December 2, 2024

Flight Medical Innovations Ltd.
Ken Raichman
Director of QA & Regulatory Affairs
7 Hatnufa St.
Petach Tikva, 4951025
Israel

Re: K223120
Trade/Device Name: Ventoux Ventilator; Models VC2 VC3
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, BTT, DQA
Dated: October 31, 2024
Received: November 4, 2024

Dear Ken Raichman:

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) 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,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K223120

Device Name
Ventoux Ventilator; Models VC2 VC3

Indications for Use *(Describe)*
The Ventoux is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the Ventoux is applicable for adult and pediatric (i.e., infant, child and adolescent) patients who weigh at least 5 kg (11 lbs).

The Ventoux is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital environments.

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.

510(k) Summary

510(K) SUMMARY

[as required by section 807.92(c)]

Ventoux Ventilator

510(k) Number K__ 223120_____

Applicant's Name:

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Israel

Contact Person:

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Trade Name:

Ventoux Ventilator

Classification Name:

Continuous Ventilator

Classification:

FDA has classified continuous ventilators as class II devices (product code 73 CBK and DQA) and they are reviewed by the Anesthesiology panel

Predicate Device:

Flight 60 Ventilator cleared under K143035

Reference Device: HAMILTON C6 Ventilator cleared under K201658

Device Description:

The Ventoux Ventilator is an electrically powered, microprocessor-controlled multi-parameter ventilator, which can be: Time, Pressure, Flow or Volume triggered; Volume or Pressure controlled; Time or Flow cycled.

Manual inflation is allowed, and the Ventoux supports the emergency intake of ambient air which permits the patient to pull ambient air into the breathing circuit in the event of a complete loss of air/gas supply.

Volume triggered is based on Inspiratory trig response time ≤100 ms from pressure drop/flow rise to PEEP level.

Ventilation is possible in both Invasive and Noninvasive settings.
The system can be expanded to include additional parameter monitoring to allow for SpO2, etCO2 and Cuff Pressure Control.
The Ventoux can be powered by external power (100 – 240 VAC, 50-60 HZ or 10 – 30 VDC) and/or by its two swappable internal Li Ion rechargeable batteries, which provide full operating power the to the ventilator for a minimal operating time of 6 hours when operating on standard ventilation parameters.
A comprehensive alarm system is built-in to alert the user to violations of set safety limits. The alarm system alerts the care giver by activating the audible alarm, screen display and the LED indicator.

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Technological characteristics

The electrical system is comprised of three primary boards:
The main board (motherboard) which holds the majority of the electronics including the main CPU and the display CPU, the power board, which holds the power subsystems, and internal communication functions, and the Communication board, which holds internal communication and external communication connectors.
The main component of the pneumatic system is an electrically controlled compressor (pump). This compressor provides a compressed gas source so no external air compressor is needed.
Additionally, the exhalation valve is activated by an electrically controlled proportional solenoid that provides a built in PEEP.
The following table presents a comparison of Technological characteristics with the predicate device.

Table 1: A comparative summary of the technological characteristics of the Ventoux with the predicate and reference devices.

Parameters	**Proposed device: VENTOUX**	**Predicate device: Flight 60 turbine K143035**	**Comparison to Flight 60 turbine**	**Reference device: HAMILTON C6 K201658**
Intended use	The VENTOUX is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the VENTOUX is applicable for adult and pediatric (i.e., infant, child and adolescent) patients who weigh at least 5 kg (11 lbs).	The VENTOUX is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the VENTOUX is applicable for adult and pediatric (i.e., infant, child and adolescent) patients who weigh at least 5 kg (11 lbs).	Substantially Equivalent	The HAMILTON-C6 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics and optionally infants and neonates. The HAMILTON-C6 Ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications

	The VENTOUX is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital environments.	The VENTOUX is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.	Substantially Equivalent but with reduced environment to hospital use.	Intended areas of use: In the intensive care ward, intermediate care ward, emergency ward, long-term acute care hospital or in the recovery room. During transfer of ventilated patients within the hospital
Product classification code and CFR citation	CBK (subsequent: DQA) 21 CFR 868.5895	CBK, NOU 21 CFR 868.5895	DQA referenced as part of Oximetry, NOU not referenced due to no Home Care	CBK (subsequent: DQA) 21 CFR 868.5895
Principal operator	Qualified, trained personnel under the direction of a physician	Qualified, trained personnel under the direction of a physician	Substantially equivalent	same
Environment of use	Intended areas of use: hospitals.	Intended areas of use: • hospitals, sub-acute emergency rooms • Transport and emergency response applications. • Home care use	The Ventoux is equivalents to the F60 turbine except that the Ventoux is approved only for Hospital use The Ventoux is provided in two versions, whereas the Flight 60 turbine is a single unit covering all environmental applications:	Intended areas of use: • Healt h care facilities • During transfer of Ventilated patients within health care facilities

Intended patient population	Adult and pediatric (i.e., infant, child and adolescent) patients who weigh at least 5 kg (11 lbs).	Adult and pediatric (i.e., infant, child and adolescent) patients who weigh at least 5 kg (11 lbs).	Substantially Equivalent	Adults, pediatrics, infants and neonates
Patient interface	Delivered invasively (via ET tube) or noninvasively (via a mask)	Delivered invasively (via ET tube) or noninvasively (via a mask)	Substantially Equivalent	The same
Power source	AC, DC, Battery	AC, DC, Battery	Substantially Equivalent	The same
Operational modes	AC-VC	ACMV-VCV	Equivalent Name change more commonly used terminology	(S)CMV (only for adult/pediatric patients)
	AC-PC	ACMV-PCV	Equivalent Equivalent Name change more commonly used terminology	PCV+
	AC-PRVC	ACMV-PRVC	Equivalent Name change more commonly used terminology	-
	SIMV-VC	SIMV-VC	Equivalent	SIMV (only for adult/pediatric patients)
	SIMV-PC	SIMV-PC	Equivalent	PSIMV+
	AC-PRVC	ACMV-PRVC	Equivalent	APVcmv/(S)CMV +
	SIMV-PRVC	SIMV-PRVC	Equivalent	APVsimv/SIMV+
	APRV	B-LEV	Equivalent Name change more commonly used terminology	APRV
	CPAP/PSV	SPONT	Equivalent Name change more commonly used terminology	SPONT

	VG	VtG	Equivalent Name change more commonly used terminology	-
	HFOT	---	Not available in F60T	HiFlowO2
	Not available	ASV/ INTELLiVENT-ASV	Not Relevant	Not available
	NIV (non- invasive ventilation) is available in all modes for the device (except for HFOT)	NIV (non- invasive ventilation) is available in all modes for the device	Equivalent	NIV
Therapy Types	Invasive, Noninvasive, O2 % Delivery HiFlowO2	Does not contain Hi Flow O2 Mode	The High Flow O2 mode is only a SW change that uses the same components that are used for O2 % Delivery	Invasive, Noninvasive, O2 % Delivery HiFlowO2
Emergency air intake	In case of a power supply, technical, or pneumatics failure the ventilator valves allow spontaneous ambient breathing.	In case of a power supply, technical, or pneumatics failure the ventilator valves allow spontaneous ambient breathing.	Equivalent	Yes
Exhalation valve	Yes, pneumatic	Yes, pneumatic	Equivalent	Yes
Alarms and monitoring	Yes	Yes	Equivalent	Yes
Supply gas	Oxygen, ambient air	Oxygen, ambient air	Substantially equivalent	Yes
Method of supply gas pressurization	Internal turbine for air, compressed source for O2	Internal turbine for air, compressed source for O2	Substantially equivalent	Yes
Capnography monitoring option	Yes	No	Equivalent to reference device	Yes

Oximetry (SpO2) monitoring option	Yes	No	Equivalent to reference device	Yes
Cuff pressure control	Yes	No	Equivalent to reference device	Yes
Transportation	Transportable	Yes	Equivalent	Mobile
Data Storage	NVRAM + eMMC	NVRAM	Equivalent	Compact flash
Ingress of Dust and Water	IP 34	IP 34	Equivalent	IP21

Table 1 above demonstrate that the proposed device Ventoux has the same technological characteristics as the predicate device. Altogether, the technological characteristics of the proposed device Ventoux are substantially equivalent to the predicate device. Thus, the comparison of the Ventoux to its predicate device does not raise new safety and effectiveness concerns.

Intended Use:

The Ventoux is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the Ventoux is applicable for adult and pediatric (i.e., infant, child and adolescent) patients who weigh at least 5 kg (11 lbs).
The Ventoux is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital environments.

Performance Data:

The Ventoux Ventilator meets all applicable device specification requirements for performance testing as identified in the FDA reviewer guidance for ventilators. Verification of compliance with recognized standards has been made to support safe use of the device for its intended use and in its intended environment.

A series of tests and analyses were performed to evaluate the safety and effective performance of the Ventoux Ventilator. Presented below is a list of standards the Ventoux Ventilator complies with and tests that have been successfully performed.

- IEC 60601-1: (ed. 3.1, 2012) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: (ed. 4, 2015) Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-2: (4.1 ed. 2020) EMC Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- ISO 80601-2-12 :(ed. 1, 2011) Medical Electrical Equipment -- Part 2-12: Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators
- IEC 60601-1-8: (ed. 2.1, 2012) Medical Electrical Equipment - Part 1-8: General Requirements for Basic Safety and Essential Performance - Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical System
- ISO 80601-2-55: 2018 Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors -anesthetic gas monitoring, carbon dioxide monitoring, and oxygen monitoring.
- ISO 80601-2-61: 2018 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 80601-2-84:2018 Medical electrical equipment Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment
- IEC 60601-1-6 : 2020 General requirements for basic safety and essential performance – Collateral standard : Usability
- IEC 62304 : 2015 Edition 1.1 SW Life Cycle
- CISPR 11: 2016 (- Limits and Methods of Measurement of Radio Disturbance Characteristics of Industrial, Scientific, and Medical (I.S.M) Radio Frequency Equipment – covered under IEC 60601-1-2 (4.1 ed. 2020) above.
- Environmental:
  IEC 60529 Degrees of Protection Provided by Enclosures (IP 34 Code) – covered under IEC 60601-1: (ed. 3.1, 2012) above.
  - IEC 60068-2-27 (ed. 4, 2008) Environmental Testing - Part 2-27: Tests -
    Test Ea and Guidance: Shock
  - IEC 60068-2-31 (ed. 2, 2008) Environmental Testing –

Part 2-31: Tests – Test Ec: Rough Handling Shocks, Primarily for Equipment-Type Specimens
    - IEC 60068-2-64 (ed. 2, 2008) Environmental Testing - Part 2-64: Tests - Test Fh: Vibration, Broadband Random and Guidance – Covered under ISO 80601-2-84:2018
- Altitude Validation
- Internal Temperature Validation
- Verification and Validation of Li-Ion Battery
- Measurement of Expiratory Volume

The software design and validation process, together with the bench testing of the device, demonstrated Ventoux Ventilator performs as intended.
Additional testing were conducted to assure that the Ventoux ventilator meets its predefined specifications in accordance with internal procedures as mandated by the quality Management system.
The ventilation modes were subjected to waveform performance testing.
The data provided from these tests was shown to support substantial equivalency to the legally marketed devices

Biocompatibility:
The gas pathways of the Ventoux were assessed and tested in accordance with ISO 18562:2024, parts 1,2&3.

Summary of clinical testing:
No clinical testing was conducted or required in support of this premarket notification.

Conclusion:

Substantial equivalence has shown similar technological characteristics, intended use, principles of operation and verification and validation. The proposed device has software and hardware to maintain the intended performance. No new questions of safety and effectiveness have been raised. The Ventoux ventilator is as substantially equivalent as the legally marketed devices identified in this submission. Flight Medical Innovations Ltd. believes that, based on the information provided in this submission, the Ventoux Ventilator is substantially equivalent to its predicate devices.