DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 30, 2016

Flight Medical Innovations Ltd.
% Bosmat Friedman
Regulatory Affairs Consultant
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1208-12 Rockford Rd,
Toronto, ON M2R 3A2
Canada

Re: K143035
Trade/Device Name: Flight 60® Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, NOU
Dated: March 1, 2016
Received: March 2, 2016

Dear Ms. Friedman,

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,

Tejashri Purohit-Sheth, M.D.

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

Erin I. Keith, M.S.
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)*

K143035

Device Name
FLIGHT60® Ventilator

Indications for Use *(Describe)*

The FLIGHT 60 Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the FLIGHT 60 is applicable for adult and pediatric (i.e., infant, child and adolescent) patients, greater than or equal to 5kg (11 lbs).

The FLIGHT 60 Ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.

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

[as required by section 807.92(c)]

FLIGHT 60 Ventilator

510(k) Number K143035

1. SUBMITTER

Applicant's Name:

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Date Prepared:

March 23, 2016

2. DEVICE

Trade Name:

FLIGHT 60 Ventilator

Classification Name:

Continuous Ventilator

Classification:

Name: Continuous ventilator
Product Code: CBK
Regulation No: 868.5895
Class: 2

Classification Panel: Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID)
Respiratory Devices Branch (RPDB)

and

Name: Continuous, Ventilator, Home Use
Product Code: NOU
Regulation No: 868.5895
Class: 2
Classification Panel: Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID)
Respiratory Devices Branch (RPDB)

3. PREDICATE DEVICES

Main Predicate:

- Flight 60 Ventilator - K130171

Secondary Predicates:

- Trilogy 100 – K083526

4. DEVICE DESCRIPTION

The FLIGHT 60 Ventilator is an electrically powered, microprocessor controlled ventilator with the following types of ventilatory support: A/CMV Volume or Pressure Control, SIMV Volume or Pressure Control, Pressure Support & SPONT mode with Pressure Support. It can be pressure or time triggered; volume or pressure limited; time, pressure or flow cycled. Manual inflation is possible, and an emergency intake valve allows the patient to pull ambient air into the breathing circuit in the event of a complete loss of supply gas pressure.
The FLIGHT 60 may be powered by external power (100 – 240 VACS or 12 – 15 VDC) or by its two internal Li Ion rechargeable batteries.
The electrical system is comprised of three primary boards: the Main board (motherboard) which holds the majority of the electronics including the main CPU and the display CPU, the Power board, which holds the power subsystems, and internal communication functions, and the Communication board, which holds internal communication and external communication connectors.
The main component of the pneumatic system is an electrically controlled compressor (pump). This compressor provides a compressed gas source so no external air compressor is needed. Additionally, the exhalation valve is activated by an electrically controlled proportional solenoid that provides a built in PEEP.

A comprehensive alarm system is built-in to alert the user to violations of set limits. The alarm system alerts the care giver by activating the audible alarm, screen display and the LED indicator.
The purpose of this 510(k) is to allow for the addition of a blower type compressor instead of the piston type compressor.

5. INDICATIONS FOR USE

The FLIGHT 60 Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the FLIGHT 60 is applicable for adult and pediatric (i.e., infant, child and adolescent) patients, greater than or equal to 5kg (11 lbs).
The FLIGHT 60 Ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The suggested modification to the Flight 60 has been tested and validated. No new issues of safety or effectiveness have been identified as a result of this change.
A comparison of FLIGHT 60's technological characteristics with the predicate devices is presented in the table below:

DEVICE NAME / *SUBJECT*	**FLIGHT 60 (REVISED)**	**FLIGHT 60**	**TRILOGY 100**
MANUFACTURER	Flight Medical Innovations Ltd.	Flight Medical Innovations Ltd.	Respironics Inc.
510(K) NUMBER		K130171	K083526
PRODUCT CODE	CBK, NOU	CBK, NOU	CBK
INTENDED USE	**The FLIGHT 60 Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the FLIGHT 60 is applicable for adult and pediatric (i.e., infant, child and adolescent) patients, greater than or equal to 5kg (11 lbs).**	**The FLIGHT 60 Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the FLIGHT 60 is applicable for adult and pediatric (i.e., infant, child and adolescent) patients, greater than or equal to 5kg (11 lbs).**	The Philips Respironics Trilogy 100 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy 100 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs).
PHYSICAL DIMENSIONS	**11.641 x 11.457 x 9.803 (295mm x 291 mm x 249 mm)**	**11.641 x 11.457 x 9.803 (295mm x 291 mm x 249 mm)**	16.68cm x 28.45cm x 23.52cm
USER INTERFACE	**Touch screen with alpha numeric data**	**Touch screen with alpha numeric data**	Control buttons, display screen
CONTROL BUTTONS	**Touch screen function & buttons**	**Touch screen function & buttons**	Buttons control panel
MECHANICAL SYSTEM	**Blower type compressor**	Piston type compressor	**Blower type compressor**
POWER SUPPLY AC	**100-240V 50-60Hz**	**100-240V 50-60Hz**	**100-240V 50-60Hz**
EXTERNAL DC	**12-30 V**	**12-30 V**	12/14.4 V
INTERNAL BATTERY	**Li- ion battery, 12V 5.2Ah**	**Li- ion battery, 12V 5.2Ah**	Li- ion battery, 14.4V 4176mAh
BACK-UP BATTERY	**Li-ion, 14.8V 2.6Ah**	**Li-ion, 14.8V 2.6Ah**	Li- ion battery, 14.4V 4176mAh

AVAILABLE MODES	**Volume/pressure/PRVC control ACMV Volume/pressure/PRVC control SIMV + pressure support SPONT + pressure support Bilevel, MVG, VtG**	**Volume/pressure/PRVC control ACMV Volume/pressure/PRVC control SIMV + pressure support SPONT + pressure support Bilevel, MVG, VtG**	Volume/pressure control ACMV, Volume/pressure control SIMV + pressure support CPAP (bilevel) Bilevel, ST AVAPS, AVAPS
MANDATORY BREATH CONTROLS	**Volume/pressure control Flow/Pressure/time trigger**	**Volume/pressure control Flow/Pressure/time trigger**	Volume/pressure control Flow trigger
SPONTANEOUS BREATH SUPPORT	**Pressure support Cycle variables: flow or time**	**Pressure support Cycle variables: flow or time**	Pressure support Cycle variables: flow
BASIC PRESSURE CONTROL	**Pressure targeted waveform**	**Pressure targeted waveform**	Pressure targeted waveform
BASIC FLOW CONTROL	**Descending/Square flow waveform**	**Descending/Square flow waveform**	Ramp (=Descending)/Square Flow Pattern
ALARMS	**AC Disconnection, Low Battery, Empty Battery, Patient Disconnection**	**AC Disconnection, Low Battery, Empty Battery, Patient Disconnection**	AC Power Disconnect, Low Battery, Battery Depleted, Circuit Disconnect
Non-invasive positive pressure ventilation (NPPV)	**Yes**	**Yes**	**Yes**
Reusable exhalation valve	**Yes**	**Yes**	**Yes**

As can be seen in the table above, the Revised Flight 60 has the same technological characteristics as the predicate Flight 60, with the exception of its compressor. The compressor is the same as Trilogy 100's compressor. Altogether, the technological characteristics of the Revised Flight 60 are substantially equivalent to the predicate device – the predicate Flight 60 or the Trilogy 100 (compressor type only). Thus, the comparison of the Revised Flight 60 to its predicate devices do not raise new safety and effectiveness concerns.

7. PERFORMANCE DATA

Design and verification activities were performed on the FLIGHT 60 as a result of the risk analysis and product requirements. Verification of compliance with recognized standards has been made to support safe use of the device for its intended use and in its intended environment. Specifically, FLIGHT 60 was designed and tested in accordance with the applicable requirements in relevant FDA guidance documents and international standards including:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- IEC 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance (2005), including US national deviations
- ISO 80601-2-12: Medical Electrical Equipment - Part 2-12: Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators (2011); and
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: Electromagnetic Compatibility - Requirements and Tests (2007):
    - ESD contact discharge and air discharge test levels were replaced by 8 kV and 15 kV, respectively.
    - Radiated immunity test level was 30 V/m.
    - Magnetic field immunity test level was 30 A/m

Flight 60 was subjected to environmental tests and was tested for Volatile Organic Compounds (VOC) by EPA test TO-15 and for particles by EPA's PM 2.5. All tests confirmed the product met the predetermined acceptance criteria.
Testing also included non-clinical side-by-side waveform performance test, in which the waveform characteristics of Flight 60 were compared to those of Trilogy 100 (K083526) and to Flight 60 (K130171). Characteristics tested included flow, pressure and volume waveforms, ventilation control parameter accuracy and patient trigger reliability and synchrony. The comparison of the recorded waveforms supports the claim that FLIGHT 60 is substantially equivalent to the predicate devices.

8. CONCLUSION

Flight Medical Innovations Ltd. believes that, based on the information provided in this submission, the FLIGHT 60 Ventilator is substantially equivalent to its predicate device without raising any new safety and effectiveness concerns.