Inovytech Medical Solutions Ltd.
℅ Paul Dryden
Consultant
c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K202970
Trade/Device Name: Ventway Sparrow
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: September 29, 2020
Received: September 30, 2020

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brandon Blakely, PhD
Acting Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202970

Device Name

Ventway Sparrow

Indications for Use *(Describe)*

The Ventway Sparrow ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg (11 lb.), who require the following types of ventilatory support: SIMV VC PS, SIMV PC PS or CPAP.

The Ventway Sparrow lung ventilator is intended for emergency use and during transportation. It may be used for invasive (via an endotracheal tube and tracheostomy) or noninvasive (full non-vented ventilation face mask) ventilation presets. It may be used in hospitals, pre-hospital (transport) and field environments.

Models VWSP100MR and VWSP900MR may be used in a Magnetic Resonance (MR) environment up to 3 Tesla.

The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.

Type of Use *(Select one or both, as applicable)*

XX 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: 29-Jan-21

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Official Contact: Dana Hofeller – QA&RA Manager

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: Ventway Sparrow

Common/Usual Name: Ventilator, Continuous, Facility Use

Regulation Number: 21CFR 868.5895
Regulation Code: Ventilator, Continuous, Facility Use
Product Code: CBK
Regulatory Class: II

Predicate Device: K083688 - LTV® 1200 MR Conditional Ventilator – Pulmonetic Systems Inc.

Device Description:
The Ventway Sparrow ventilator (a.k.a. Ventway Ventilator / Ventway System) is a portable ventilator, used for transport, in prehospital, field hospital, and hospital settings.

The ventilator is suitable for non-invasive ventilation for a full non-vented ventilation face mask or for invasive ventilation via an endotracheal tube or tracheostomy.

The Ventway is available in 2 models plus MR conditional use:

- VWSP-100 Civil Model
- VWSP-100MR Civil Model
- VWSP-900 Robust Model
- VWSP-900MR Robust Model

Indications for Use:
The Ventway Sparrow ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg (11 lb.), who require the following types of ventilatory support: SIMV - VC (PS), SIMV-PC, or CPAP.

The Ventway Sparrow lung ventilator is intended for emergency use and during transportation. It may be used for invasive (via an endotracheal tube and tracheostomy) or noninvasive (full non-vented ventilation face mask) ventilation presets. It may be used in hospitals, pre-hospital (transport) and field environments.

Models VWSP100MR and VWSP900MR may be used in a Magnetic Resonance (MR) environment up to 3 Tesla.

The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.

Patient Population:
Adult and pediatric patients weighing at least 5 kg (11 lb.)

Environments of use:
Hospitals, pre-hospital (transport) and field environments

Table 1 is a comparison – Subject Device vs. the Predicate, K083688 – LTV 1200.

Table 1

Technological Characteristic	Ventway Sparrow Inovytec Ltd.	Predicate - LTV 1200 MR Conditional Ventilator Pulmonetic Systems Inc. - K083688
Product Code, Class	CBK, Class II	CBK, Class II
Indications for Use	The Ventway Sparrow ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg (11 lb.), who require the following types of ventilatory support: SIMV - VC (PS), SIMV-PC, or CPAP. The Ventway Sparrow lung ventilator is intended for emergency use and during transportation. It may be used for invasive (via an endotracheal tube and tracheostomy) or noninvasive (full non-vented ventilation face mask) ventilation presets. It may be used in hospitals, pre-hospital (transport) and field environments. Models VWSP100MR and VWSP900MR may be used in a Magnetic Resonance (MR) environment up to 3 Tesla. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.	The LTV® 1200 ventilator is intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5kg (11 lbs.), who require the following types of ventilatory support: PPV, Assist/Control, SIMV, CPAP, or NPPV.
User Population	Qualified, trained personnel under the direction of a physician.	Qualified, trained personnel under the direction of a physician.
Target Population	Adults and pediatric patients weighing ≥5 kg	Adults and pediatric patients weighing ≥5 kg
Environment Used	Hospitals, field, transport	Institutional, home or transport settings
Energy Used / Delivered	No energy delivered	No energy delivered
Design:	The Ventway Sparrow consists of a ventilator unit with an LCD screen and a single use patient circuit.	The LTV® 1200 consists of a ventilator unit with LCD displays and a reusable patient circuit.

Technological Characteristic	Ventway Sparrow Inovytec Ltd.	Predicate - LTV 1200 MR Conditional Ventilator Pulmonetic Systems Inc. - K083688
- Mechanism of Action	The Ventway Sparrow provides continuous or intermittent ventilatory support.	The LTV® 1200 provides continuous or intermittent ventilatory support.
- Components	The Ventway Sparrow consists of the following components: - Ventilator - Patient Circuit - AC/DC Power Supply - DC/DC Power Adapter - Rechargeable Battery Pack - Non-rechargeable Battery Pack - Oxygen Mixer (external) - Oxygen enrichment kit - Inlet Filter	The LTV® 1200 consists of the following components: - Ventilator - Patient Circuit - AC/DC Power Adapter - DC/DC Power Adapter
- Dimensions (HxWxD)	2.36” x 6.5” x 6.57” (6.0 cm x 16.5 cm x 16.7 cm)	3.25” x 10.5” x 13.5” (8.4 cm x 27 cm x 38 cm)
- Weight	Standard version – 2.2 lbs. (1 kg) Robust version – 2.64 lbs. (1.2 kg)	14.5 lbs. (6.5 kg)
- Battery	Rechargeable: Lithium Ion Non-rechargeable: Li-Mn	Rechargeable: Sealed Lead Acid
- Duration per charge	4 hr. @ V_T=500ml, 12bmp, PEEP=5cmH_2O, FIO_2=21%	1hr @ V_T=800ml, 15bmp, PEEP=5cmH_2O, FIO_2=21%
- External power supply	Input: 100 - 264 VAC/ 50-60 Hz, max 1.6 A Output: 16-28 VDC, 120 W	Input: 100 to 250 VAC/ 50-60 Hz Output: 13 VDC
- Display/User Interface	LCD: SPI 1.8" TFT 160x128 driver st7735, Rotary encoder selector integrated with push button	7- segment control display, LEDs, push buttons and a control knob
Performance	• SIMV-VC (PS) (a.k.a SIMV) • CPAP • Apnea Backup Ventilation • Control (Trigger sensitivity “off”) • Assist/Control (AC) • SIMV-PC	• SIMV • CPAP • Apnea Backup Ventilation • Control (Trigger sensitivity “--”) • Assist/Control (AC) • NPPV
- Basic and Advanced User Modes	Yes	Yes
- Manual Triggered Breath	Yes	Yes
- Air Source	Atmospheric	Atmospheric
- Controls	“Multi-function” control knob	Dedicated control buttons and knob
- Monitors	PEEP, PIP ,Tidal Volume (Vt), I:E ratio, Breath rate (bpm), Minute Volume	PEEP, PIP, Tidal Volume (Vt), I:E Ratio, Breath rate (bpm), MAP, Minute Volume
Settings:		
- Tidal Volume [mL/breath]	50-2000	50-2000
- Respiratory Rate [bpm]	1-60	5-80
- Inspiratory Time (sec)	0.3-4 ±10%	0.3-9.9 ±0.05 s
- PIP Limit [cmH2O]	11-60 ±5	5-100

Technological Characteristic	Ventway Sparrow Inovytec Ltd.	Predicate - LTV 1200 MR Conditional Ventilator Pulmonetic Systems Inc. - K083688
- PEEP [cmH2O]	0-20	5-20
- Supplemental Oxygen (FiO2)	21% to 95% ±5	21% to 50% ±3 51% to 95% ±5
- Alarms	Blower malfunction Tube disconnect Patient disconnect Apnea System recovered from a crash Battery empty Sensor disconnect Low respiratory rate High minute volume Low minute volume High inspiratory pressure Low inspiratory pressure Leak Inverse I:E ratio High temperature Expiratory valve blocked High PEEP Low PEEP High respiratory rate Tidal Volume Limit Reached Low tidal volume Low pressure Battery low High Voltage Replace filter Service needed Altitude out of range Unexpected Restart	Start-up Self-Test Circuit Disconnect Over Pressure/Blockage Apnea External power indicator Low and Empty Battery Detect Spontaneous Breath High PEEP
Patient Breathing Circuit Disposable	Single limb Exhalation valve and PEEP valve User to add legally marketed non-rebreathing valve	Exhalation valve and PEEP valve
Accessories – User supplied	Bacterial / Viral Filter HME Non-rebreathing Valve (22mm O.D. inlet x 22mm I.D. outlet, resistance < 0.5 cmH2O)	Bacterial / Viral Filter HME
Standards Met	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-12 ISO 80601-2-12 IEC 62304 EN 1789 RTCA DO-160G RFID AIM7351731 ASTM F2119 - 3 Tesla	IEC 601-1 IEC 68-2-27 IEC 68-2-6 IEC 68-2-34 MIL-STD-810E

Technological Characteristic	Ventway Sparrow Inovytec Ltd.	Predicate - LTV 1200 MR Conditional Ventilator Pulmonetic Systems Inc. - K083688
Biocompatibility	Externally communicating, tissue, prolonged duration ISO 10993-5 ISO 10993-10 ISO 18562-2 ISO 18562-3	Externally communicating, tissue, prolonged duration
Human Factors / Usability	Preformed with the identified user group	

Substantial Equivalence Discussion

The Ventway Sparrow has the same intended use and similar technological characteristics and principles of operation as the predicate LTV 1200, K083688.

Indications for Use
The Ventway Sparrow ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. It may be used for invasive or noninvasive ventilation presets. It may be used in hospitals, pre-hospital (transport) and field environments.

This is similar to the predicate.

Technological Characteristics
Both devices have blower-based technology to provide positive pressure and have applicable alarms and sensors to maintain performance within their specifications.

Non-clinical Testing
Performance testing included:

- Cleaning and Disinfection
- Durability
- Biocompatibility
- Software Verification and Validation
- Electrical Safety
- Electromagnetic Compatibility
- RFID Immunity
- Environmental
- ISO 80601-2-12 Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators [Including: Technical Corrigendum 1 (2011)]
- ISO 10651-3: 1997 Lung ventilators for medical use - Part 3: Particular requirements for emergency and transport ventilators
- Comparative waveform testing
- Conical connectors
- MRI
- Altitude
- Human Factors / Usability

The results demonstrate similar performance.

Substantial Equivalence Conclusion

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