AF

510(K) SUMMARY

[as required by section 807.92(c)]

FLIGHT 60 Ventilator

510(k) Number K130171

Date Prepared (revised):
April 7, 2014

Applicant's Name:
Flight Medical Innovations Ltd.
13 Hamelacha Street
North Industrial Park
Lod 71520, Israel
Tel: (972) 8-9235111
Fax:(972) 8-9236111
Company Contact: Yanir Shaked, RAQA Manager
yanirs@flight-medical.com

Contact Persons:
Shoshana (Shosh) Friedman, RAC; and
Bosmat Friedman
Address: 1914 J N Pease Pl., Charlotte, NC 28262
Telephone: 704-430-8695 or 704-899-0092
Fax: 704-899-0098
E-mail: shosh@pushmed.com
bosmat@pushmed.com

Trade Name:
FLIGHT 60 Ventilator

Common & Classification Name:
Continuous Ventilator

Classification:
Class II; product code 73 CBK and NOU; regulation 21 CFR 868.5895

Classification and Review Panel:
Anesthesiology

Predicate Devices:
- Flight 60 Ventilator, cleared under K120726, manufactured by Fligh Medical Innovations Ltd
- Vela Ventilator, cleared under K032451, manufactured by Bird Product

Device Description:

The FLIGHT 60 Ventilator is an electrically powered, microprocessor controlle ventilator with the following types of ventilatory support: ACMV Volum Pressure or PRVC, SIMV Volume, Pressure or PRVC, PSV/SPONT mode wit Pressure Support and Volume Guarantee, Bi-Level (APRV). It can be pressur flow or time triggered; volume or pressure limited; time, pressure or flo cycled. Manual inflation is possible, and an emergency intake valve allows th patient to pull ambient air into the breathing circuit in the event of a complet loss of supply gas pressure.

The FLIGHT 60 may be powered by external power (100 – 240 VACS or 12 – 1 VDC) or by its two internal Li Ion rechargeable batteries, which power th ventilator for up to 12 hours when fully charged.

The electrical system is comprised of three primary boards: the Main boar (motherboard) which holds the majority of the electronics including the mai CPU and the display CPU, the Power board, which holds the power subsystem and internal communication functions, and the Communication board, whic holds internal communication and external communication connectors.

The main component of the pneumatic system is an electrically controlle compressor (pump). This compressor provides a compressed gas source so n external air compressor is needed. Additionally, the exhalation valve activated by an electrically controlled proportional solenoid that provides built in PEEP.

A comprehensive alarm system is built-in to alert the user to violations of s safety limits. The alarm system alerts the care giver by activating the audibl alarm, screen display and the LED indicator.

Intended Use:

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

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

Performance Data

The FLIGHT 60 Ventilator meets all applicable device specificatic requirements for performance testing as identified in the FDA reviewe guidance for ventilators. Verification of compliance with recognized standard has been made to support use of the device for its intended use and in i intended environment. Additionally, comparison between the performance the revised Flight 60 Ventilator (subject of this submission) with its predica

l Equivalence Table:

	Trilogy100 Ventilator	Vela Ventilator	FLIGHT 60 Ventilator	FLIGHT 60-O_2 (100) Ventilator
	Respironics Inc.	Bird Products Corp	Flight Medical Innovations Ltd	Flight Medical Innovations Ltd
r	K083526	K032451	K120726	K130171
	CBK	CBK	CBK, NOU	CBK, NOU
	The 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.). The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation. It is not intended to be used as a transport ventilator.	The TBird VELA Ventilator is intended to provide continuous or intermittent mechanical ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lbs.), who require the following general types of ventilatory support, as prescribed by an attending physician: • Positive pressure ventilation • Assist/Control, SIMV, CPAP modes of ventilation The ventilator is suitable for use in institutional and transport settings. It is not intended for use as an emergency medical transport ventilator.	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.	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.
tures				
nt	-	Yes	-	Yes
	-	Yes	-	Yes
	-	Yes	-	Yes
	Yes	-	-	Yes
	Yes	-	-	Yes

Standards

FLIGHT 60 Ventilator has been tested and shown to be compliant with the f standards:

IEC 60601-1:1998 +A1:1991+A2:1995	Medical electrical equipment - Part 1: General requirements for safety and essential performance
IEC 60601-1-2:2007	Medical electrical equipment General requirements for basic saf essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
IEC 60601-1-8:2006	Medical electrical equipment -- Part 1-8: General requirements f safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical e equipment and medical electrical systems
IEC 60601-2-12:2001	Medical electrical equipment -- Part 2-12: Particular requireme the safety of lung ventilators -- Critical care ventilators
ASTM F 1246-91	Standard Specification for Electrically Powered Home Care Vent Part 1-Positive-Pressure Ventilators and Ventilator Circuits

Conclusion

Verification and validation activities were conducted to establish the perf characteristics of the FLIGHT 60 Ventilator. All testing demonstrated that the 60 Ventilator met required design verification criteria and has acceptable perf when used in accordance with its labeling. The device's intended use, o principles, ventilation modes and performance parameters are comparabl referenced predicate devices. Therefore, the FLIGHT 60 Ventilator is subs equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 8, 2014

Flight Medical Innovations, Ltd
C/O Ms. Soshana Friedman, President
Push-Med LLC
1914 J.N. Pease Place
Charlotte, NC 28262

Re: K130171

Trade/Device Name: FLIGHT 60 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Class: II
Product Code: CBK
Dated: March 18, 2014
Received: March 19, 2014

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 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,

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):__K130171_____

Device Name:

FLIGHT60® Ventilator

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.

Prescription Use __X__
(Per 21 CFR 801 Subpart D)

OR

Over the Counter Use_____
(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 -S
2014.04.08 15:03:12
-04'00'