DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 6, 2015

PulmOne Advanced Medical Devices, Ltd.
Dr. Susan Alpert
Principal
200 Park Ave, Unit 403
Minneapolis, MN 55415

Re: K141793
Trade/Device Name: PulmOne MiniBoxPFT™ 2.0
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: Class II
Product Code: BZG, BZC
Dated: January 27, 2015
Received: January 30, 2015

Dear Dr. Alpert:

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 Keith
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)*
pending K141793

Device Name
PulmOne MiniBoxPFT™ 2.0

Indications for Use *(Describe)*
The PulmOne MiniBoxPFT™ 2.0 is intended to measure lung function in adult and pediatric patients while at rest (including spirometry and lung volumes). The PulmOne MiniBoxPFT™ 2.0 is to be used by either a physician, respiratory therapist, or technician.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 SECTION 5 – 510(K) SUMMARY

5.1 ADMINISTRATIVE INFORMATION

Date:	November 12, 2014
Submitter:	PulmOne Advanced Medical Devices, Ltd. 14 HaCharoshet St., Ra'ananna 4365707 , ISRAEL Tel: +972 77 5100 938 Fax: +972 77 5100 939
Official Correspondent:	Avi Lazar, CEO
Trade Name:	PulmOne MiniBoxPFT™ 2.0
Classification Name:	Diagnostic spirometer
Classification Number:	21 CFR 868.1840
Product Code:	BZG
Additional Code:	BZC
Device Class:	Class II
Predicate Devices:	PulmOne MiniBoxPFT™ 510(k) Number – K133051

5.2 DEVICE DESCRIPTION

The PulmOne MiniBoxPFT™ 2.0 is intended to measure lung function in adult and pediatric patients while at rest (including spirometry and lung volumes). The PulmOne MiniBoxPFT™ 2.0 is to be used by either a physician, respiratory therapist, or technician. A single-use, disposable viral-bacterial filter separates the patient from the internal components of the device.

The MiniBoxPFT™ 2.0 measures all common spirometric measurements as well as relative and absolute lung volumes, including the following (the full list is detailed in Section 11 – Device Description):

Absolute Lung Volumes:	*units*
Total lung capacity (TLC)	L
Thoracic Gas Volume (TGV)	L
Residual volume (RV)	L
Relative Lung Volumes:	
Inspiratory capacity (IC)	L
Expiratory reserve volume (ERV)	L

Spirometry:

Forced vital capacity (FVC)	L
Forced inspiratory vital capacity (FIVC)	L
Slow vital capacity (SVC)	L
Slow inspiratory vital capacity (IVC)	L
Forced expiratory volume in 1 second (FEV1)	L
Forced inspiratory volume in 1 second (FIV1)	L
Ratio of FEV1 to SVC (FEV1/SVC)	%
Ratio of FEV1 to FVC (FEV1/FVC)	%
Forced expiratory volume in 6 seconds (FEV6)	L
Ratio of FEV1 to FEV6 (FEV1/FEV6)	%
Peak expiratory flow (PEF)	L/s
Peak inspiratory flow (PIF)	L/s
Forced Expiratory Flow at 50% of FVC (FEF50)	L/s
Maximum Voluntary Ventilation (MVV)	L/min

5.3 INTENDED USE AND INDICATIONS FOR USE

The PulmOne MiniBoxPFT™ 2.0 is intended to measure lung function in adult and pediatric patients while at rest (including spirometry and lung volumes). The PulmOne MiniBoxPFT™ 2.0 is to be used by either a physician, respiratory therapist, or technician.

5.4 SUMMARY OF TECHNICAL CHARACTERISTICS

The MiniBoxPFT™ 2.0 provides both lung volume and spirometry measurements in a single device. The MiniBoxPFT™ 2.0's predicate device is the MiniBoxPFT™ which also provides both lung volume and spirometry measurements however the predicate is comprised of two modules.
The MiniBoxPFT™ 2.0 is substantially equivalent to the MiniBoxPFT™ and both utilize the same technologies and methods of operations, with the main difference being that the MiniBoxPFT™ uses an OEM spirometer and the MiniBoxPFT™ 2.0 integrates all measurements in one integrated device. The lab and bench testing demonstrates that the differences between the devices do not raise any new questions and that the proposed device is substantially equivalent to the predicate device.

Device Construction: Both devices utilize well-recognized flow sensors, the same pressure sensor, a valve and a sealed container in their operation. The MiniBoxPFT™ 2.0 has a detachable hand-held unit for use with the spirometric measurements as opposed to an OEM spirometer in MiniBoxPFT™.

Methods of Operation: The methods of operation for both devices require the subject to perform breathing maneuvers – breathing via a disposable viral-bacterial filter during flow interruptions. The MiniBoxPFT™ 2.0 requires less time to perform some of the breathing maneuvers, and has shorter duration flow interruptions.

Principles of Operation: The principles of operation for both devices are the same. Both devices uses data from spirometry measurements and data obtained during flow interruptions with a proprietary formula to calculate Total Lung Capacity.

5.4.1 Summary table of Comparison

	MiniBoxPFT™ [K133051]	**MiniBoxPFT™2.0 [Proposed Device]**
Intended Use and Indications for Use	The PulmOne MiniBoxPFT™ is intended to measure lung function in adult and pediatric patients while at rest (including spirometry and lung volumes). The PulmOne MiniBoxPFT™ is to be used by either a physician, respiratory therapist, or technician.	Identical
Target Population	Adult and pediatric subjects	Identical
Biocompatibility	- Mouthpiece: Single-use FDA-cleared viral bacterial filter (K051712) - Hand-Held sub-system: Skin Contact - Using Cleared OEM handle MIR , [K122384]	- Mouthpiece: Identical - Hand-Held sub-system: Skin Contact , Using Biocompatible Makrolon 2825 Polycarbonate material in compliance with ISO10993-1
Standards / Performance guideline compliance	-General medical device safety: IEC 60601-1:2005 (3rd Ed) -Electromagnetic compatibility: IEC 60601-1-2:2007 (3rd Ed) -Performance per ATS 2005 Standards	Same with additional of ISO 26782 compliance to section 7.2, 7.4-7.6 & 7.8-7.9
Environmental Operating Conditions	Temperature: 0 to 40 °C Relative Humidity: 20 to 90 % Atmospheric Pressure: 900 to 1060 cmH2O	Identical
Flow Sensor	1. Bi-directional hot-wire mass airflow sensor Range: +/- 5.0 L/s 2. Bi-directional digital turbine Range: +/- 16.0 L/s [Part of the incorporated OEM cleared MIR Minispir, K122384]	Bi-directional Symmetric and averaging Pitot-Tube Range: +/- 16.0 L/s
Pressure Sensor	Bi-directional piezo-resistive <u>Mouth Sensor</u>: Range: ±70 cmH2O (±1 PSI) Accuracy: 0.25% Full Scale	Identical

Valve	Computer-controlled solenoid valve Closing response time: <30 ms Closing duration: less than 300 ms	Computer-controlled solenoid valve Closing response time:<30 ms Closing duration: ~100 ms
Software	PulmOne 4.0, Matlab based	PulmOne C# .NET application
LUNG VOLUME MEASUREMENT		
Measurements	Mouth pressure and mouth flow	Identical
Calculations	TLC, TGV (FRC), RV, VC, IC	Same with addition of ERV
Principle of Operation	1) Pressure and flow are measured at the mouth 2) Spirometry is measured with the handheld spirometer. 3) Proprietary equation is used to calculate total lung capacity	Identical
Method of Operation	1) Patient seated at desk/table 2) 1-2 minutes normal breathing 3) 300 ms shutter closure per breath 4) Inspiration to TLC 5) Slow expiration to RV	Same, except shutter closure per breath is 100 ms
Container	16.3 round container	15L elliptic container
SPIROMETRY MEASUREMENT	Cleared OEM MIR Minispir spirometer [K122384] incorporated	MiniBox spirometer design incorporated
Measurements	Mouth flow	Identical
Calculated Parameters	Used a cleared OEM MIR Minispir [K122384] incorporated : FEV1, FVC, FEV6, FEV1/FVC, FEV1/SVC, FEV1/VC, EFV1/FEV6, PEF, FEF25-75, FEV3, FEV3/FVC, FET, FEF 25, FEF50, FEF75, Evol, FIVC, FIV1, FIVC1/FIVC, PIF, IC, SVC, ERV, TV, IVC, EVC, MVV	same calculated parameters with addition of MVV Rate
Displayed Parameters by MiniBox GUI	FVC, FEV1, FEV1/SVC, FEV1/FVC, FEV6, FEV1/FEV6, PEF, SVC, IC, ERV	FEV1, FVC, FEV6, FEV1/FVC, FEV1/SVC, FEV1/VC, EFV1/FEV6, PEF, FEF25-75, FEV3, FEV3/FVC, FET, FEF 25, FEF50, FEF75, Evol, FIVC, FIV1, FIVC1/FIVC, PIF, IC, SVC, ERV, TV, IVC, EVC, MVV and MVV Rate
Technical Specifications	Flow range: +/- 16 L/s Volume accuracy: +/- 3% or 50mL Flow accuracy: +/- 5% or 200 mL/s Dynamic resistance at 12 L/s: <0.5 cmH2O/(L/s) Dimension: 142x49.7x26 mm Weight: 65 grams	Flow range: +/- 16 L/s Volume accuracy: +/- 3% or 50mL Flow accuracy: +/- 5% or 200 mL/s Dynamic resistance at 14 L/s: <0.7 cmH2O/(L/s) Dimension: 210x105x45 mm Weight: 300 grams

BTPS Correction	Manual	Automatic
ACCESSORIES		
Bacterial Filters	FDA 510(K) Number K051712 Air Safety Spiroguard - Integral Mouthpiece single-use, disposable viral-bacterial filter	Identical

5.5 UTILIZATION OF STANDARDS

The MiniBoxPFT™ 2.0 has met the following recognized standards:

IEC 60601-1:2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, 3rd edition

IEC 60601-1-2:2007 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 3rd edition.

ASTM D4169-09, Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM D4332-01, Standard practice for conditioning containers, packages, or packaging components for testing

ASTM D999-01 Standard Test Methods for Vibration Testing of Shipping Containers

ISO 26782:2009, to section 7.2, 7.4-7.6 & 7.8-7.9

5.6 SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Laboratory tests were performed to establish substantially equivalent performance of the MiniBoxPFT™ 2.0 vs its predicate, and included electrical safety, software validation, and environmental testing. In addition, non-clinical bench testing was conducted to verify the performance of both the spirometry and lung volume measurements of the device.

The spirometry bench tests (FDA 510(k) sections 18-1 and 18-2) verified that the performance of the MiniBoxPFT ™ 2.0 spirometry measurements met the ATS guidelines[1] requirements of accuracy and repeatability for spirometry equipment.

A Repeatability & Reproducibility test was conducted (FDA 510(k) sections 18-3 and 18-4) and validated that inter-device repeatability and intra-device reproducibility were within the accepted known range for lung volume measurement.

An LVM validation test was conducted (FDA 510(k) sections 18-5 and 18-6), comparing the Total Lung Capacity (TLC) measurement of the proposed device with that of the predicate. TLC measurements were performed using the proposed device, MiniBoxPFT™ 2.0 and the predicate device and pre-defined success criteria were set which demonstrate substantial equivalence of Lung Volume Measurement of the proposed device and the predicate device. The study results demonstrate that the MiniBoxPFT™ 2.0 successfully met the study success criteria and the performances of the Lung Volume Measurements are substantially equivalent to those of the predicate device.

5.7 SUMMARY OF CLINICAL PERFORMANCE DATA

No clinical study was conducted to support this application.

5.8 CONCLUSIONS

Based on its underlying technology and the lab and bench tests performed, the PulmOne MiniBoxPFT™ 2.0 is substantially equivalent to the predicate device.

[1] M.R. Miller et al, Standardization of spirometry; Eur Respir J 2005; 26: 319–338