510(K) SUMMARY

[as required by section 807.92(c)]

FLIGHT 60 Ventilator

510(k) Number K 120726

JUL 6 2012

Date Prepared:
March 7, 2012

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 Person:

Shoshana (Shosh) Friedman, RAC
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

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 K111683, manufactured by Flight Medical Innovations Ltd
- Vela Ventilator, cleared under K032451, manufactured by Bird Products Corp .
- Trilogy 100 Ventilator, cleared under K083526, manufactured by Respironics Inc.

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, which power the ventilator for up to 12 hours when fully charged.

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 safety limits. The alarm system alerts the care giver by activating the audible alarm, screen display and the LED indicator.

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 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..

Performance Data

The FLIGHT 60 Ventilator meets all applicable device specification requirements for performance testing as identified in the FDA reviewer guidance for ventilators. 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. Additionally, comparison between the performance of the revised Flight 60 Ventilator (subject of this submission) with its predicate devices demonstrated that the FLIGHT 60 Ventilator is substantially equivalent to it predicate devices without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Flight Medical Innovations, Limited
C/O Ms. Shoshana Friedman
President & CEO
Push-Med LLC
1914 J.N. Pease Place
Charlotte, North Carolina 28262

JUL 6 2012

Re: K120726
Trade/Device Name: FLIGHT60® Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, NOU
Dated: June 11, 2012
Received: June 12, 2012

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 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):_____

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)

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

510(k) Number: K120726