power or Reserve battery power<br>Endurance/Reliability<br>Essential Performance and Worst Case VBS<br>Environmental<br>Cleaning & Disinfection<br>Biocompatibility<br>Waveform Comparison with Predicate<br>Human Factors/Usability<br>Risk Management<br>Accessory Compatibility | Software Verification<br>Electrical Safety & EMC Testing<br>Performance of Ventilation Modes and Control Settings<br>Device Functionality<br>Power performance with AC Mains power or Reserve battery power<br>Endurance/Reliability<br>Cleaning & Disinfection<br>Biocompatibility<br>Waveform Comparison with Predicate<br>Human Factors/Usability<br>Risk Management<br>Accessory Compatibility | Software Verification<br>Electrical Safety & EMC Testing<br>Performance of Ventilation Modes and Control Settings<br>Device Functionality<br>Power performance with AC Mains power or Reserve battery power<br>Endurance/Reliability<br>Cleaning & Disinfection<br>Biocompatibility<br>Waveform Comparison with Predicate<br>Human Factors/Usability<br>Risk Management<br>Accessory Compatibility | Similar             |
| <b>Storage Temperature</b>       | -20 °C to + 65 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Not listed                                                                                                                                                                                                                                                                                                                                                                                         | -25 °C to + 70 °C                                                                                                                                                                                                                                                                                                                                                                                  | Similar             |
| <b>Storage Relative Humidity</b> | 10 to 95 %                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Not listed                                                                                                                                                                                                                                                                                                                                                                                         | 0 to 95 %                                                                                                                                                                                                                                                                                                                                                                                          | Similar             |
| <b>Nurse Call</b>                | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Yes                                                                                                                                                                                                                                                                                                                                                                                                | Yes                                                                                                                                                                                                                                                                                                                                                                                                | Similar             |
| <b>Communications</b>            | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | N/A                                                                                                                                                                                                                                                                                                                                                                                                | N/A                                                                                                                                                                                                                                                                                                                                                                                                | Similar             |
| <b>Device weight</b>             | 7.6 kg (including the 2 batteries, but not including other accessories)                                                                                                                                                                                                                                                                                                                                                                                                                                   | Not listed                                                                                                                                                                                                                                                                                                                                                                                         | 5.8 kg (including the 2 batteries, but not including other accessories)                                                                                                                                                                                                                                                                                                                            | Similar             |
| <b>Dimensions</b>                | 330 (W) x 340 (H) x 175 (D) mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Not listed                                                                                                                                                                                                                                                                                                                                                                                         | 214 (W) x 219 (H) x 338 (W) mm                                                                                                                                                                                                                                                                                                                                                                     | Similar             |
| <b>Interface</b>                 | Operation Keys, Operation Knob, Touch screen.                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Operation Keys, Operation Knob, Touch screen.                                                                                                                                                                                                                                                                                                                                                      | Operation Keys, Operation Knob, Touch screen.                                                                                                                                                                                                                                                                                                                                                      |                     |
| <b>Power / Energy Source</b>     | 100 to 240 V~, 50 to 60 Hz, Li-ion, 14.4 Vd.c                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 100 to 240 V~, 50 to 60 Hz, Battery                                                                                                                                                                                                                                                                                                                                                                | 100 to 240 V~, 50 to 60 Hz, Li-ion, 14.4 Vd.c                                                                                                                                                                                                                                                                                                                                                      | Similar             |
| <b>Biocompatibility</b>          | ISO 10993-1 Ed.5 2018-05<br>ISO 18562-1 Ed.1 2017-03                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ISO 10993-1 Ed.5 2018-05<br>ISO 18562-1 Ed.1 2017-03                                                                                                                                                                                                                                                                                                                                               | ISO 10993-1 Ed.5 2018-05<br>ISO 18562-1 Ed.1 2017-03                                                                                                                                                                                                                                                                                                                                               | Similar             |
| <b>Accessories</b>               | When connected to an external                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Sponsor provided                                                                                                                                                                                                                                                                                                                                                                                   | User supplied                                                                                                                                                                                                                                                                                                                                                                                      | Similar accessories |

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|  | <b>Primary Predicate</b>                                                                                                                            | <b>Secondary Predicate</b>                                                                                                   | <b>Subject device</b>                                                                                                        | <b>Comparison</b> |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-------------------|
|  | cleared humidifier then user supplied<br>Heated wire circuits<br>Water chambers<br>Patient interfaces (mask) for NIV are<br>needed but not supplied | Heated wire circuits<br>Water chambers<br>Patient interfaces (mask) for NIV<br>Nasal Cannula<br>T-piece for trach connection | Heated wire circuits<br>Water chambers<br>Patient interfaces (mask) for NIV<br>Nasal Cannula<br>T-piece for trach connection | required          |

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**Discussion of the Comparison and Differences**

The subject device differs in the following ways from the predicate but is addressed with the provided secondary predicate device:

1. Includes an integrated heated humidifier vs. the predicate attaches to an external heated humidifier, but the secondary predicate includes an integrated heated humidifier
2. Has fewer ventilator modes and thus fewer measured parameters, but is a subset of the predicate but similar to the secondary predicate
3. Does not include EtCO<sub>2</sub> monitoring option which the secondary predicate does not as well
4. Expiratory Tidal Volume
  - a. The predicate measures and present *VT* (expiratory tidal volume)
  - b. The subject device presents both *V delivery* and *Vt est* which represent the **expiratory tidal volume**, and due to the nature of **single limb circuits**, both values are **indirectly measured**. However, we differentiate them based on how they are derived under different ventilation modes:
  - c. In **Volume Guarantee (VG) mode ON**, the ventilator adjusts its output to achieve a set target tidal volume. The calculated value reflects **the volume intentionally delivered** by the ventilator as part of its control strategy. For this reason, we refer to it as “**V delivery**”, emphasizing its alignment with the intended therapy goal.
  - d. In **VG mode OFF**, the ventilator does not regulate tidal volume. The resulting expiratory volume varies depending on patient condition and is **an indirectly estimated value without active control**. Therefore, it is labeled “**Vt est**” (estimated tidal volume).
  - e. Both devices present expiratory tidal volume.
5. Calculated indexes: S/F, ROX.

**S/F Ratio** =  $\text{SpO}_2 (\%) / \text{FiO}_2$  (as a decimal)

**S/F Ratio** is well-recognized as a non-invasive surrogate for the P/F ratio ( $\text{PaO}_2/\text{FiO}_2$ ) which is used in assessing oxygenation status, particularly when arterial blood gas is not available.

**ROX index** is calculated as:

$\text{ROX Index} = (\text{SpO}_2 / \text{FiO}_2) / \text{Respiratory Rate (breaths/min)}$

This index is commonly used to predict the success of high-flow nasal cannula (HFNC) therapy and has been described in peer-reviewed literature as a validated clinical tool.

These parameters are derived using clinically accepted formulas based on existing measurements— $\text{SpO}_2$ ,  $\text{FiO}_2$ , and respiratory rate—all of which are available in the subject device and the predicate device.

The subject device merely automates the calculation of these values, which clinicians could compute manually.

Furthermore:

- These calculated parameters are for informational purposes only and are not used to drive or control therapy.
  - Their inclusion does not raise new questions of safety or effectiveness, as they are passive displays based on known data.
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For these reasons, the inclusion of the **S/F ratio** and **ROX index** do not impact the safety, effectiveness, or intended use of the device. These differences do not raise different concerns of risk of safety compared to the predicate.

**Discussion of Differences**

As presented above the outlined differences do not raise different concerns of risk or safety compared to the predicate or as applicable the secondary predicate device with integrated humidifier.

As demonstrated in the discussion of differences above, the differences do not fundamentally change the indications for use, technology, or environment of use.

**Indications –**

- The Indications for Use are similar to the predicates.

**Patient Population –**

- The patient population is similar to the predicates.

**Environment of Use –**

- The environment of use are similar to the predicates.

**Technological Characteristics –**

- The technology is similar to the predicates.

**Performance Testing**

Performance of the HFT750U 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
- Service-life
- Environmental
- Cleaning & Disinfection
- Biocompatibility
- Waveform Comparison with Predicate
- Human Factors/Usability
- Risk Management
- Accessory Compatibility

**Substantial Equivalence Conclusion**

The sponsor has demonstrated through performance testing, design and non-clinical testing that the proposed device and predicates have been found to be substantially equivalent.

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