

Thornhill Research Inc.
MOVES® SLC™ 510(k) Submission

Release Date: May 28, 2014

Section 5 – Page 1 of 4

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: Cliff Ansel, President

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	21 CFR 868.5440
Patient Monitoring Equipment	MWI	II	21 CFR 870.2300
Powered Suction Pump	BTA	II	21 CFR 878.4780

DEVICE DESCRIPTION

The MOVES® SLC™ (SLC) is an upgraded version of the cleared MOVES® device (K093261), 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), SPO₂, Temperature, Respiration Rate, CO₂, and O₂.

- 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.

INTENDED USE

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

MOVES® SLC™ is intended to deliver high inspired oxygen concentrations to spontaneously breathing patients who require elevated inspired oxygen.

MOVES® SLC™ is intended to be used in a transport or emergency setting on adult patients who weigh between 40 and 120kg.

MOVES® SLC™ provides the following supplemental functions for patients that it is ventilating or supplying with supplemental oxygen:

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.

SUBSTANTIAL EQUIVALENCE

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

Device	510(k) #
MOVES®	K093261
SeQual Eclipse® 2	K013931
LIFEPAK® 15	K103657

Comparison to Predicate Devices

MOVES® SLC™ is an upgrade to the previously cleared MOVES® device (K093261), which serves as the primary predicate device. Additional functionality has been added to SLC as follows:

- 12 Lead ECG capability
- A 2nd temperature channel
- A 3rd Invasive pressure channel
- Removal of the requirement for use of the MOVES® O2 mask and replacement with a direct output from the onboard concentrator which is equivalent to the SeQual Eclipse® 2 (K013931).

In all cases the extended indications for use or functionality are found in the identified substantially equivalent predicate devices. Furthermore, the performance specifications of MOVES® SLC™ are substantially equivalent to those of the identified predicate devices. Where differences exist, they raise no concerns about safety and efficacy.

Compliance to Standards and Regulations

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

Summary of Performance Testing

Safety and performance 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.

The results of performance testing demonstrate that the characteristics 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. Where differences in performance or technology exist, it has been demonstrated that they do not adversely impact safety or effectiveness. In addition, SLC has been tested to comply with relevant recognized consensus safety and performance 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 SLC system.

Conclusions:

The MOVES® SLC™ is substantially equivalent to the identified predicate devices and does not raise any new concerns of safety or efficacy.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2014

Thornhill Research Inc.
Cliff Ansel
President
210 Dundas St. W, Suite 200
Toronto, ON, Canada M5G 2E8

Re: K140049
Trade/Device Name: MOVES® SLCT™
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered emergency ventilator
Class: II
Product Codes: BTL, CAW, MWI, BTA
Dated: April 24, 2014
Received: April 28, 2014

Dear Mr. Ansel:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

 Tejasri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140049

Device Name: MOVES® SLC™

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

MOVES® SLC™ is intended to deliver high inspired oxygen concentrations to spontaneously breathing patients who require elevated inspired oxygen.

MOVES® SLC™ is intended to be used in a transport or emergency setting on adult patients who weigh between 40kg and 120kg.

MOVES® SLC™ provides the following supplemental functions for patients that it is ventilating or supplying with supplemental oxygen:

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

MOVES® SLC™ is intended to be operated in a transport, or emergency setting.

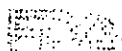
Target Population

The intended patient population is adults who weigh between 40 and 120 kg.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Anya C. Harry -5
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