DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 6, 2017

Thornhill Research Inc.
Kipton Lade
CEO
210 Dundas Street West, Suite 200
Toronto, M5G 2E8
CANADA

Re: K161420
Trade/Device Name: MOVES® SLC™
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: Class II
Product Code: BTL, CAW, MWI, BTA
Dated: May 5, 2017
Received: May 8, 2017

Dear Kipton Lade:

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" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for 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,

Tina Kiang -S

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

Enclosure

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)*
K161420

Device Name
MOVES® SLC™

Indications for Use *(Describe)*
The MOVES® SLC™ is a portable computer controlled, electrically powered emergency ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

a. Suction
The MOVES® SLC™ suction pump is intended for aspiration and removal of fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system.

b. Supplementary Oxygen
The MOVES® SLC™ is intended to provide supplemental oxygen enriched air to patients that require supplemental oxygen.

c. Patient Monitoring
The MOVES® SLC™ is intended to monitor physiological parameters of patients and provide these parameters to a health care provider for interpretation in the form of physiological data and system alarms. Physiological data and system alarms will be available to the care provider from the monitor.

Operating Environment
The MOVES® SLC™ is intended to be operated in a transport and emergency setting.

Target Population
Adults and pediatric(Infant, Child, Adolescent) patients who weigh between 10kg and 120 kg.

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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510(k) SUMMARY

SUBMITTER INFORMATION

Company Name: Thornhill Research Inc.
Company Address: 210 Dundas St. W, Suite 200
Toronto, ON, Canada M5G 2E8

Company Phone: (416) 597-1325
Company Fax: (416) 597-1330

Contact Person: Kipton Lade, CEO

DEVICE IDENTIFICATION

Trade/Proprietary Name: MOVES® SLC™
Classification: II
Generic Device Name: Emergency and transport ventilator with suction, multi-parameter patient monitoring, and Oxygen Concentrator

Classification Names

Classification Name	Product Code	Class	Regulation Number
Ventilator, Emergency and Transport	BTL	II	21 CFR 868.5925
Oxygen Concentrator	CAW	II	
Patient Monitoring Equipment	MWI	II	
Powered Suction Pump	BTA	II	

DEVICE DESCRIPTION

The MOVES® SLC™ (SLC) is an upgraded version of the cleared MOVES® SLC™ device (K140049), a portable multifunction patient support and monitoring system with the following capabilities:

- Computer controlled, electrically powered circle ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.
- Delivery of oxygen-enriched air that may be supplied from an external oxygen source or generated internal to the system with the on-board oxygen concentrator.
- Patient monitoring functions including the following patient parameters: Pulse Rate, Noninvasive BP (NIBP), Invasive BP (IBP), SPO_2, Temperature, Respiration Rate, CO_2, and O_2.
- Suction/aspirator pump for medical suction procedures where secretions, blood and other body fluids must be removed through the application of continuous negative pressure.

The MOVES® SLC™ is capable of operating under battery power or external AC supply. It includes a handle and mounting equipment that allows it to attach to a stretcher.

INDICATIONS FOR USE

The MOVES® SLC™ is a portable computer controlled, electrically powered emergency ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

a. Suction

The MOVES® SLC™ suction pump is intended for aspiration and removal of fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system.

b. Supplementary Oxygen

The MOVES® SLC™ is intended to provide supplemental oxygen enriched air to patients that require supplemental oxygen.

c. Patient Monitoring

The MOVES® SLC™ is intended to monitor physiological parameters of patients and provide these parameters to a health care provider for interpretation in the form of physiological data and system alarms. Physiological data and system alarms will be available to the care provider from the monitor.

Operating Environment

The MOVES® SLC™ is intended to be operated in a transport and emergency setting.

Target Population

Adults and pediatric patients who weigh between 10kg and 120 kg.

SUBSTANTIAL EQUIVALENCE

The MOVES® SLC™ is of comparable type and is substantially equivalent to the following predicate devices:

Device	510(k) #
MOVES® SLC™ (Primary Predicate)	K140049
Univent 754	K931473
Viasys AVEA (Reference Device)	K062093
The Medela® Vario 18	K061205
SeQual Eclipse® 2	K013931
Criticare 8100	K012059
Lifepak 15 (Reference Device)	K103567
Hamilton T1 (Reference Device)	K120670

Comparison to Predicate Devices

The MOVES® SLC™ is an upgrade to the previously cleared MOVES® SLC™ (K140049), which serves as the primary predicate device. Additional functionality has been added to the MOVES® SLC™ as follows:

- Extension to pediatric patients >10kg included extended tidal down to 50 ml
- Addition of a wired external screen/controller.
- Enabling of previously disabled extended oximetry capabilities.
- Addition of a rotary control knob.
- Addition of extended oximetry parameters: hemoglobin (SpHb), total oxygen content (SpOC), methemoglobin (SpMet), carboxyhemoglobin (SpCO) and/or pleth variability index (PVI)

Comparison of Ventilator and User Interface Characteristics.

Feature/ Characteristic	Modified MOVES® SLC™	MOVES® SLC™ (K140049)	Univent 754 (K931473)	Viasys AVEA (K062093) REFERENCE DEVICE
Environment	Transport and emergency care	Transport and Emergency Care.	Clinical, field hospital, transport, aeromedical and pre-hospital (BLS through ATLS) environments.	Transport, Emergency Care, and Critical Care
Patient Population	Adults and Peditric Patients between 10 and 120kg	Adults between 40kg and 120kg	No restriction	Neonatal, infant, pediatric, and adults
Frequency	6-40 BPM	6-40 BPM	1 to 150 BPM	1-150
Tidal Volume	50 -750 ml	100 -750 ml	Based on peak flow not exceeding 10 LPM	100 to 2500 ml (adult) 25-500ml

Feature/ Characteristic	Modified MOVES® SLC™	MOVES® SLC™ (K140049)	Univent 754 (K931473)	Viasys AVEA (K062093) REFERENCE DEVICE
				(Pediatric) 2.0-300ml (Neonate)
I:E Ratio	1:1 to 1:3	1:1 to 1:3	1:599	Not explicitly settable. Set by adjusting RR and inspire time.
PEEP	0 to 20 cm H_2O	0 to 20 cm H_2O	1 to 20 cmH20	0 to 50 cm H_2O
PSV	0.5 to 40 cmH_2O	0.5 to 40 cmH_2O	No PSV	0-90 cmH_2O
CPAP	No	No	No	Yes
APRV	Yes	No	No	Yes (also included in Hamilton T1 which is intended for transport)
Oxygen Supply	15 LPM maximum flow Internal oxygen concentrator	15 LPM maximum flow Internal oxygen concentrator	50 PSI	20 to 80 psig
CO2 Absorber	Extendaire (Calcium Hydroxide, Potassium Hydroxide, and Sodium Hydroxide)	Extendaire (Calcium Hydroxide, Potassium Hydroxide, and Sodium Hydroxide)	None	None
Airway Pressure, Display Range	End inspiratory pressure, end expiratory pressure (numeric) Airway pressure graph labeled as Paw graph. 0-99 cmH_2O	End inspiratory pressure, end expiratory pressure (numeric) Airway pressure graph labeled as Paw graph. 0-99 cmH_2O	Airway Pressure Graph	Peak Inspiratory Pressure, end expiratory pressure, mean airway pressure 0 to 120 cmH_2O
Electrical Source Displayed	Yes	Yes	Yes	Yes
Battery Level Displayed	Yes	Yes	Yes	Yes

Feature/ Characteristic	**Modified MOVES® SLC™**	**MOVES® SLC™ (K140049)**	**Univent 754 (K931473)**	**Viasys AVEA (K062093) REFERENCE DEVICE**
Power Supply	100-240 VAC 50-60Hz	100-240 VAC 50-60Hz	90-265 VAC, 47-440HZ	100-240 VAC 50-60Hz depending on supply used
Internal Battery	Two Lithium Polymer, >2.5 hours total operation time, 25.9 V nominal (Rechargeable)	Two Lithium Polymer, >2.5 hours total operation time, 25.9 V nominal (Rechargeable)	20-36 Volts	Internal battery backup and optional external battery 20-29 V Battery
Weight (Battery)	Two Batteries at 3.25 lbs	Two Batteries at 3.25 lbs	3 hours maximum operating time using internal compressor.	Not separately listed
Weight	37.5lbs (system excluding battery)	37.5lbs (system excluding battery)	13 lbs	83-90 lbs
Dimensions (w x h x d)	33 x 10.25 x 6.5 inches	33 x 10.25 x 6.5 inches	8.87 x 11.5 x 4.5 inches	17 x 10.5 x 16 inches
External Interfaces	Isolated RS232 through custom connector to power and communicate with external windows based tablet controller	Isolated RS232 through custom connector + isolated 5V	None	Analog inputs(2) SVGA output
Monitor	Color screen External Windows based tablet	Color screen	Monochrome screen	Color screen External VGA port to secondary monitor
User Interface	Context sensitive and permanent buttons near screen And rotary knob Touch screen on external tablet.	Context sensitive and permanent buttons near screen.	Dials & buttons	Context sensitive and permanent buttons near screen. Touch screen.
Water Trap	Separable Water trap accessory	Water trap embedded in scrubber cartridge	NA	NA

Comparison of Oximetry between Subject and Predicate Devices

Feature/ Characteristic	Modified MOVES® SLC™	MOVES® SLC™ (K140049)	Criticare 8100 (K012059)	LIFEPAK® 15 (K103567) REFERENCE DEVICE
SPO2 sensitivity	Fixed	Fixed	Fixed	User selectable: Normal, High
SPO2 pulse rate range	25 to 240 bpm	25 to 240 bpm	20-300	25 to 240 bpm
SPO2 pulse rate accuracy	+/- 3%	+/- 3%	+/-1 BMP	+/- 3 digits (during no motion conditions) +/- 5 digits (during motion conditions)
Additional oximetry parameters	• Optional include hemoglobin (SpHb), total oxygen content (SpOC), methemoglobin (SpMet), carboxyhemoglobin (SpCO) and/or pleth variability index (PVI)	None	None	• Optional include hemoglobin (SpHb), total oxygen content (SpOC), methemoglobin (SpMet), carboxyhemoglobin (SpCO) and/or pleth variability index (PVI)

In all cases the extended indications for use or functionality are found in the identified substantially equivalent predicate devices. Furthermore, the performance specifications of the MOVES® SLC™ are substantially equivalent to those of the identified predicate devices.

Compliance to Standards and Regulations

IEC 60601-1
IEC 60601-1-2
IEC 60601-2-27
IEC 60601-2-34
IEC 60601-2-49
ISO 80601-2-30
ISO 80601-2-55
ISO 80601-2-61
EN 794-3
ISO 8359
ASTM E1112-00
IEC 62133

Testing was conducted in accordance with all referenced standards and regulations, and to validate all system requirements. EMC, environmental, and shock and vibration testing was conducted in accordance with IEC 60601-1-2, EN794-3 and MIL-STD-810F.

Summary of Performance Testing

The results of performance testing demonstrate that the characteristics the MOVES® SLC™ are substantially equivalent to the identified predicates in terms of ventilator characteristics, patient monitoring performance, ability to delivery supplemental oxygen, and provide airway suction.

Determination of Substantial Equivalence

The MOVES® SLC™ system is substantially equivalent to the predicate devices. In addition, the MOVES® SLC™ has been tested to comply with relevant recognized consensus standards as well as voluntary standards (detailed above). The combination of performance verification testing and testing to applicable objective standards substantiates the claim of substantial equivalence of the MOVES® SLC™ system.

CONCLUSION

The MOVES® SLC™ is substantially equivalent to the identified predicate devices.