K093261

510(k) SUMMARY

MAR 2 6 2010

SUBMITTER INFORMATION

Company Name:	Thornhill Research Inc.
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DEVICE IDENTIFICATION

Trade/Proprietary Name:	MOVES™
Classification:	II
Generic Device Name:	Emergency Ventilator with Suction, Multi-Parameter Patient Monitoring, and oxygen concentrator

Classification Names

Classification Name	Product Code	Class	Regulation Number
Ventilator, Emergency Powered	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
Valve, Non-Rebreathing	CBP	II	21 CFR 865.5870
Mask, Oxygen, Non-Rebreathing	KGB	II	21 CFR 868.5570

DEVICE DESCRIPTION

The MOVES™ is 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 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 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

Intended Use:

The MOVES™ 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.

The MOVES™ is intended to deliver high inspired oxygen concentrations via the MOVES™ O2 mask to spontaneously breathing patients who require elevated inspired oxygen.

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

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

a. *Suction*
The MOVES™ 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™ is intended to provide supplemental oxygen enriched air to patients that require supplemental oxygen.

c. *Patient Monitoring*
The MOVES™ 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™ is of comparable type and is substantially equivalent to the following predicate devices:

Device	510(k) #
Sequal Eclipse 2	K013931
VersaMed iVent 201	K052554
Univent Eagle 73x	K051476
Univent Eagle 754	K931473
Hi-Ox^{80}	K030943
Medela Vario 8 & 18	K061435
Criticare Poet Plus Patient Monitor (Model 8100)	K012059
Welch Allyn Propaq Encore	K012451

Comparison to Predicate Devices

A Comparison of specifications demonstrates that the MOVES is substantially equivalent to the identified devices. The MOVES™ has substantially equivalent intended uses to the predicates. The differences in intended use between MOVES™ and the defined predicates are related to additional restrictions placed on MOVES™. MOVES™ is only intended to be used on adults 40-120kg and in a transport and emergency environment.

The performance specifications of MOVES are substantially equivalent to those of the identified predicate devices. Where differences exist, they raise no concerns about safety and efficacy.

The primary difference between MOVES™ and predicate ventilators is in the use of a circle system to conserve oxygen. Although MOVES™ is intended for transport, this technology is the standard of care for BSZ ventilators such as the Datex Ohmeda 7900 (K081844). All ventilator modes provided by MOVES™ have equivalents among the identified predicates.

The differences in technological characteristics of MOVES™, including the use of a circle system in a transport environment, have been assessed as part of the risk analysis and during performance testing. The MOVES™ meets all of its performance requirements and does not introduce any unmitigated risks when compared to predicate devices.

Differences in technological characteristics between MOVES™ and the identified do not raise any new concerns of safety and efficacy, particularly when reviewed in light of the restrictions MOVES™ places on its target population and intended use environment. This, coupled with the integrated nature of the MOVES™ device, adequately addresses these differences.

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
ISO 21647
EN-794-3
ISO 9919
ASTM E1112-00
ANSI/AAMI EC-13
ANSI/AAMI SP10

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 of MOVES 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™ 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, MOVES™ 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 and the safety and efficacy of the MOVES™ system.

Conclusions:

The MOVES is substantially equivalent to the identified predicate devices and does not raise any new concerns about safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Cliff Ansel
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Canada M5V 2G5

MAR 2 6 2010

Re: K093261
Trade/Device Name: MOVES™
Regulation Number: 21CFR 868.5925
Regulation Name: Powdered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: March 22, 2010
Received: March 23, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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): Not Known

Device Name: MOVES™

The MOVES™ 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.

The MOVES™ is intended to deliver high inspired oxygen concentrations via the MOVES™ O2 mask to spontaneously breathing patients who require elevated inspired oxygen

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

MOVES™ provides the following supplemental functions for patients that it is ventilating or to whom it is delivering elevated inspired oxygen:

a. *Suction*
The MOVES™ 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™ is intended to provide supplemental oxygen enriched air to patients that require supplemental oxygen.

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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)

Operating Environment

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

Target Population

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093261