DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 16, 2015

O-Two Medical Technologies Inc.
Mr. David Zhang
Quality Assurance Manager
7575 Kimbel Street
Mississauga, Ontario
CANADA

Re: K141595
Trade/Device Name: o_two e700, e600 and e500
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: February 12, 2015
Received: February 18, 2015

Dear Mr. Zhang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
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Erin I. Keith, M.S.
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141595

Device Name
o_two e700, e600, e500 Electronic Transport Ventilators

Indications for Use *(Describe)*
o_two e700, e600 and e500 are a time-cycled, volume-constant and pressure-controlled (only e700) emergency and transport ventilator designed for use in the pre-hospital, intra-hospital, inter-hospital and transport settings. It is intended for use with adult, child, infant patients with a tidal volume from 50 ml (100 ml for e500) upwards who are in respiratory and/or cardiac arrest or respiratory distress and who require ventilatory 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.

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510k Summary

Submitter's Name & Address: O-Two Medical Technologies
7575 Kimbel St.
Mississauga, Ontario L5S1C8
Canada
Tel – 905-677-9410

Official Contact: David Zhang

Application Date: 2014-04-25

Proprietary or Trade Name: o_two e700, o_two e600, o_two e500

Common/Usual Name: Electronic Transport Ventilators

Classification Name: Ventilator, emergency, powered (resuscitator)
(21 CFR 868.5925, product code: BTL)

Device Class: Class II

Classification Panel: Anesthesiology

Predicate Devices: Oxylog 3000

- Manufactured Draeger medical GmbH
- 510(k) number K062267

Carevent PAR

- Manufactured by O-Two Medical Technologies Inc.
- 510(k) number K081330

Device Description:

The proposed o_two e700, o_two e600 and o_two e500 are time-cycled, volume-constant and pressure controlled (o_two e700 only) emergency and transport ventilators.

They are electronically controlled, pneumatically powered ventilators which can be run using AC/DC power adapter or an internal rechargeable Lithium Ion battery pack.

The devices use a 4.3" TFT screen to display live ventilation parameters (Tidal and minute volumes, proximal airway pressure and breathing rate) as well as ventilation pressure & volume wave forms, ventilation modes, settings, alarm limits and status and battery status. The wide range of both visual and audible alarms provides the healthcare professional with warnings of any changes in patient or device parameters.

Indications for Use:

o_two e700, e600 and e500 are a time-cycled, volume-constant and pressure-controlled (only e700) emergency and transport ventilator designed for use in the pre-hospital, intra-hospital, inter-hospital and transport settings. It is intended for use with adult, child and infant patients with a tidal volume from 50 ml (100 ml for e500) upwards who are in respiratory and/or cardiac arrest or respiratory distress who require ventilatory support.

Patient Population:

Adult, child and infant patients with a tidal volume from 50 ml (100 ml for o_two e500) upwards.

Contraindications: NA

Environment of Use:

They are intended for use in the prehospital, intrahospital, interhospital and ground transport settings.

Comparative table- Intended use

Intended use	**Proposed o_two e700, o_two e600, o_two e500**	**Predicate K062267 Oxylog 3000®**	**Substantial Equivalence**
Operating principle	time-cycled, volume-constant and pressure-controlled (only o_two e700) emergency and transport ventilators	time-cycled, volume-constant and pressure controlled emergency and transport ventilator	Yes
Patient population	intended for adult, child and infant patients with a tidal volume from 50 ml* upwards who are in respiratory and/or cardiac arrest or respiratory distress and who require ventilatory support. * o_two e500: from 100 ml upwards	intended for patients with a tidal volume from 50 ml upwards.	Yes
Environment of use	pre-hospital, intra-hospital, inter-hospital and ground transport settings	**Mobile use for emergency medical care or primary care of emergency patients:** - During transport in emergency rescue vehicles or aircrafts including helicopters *(pre-hospital, transport)*; - In accident and emergency departments, in the recovery room. *(intra-hospital)* **Mobile use for secondary transfers:** - During transfer by road or air*(inter-hospital, transport)* - When moving ventilated patients around in the hospital. *(intra-hospital)*	Yes (air transport excluded)

Comparative table- Operating principle

Operating principle	**Proposed o_two e700, o_two e600, o_two e500**	**Predicate K062267 Oxylog 3000®**	**Substantial Equivalence**
Control logic	time-cycled, volume-constant and pressure-controlled emergency and transport ventilators	time-cycled, volume-constant and pressure controlled emergency and transport ventilator	Yes
Flow & frequency control	Solenoid Valves activated by the microprocessor at the controlled intervals to deliver the desired flow rates and breathing rates	Gas blender controlled by the microprocessor to deliver the variable flow rates as per the ventilation mode	Yes
Expiration	During inhalation, the pressure control valve (VCA) controls the breathing valve (Anti-Lock up valve) blocking the exhaust path resulting in all gas delivered to patient During expiration , the VCA controls the breathing valve (Anti-Lock up valve) to open the patient airway exhaust path and releasing all exhaled gas to ambient.	During inspiration, the pressure control (V6) controls the Breathing Valve (V10) to seal off against atmosphere air During expiration, the V6 controls Breathing Valve (V10) to adjust the required patient pressure by controlling the pressure in the inspiration hose.	Yes
Pressure Control	the pressure control valve (VCA) provide pressure ventilation and support by controlling Airway pressure to desired values	the pressure control (V6) reduces the pressure in the inspiration hose to control pressure support or Pmax when the target values are reached	Yes
Safety	In the event of a fault, the pressure control valve (VCA) opens to atmosphere to vent excess pressure; A safety valve limits patient airway pressure to 80 cm H_2O in the presence of an excesses pressure	In the event of a fault, the pressure control (V6) opens to atmosphere to vent excess pressure; The relieve SV (set to 80 cmH_2O) opens in the presence of an excesses pressure	Yes
Monitoring	The flow and airway pressure signals measured on the patient side are transmitted to the pressure sensors for flow and airway pressure curve display as well as the measured tidal volume and P_{max}, P_{mean}.	The flow and airway pressure signals measured on the patient side are transmitted to the pressure sensors for flow and airway pressure curve display as well as the measured tidal volume and P_{max}, P_{mean}.	Yes

Comparative table- Technological characteristics/specifications of performance

Characteristic		**Proposed** **o_two e700, o_two e600 and o_two e500**	**Predicate** **K062267 Oxylog 3000** or **K081330 CAREvent PAR**	**Substantial Equivalence**
Product code		BTL	BTL	Equivalent to CAREvent PAR
Ventilation modes		CMV, ACV, SIMV, SIMV / PS BiLVL, BiLVL /PS, CPAP, CPAP /PS	CMV, CMVassist (ACV) SIMV, SIMV /PS BIPAP(BiLVL), BIPAP (BiLVL)/PS CPAP, CPAP /PS	Equivalent to Oxylog 3000
CPR mode		CPR mode synchronized with audible prompts and visual animated display	CPR mode synchronized with audible prompts and visual animated display	Equivalent to CAREvent PAR
CPR mode	Chest compression	30 compression within 18 sec	30 compression within 18 sec	Equivalent to CAREvent PAR
		audible prompts and visual animation	audible prompts and visual animation	Equivalent to CAREvent PAR
	Ventilation	Two 1 sec mandatory breaths ; Breath interval: 2 sec Compression/ ventilation rate: 30:2	Two 1 sec mandatory breaths; Breath interval: 2 sec Compression/ ventilation rate: 30:2	Equivalent to CAREvent PAR
		visual animation	visual animation	Equivalent to CAREvent PAR
		Pmax: 60 cmH_2O-adult, 40 cmH_2Ol-child & infant	Pmax: 60 cmH_2O-adult only	Equivalent to CAREvent PAR
Waveforms		volume-time, pressure-time and flow- time	volume-time, pressure-time and flow- time	Equivalent to Oxylog 3000
Trigger Sensitivity		1 to 15 L/min	3 to 15 L/min	Equivalent to Oxylog 3000
Input pressure		Compressed O_2 45 PSI to 87 PSI	Compressed O_2 43.5 PSI to 87 PSI	Equivalent to Oxylog 3000
PSV (pressure support ventilation)		0, 4- 35 cmH_2O (e700)	0- 35 cmH_2O	Equivalent to Oxylog 3000
Ventilation Frequency		5 to 60 breath/min	2 to 60 breath/min (SIMV, BIPAP) 5 to 60 breath/min (CMV, ACV)	Equivalent to Oxylog 3000
Tidal Volume (L)		50 ml to 2.0 L	50 ml to 2.0 L	Equivalent to Oxylog 3000
Manual ventilation/ Inspiration hold		Yes	Yes	Equivalent to Oxylog 3000
Inspiration time to expiration time ratio		3: 1 to 1: 4	3:1 to 1: 4	Equivalent to Oxylog 3000
Inspiration time Ti (sec.)		0.3 – 9 sec	0.2 to 10 sec	Equivalent to Oxylog 3000
PEEP/ CPAP (cmH_2O)		0 – 20 cm H_2O	0 – 20 cm H_2O	Equivalent to Oxylog 3000
F_iO_2 (%)		60% & 100%	60% & 100%	Equivalent to Oxylog 3000

Pmax	10- 80 cmH_2O	20- 60 cmH_2O	Equivalent to Oxylog 3000
Safety relief valve	Opens at 80 cmH_2O	Opens at 80 cmH_2O	Equivalent to Oxylog 3000
Inhalation pressure ($cm\ H_2O$)	4 - 50	3 - 55	Equivalent to Oxylog 3000
Apnea back up time	10 to 60 sec	15 to 60 sec	Equivalent to Oxylog 3000
Battery Operating time	18 hrs	4 hrs	Better than Oxylog 3000
Live monitoring	Mve, Vte, $Paw_{(AV)}$, $Paw_{(Peak)}$, Fbpm	Mve, Vte, $Paw_{(AV)}$, $Paw_{(Peak)}$, Pplat, PEEP Fbpm, F_iO_2 (%)	Equivalent to Oxylog 3000
Wave form displayed	Pressure and flow	Pressure and flow	Equivalent to Oxylog 3000
Alarms Audible/Visual & indications	P_{max}, P_{min}, Mv_{High}, Mv_{Low}, Low Battery (20% increments) BCI, Supply pressure Low or No, APNEA	P_{max}, P_{min}, Mv_{High}, Mv_{Low}, Low Battery (25% increments) Leakage, Supply pressure, APNEA	Equivalent to Oxylog 3000
Accessories	- AC/DC power supply - Lithium ion battery pack - Patient ventilation circuit - Oxygen supply hose	- AC/DC power supply Input: - Lithium ion battery pack - Patient ventilation circuit - Oxygen supply hose	Equivalent to Oxylog 3000

Substantially equivalence to the predicate devices:

The proposed devices (o_two e700, o_two e600 and o_two e500) have the equivalent intended use, Patient populations, environment of use, contra-indications and intended user to predicate devices.

The proposed devices and the Oxylog 3000/K062267 provide the similar ventilation modes including CMV, SIMV, ACV, BiLevel, CPAP and Pressure Control and Pressure Support. Furthermore, o_two e700, o_two e600 and o_two e500 use the similar operating principle as the Oxylog 3000. Specific features and range of performance specifications of the o_two e700, o_two e600 and o_two e500 are also found equivalent to those on the Oxylog 3000/K062267.

As there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices regarding the intended use, the intended patient population, use environment/setting, contraindications, end users, as well as the technological characteristics (operating principles, waveforms, start-up mode, breath triggering and range of performance specifications), the proposed o_two e700, o_two e600 and o_two e500 are viewed as substantially equivalent to the predicate devices - Oxylog 3000/K062267 with the exception of CPR mode.

In addition, o_two e700, o_two e600 and o_two e500 incorporate an extra CPR mode which use the same CPR function as the predicate CARevent PAR/K081330. As a result, they are considered as substantially equivalent regarding their intended use, use environment/setting, contraindications, end users and technological characteristics.

Summary of Performance Testing:

A comparative side-by-side bench testing was performed on o_two e700 and Oxylog 3000 to demonstrate substantial equivalence of the proposed to the predicate Oxylog 3000.

The summary of the test results follows:

- Both ventilators delivered equivalent volume-time, pressure-time and flow- time wave forms under the same ventilation mode;
- Both ventilators were responsive to spontaneous breathing trigger;
- Ventilation Vt, frequency and I:E ratio or Ti of both units were close to target or preset parameters;
- Both units delivered similar pressure supports

We have also performed the following safety/essential performance bench testing as per to IEC60601-1, IEC60601-1-2 and other applicable standards with respect to mechanical, electrical, software, usability and biocompatibility.

Safety & Essential performance testing	Testing standards/ Comparative testing	Test Result
Safety & Essential performance	IEC 60601-1:2005	Comply
	EN794-3:1998/A2 :2009, ISO10651-3:1997, Product specifications, ISO 80601-2-12 :2011	Comply
EMC	IEC 60601-1-2:2007 w/ increased levels: - ESD: ±8kV contact & ±15kV Air - Radiated Immunity: 30V/m - Power Freq Magnetic: 30A/m	Comply
Vibration/ Bump	Vibration (sinusoidal) per IEC60068-2-6 Fc Random vibration per IEC60068-2-36 Fdb, IEC60068-2-64 Fh Bump per IEC60068-2-29 Eb, IEC60068-2-27 Type 1 Crash (10 g) per EN 1789 :2007 Clause 4.5.9 6.2, 6.3.5	Comply
Environmental	ISO10651-3:1997 Clause 10.2.1, EN 794-3:1998/ A1: 2005 Sec.10.2.1 R)	Comply
Altitude	EN794-3:1998/A2 :2009 10.2.1 c)	Comply
Software	IEC 60601-1:2005 Sec.14, ANSI/AMMI/IEC 62304:2006	Comply
Usability	IEC 60601-1-6 :2010, IEC62366 :2007, Human Factor/Usability Validation	Comply
Safety - Battery	IEC62133:2002, EN60950-1:2006/ A11:2009/ A1:2010/A12:2011	Comply
Transportation- battery	UN 38.3 test	Comply
Bio-compatibility	ISO 10993-1: 2009, ISO 10993-5:2009, ISO 10993-10: 2010	Comply
Function/ Validation test	O-Two Validation Protocol-e700/e600 and Validation Protocol-e500	Comply

Conclusion:

The results of the above comparative performance and specification as well as bench testing demonstrate that the proposed o_two e700, o_two e600 and o_two e500 are as safe, as effective and perform as well as the legally marketed predicate devices - Oxylog 3000 (K062267) and CARevent PAR (K081330).