DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 21, 2016

PulmOne Advanced Medical Devices, Ltd
% Dr. Susan Alpert
Principal
SFA Consulting, LLC
200 Park Avenue, Unit 111
Minneapolis, Minnesota 55415

Re: K161295
Trade/Device Name: MiniBox +
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-Function Data Calculator
Regulatory Class: Class II
Product Code: BZC, BZG
Dated: September 20, 2016
Received: September 22, 2016

Dear Dr. Susan 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

Tina Kiang, Ph.D.
Acting 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)*
K161295

Device Name
MiniBox+

Indications for Use *(Describe)*
The PulmOne MiniBox+ is intended to measure lung function in adult and pediatric patients, 5 years and older, while at rest (including spirometry, lung volumes and diffusing capacity). The PulmOne MiniBox+ is to be used by a physician, respiratory therapist, or technician in a hospital or clinic setting

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)*

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5 SECTION 5 – 510(K) SUMMARY

5.1 ADMINISTRATIVE INFORMATION

Date:	15-October-2016
Submitter:	PulmOne Advanced Medical Devices, Ltd. 14 HaMelacha Street, Ra'ananna 4366107 , ISRAEL Tel: +972 77 5100 938 Fax: +972 77 5100 939
Official Correspondent:	Avi Lazar, CEO
Trade Name:	MiniBox+
Classification Name:	Pulmonary-function data calculator
Classification Number:	21 CFR 868.1880
Product Code:	BZC, BZG
Device Class:	Class II
Predicate Devices:	Primary Predicate: PulmOne MiniBoxPFT™ 2.0 510(k) Number –K141793 Secondary Predicate: ZAN LUNG-FUNCTION LAB 510(k) Number - K052328
Application Correspondent:	Dr. Susan Alpert SFA Consulting, LLC 200 Park Ave., unit 111 Minneapolis, MN 55415 Phone- 612-202-7019 drsusanalpert@gmail.com

5.2 DEVICE DESCRIPTION

The PulmOne MiniBox+ is intended to measure lung function in adult and pediatric patients while at rest (including spirometry, lung volumes and diffusing capacity). The PulmOne MiniBox+ is to be used by either a physician, respiratory therapist, or technician. A cleared single-use, disposable viral-bacterial filter separates the patient from the internal components of the device.
The MiniBox+ measures all common spirometric measurements as well as relative and absolute lung volumes and diffusing capacity.

The MiniBox+ is equipped with a diffusing capacity module which is embedded into the MiniBox+ enclosure and located in the upper end of the device. This feature allows easy measurement of the volumes and concentrations (CO and CH4) of inspired and expired breath, of the test gas mixture and patient sample respectively, making possible the calculation of the diffusion capacity [DLco]. MiniBox + DLco [diffusing capacity factor of the lung for carbon monoxide (CO)] module uses the single breath concept and enables the measurements by setting and controlling the maneuver stages as defined in ATS/ETS DLco guidelines.

5.3 INTENDED USE AND INDICATIONS FOR USE

The PulmOne MiniBox+ is intended to measure lung function in adult and pediatric patients, 5 years and older, while at rest (including spirometry, lung volumes and diffusing capacity). The PulmOne MiniBox+ is to be used by a physician, respiratory therapist, or technician in a hospital or clinic setting.

5.4 SUMMARY OF TECHNICAL CHARACTERISTICS

The MiniBox+ has been updated from the predicate version K141793. There have been no changes to the general intended use of the device to measure lung function or to the fundamental scientific technology. The Indications for use were updated to include the diffusing capacity module which is substantially equivalent to the one in ZAN 500 [K052328] and both utilize the same technologies and methods of operations. In addition, the software, firmware and hardware for the MiniBox+ in this submission has been updated to introduce minor software, firmware and hardware modifications to support this change.

5.4.1 Summary table of Comparison

Specification	MiniBox+	MiniBoxPFT™ 2.0	ZAN LUNG-FUNCTION LAB (ZAN 500 Body Plethysmograph)	Differences discussion
510(k) Number	Proposed Device	K141793	K052328	NA
Product Code / Classification	BZC- Calculator, Pulmonary Function Data BZG- Spirometer, Diagnostic Class II	BZC- Calculator, Pulmonary Function Data BZG- Spirometer, Diagnostic Class II	BZC- Calculator, Pulmonary Function Data BZG- Spirometer, Diagnostic Class II	Identical
Intended Use and Indications for Use	The PulmOne MiniBox+ is intended to measure lung function in adult and pediatric patients, 5 years and older, while at rest (including spirometry, lung volumes and diffusing capacity). The PulmOne MiniBox+ is to be used by a physician, respiratory therapist, or technician in a hospital or clinic setting	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.	ZAN Lung-Function Lab may measure or monitor pulmonary function in adult and pediatric subjects during exercise (including diagnosis, training, and stress testing) or while at rest (including spirometry, airway strength and compliance, diffusion capacity, body plethysmography, nutritional assessment, and indirect cardiac output) for diagnosis, rehabilitation, performance enhancement, and other related activities	Equivalent. MiniBox + shares the same intended use as the cleared MiniBoxPFT™ 2.0 device with addition of diffusing capacity module. diffusing capacity module added to Minibox + is included with ZAN 500 intended use
Target Population	Adult and Pediatric, 5 years and older	Adult and Pediatric	Adult and Pediatric	Identical to MiniBoxPFT™ 2.0
Standards / Performance guideline compliance	General medical device safety: IEC 60601-1:2005+A1:2012 [3.1 Ed.] Medical electrical safety: Electromagnetic compatibility: IEC 60601-1-2:2014 [4th Ed] - ATS/ETS :2005, Standardization of lung function testing -- ISO 26782 compliance to section 7.2, 7.4-7.6 & 7.8-7.9	General medical device safety: IEC 60601-1:2005 (3rd Ed) Electromagnetic compatibility: IEC 60601-1-2:2007 (3rd Ed) -Performance per ATS 2005 Standards - ISO 26782 compliance to section 7.2, 7.4-7.6 & 7.8-7.9	General medical device safety: EN 60601-1 Medical electrical safety: Electromagnetic compatibility: EN 60601-1-2	Equivalent. MiniBox + complies with the IEC 60601-1 [3.1Ed] and IEC 60601-1-2[4th Ed]
Patient Contacting Parts	Patient direct contact with the cleared disposable viral and bacterial filter, K051712	Patient direct contact with the cleared disposable viral and bacterial filter, K051712	Single-use, disposable FDA-cleared viral bacterial filter or a mouthpiece. Single-use, disposable nose clips	Identical to MiniBoxPFT™ 2.0
User Interface and reports	LCD display with touch panel; top table device	LCD display with touch panel; top table device	LCD display with keyboard and mouse	Identical to MiniBoxPFT™ 2.0
Physical Dimension	21 x 10.5 x 4.5 cm Weight: ~10 kg	21 x 10.5 x 4.5 cm Weight: ~300gr	Dimensions: 71 x 87 x 174 cm Volume: 980 L Weight: 145 kg	Equivalent. Additional Weight due to embedded DLco module
DIFFUSING CAPACITY [Gas Analyzer]				
CO Analyzer	-Technology: Infrared absorption	Not Applicable	-Technology: Infrared absorption	Identical

Specification	MiniBox+	MiniBoxPFT™ 2.0	ZAN LUNG-FUNCTION LAB (ZAN 500 Body Plethysmograph)	Differences discussion
	-Measurement range: 0 to 3000 ppm -Accuracy: <1% -Neutral point drift: <2% per week -Linearity: <1%		-Measurement range: 0 to 3000 ppm -Accuracy: <1% -Neutral point drift: <2% per week -Linearity: <1%	
CH4 analyzer	Technology: Infrared absorption -Measurement range: 0 to 3000 ppm -Accuracy: 2.5% -Neutral point drift: <2% per week -Linearity: <1%	Not Applicable	-Technology: Infrared absorption -Measurement range: 0 to 3000 ppm -Accuracy: 1% -Neutral point drift: <2% per week -Linearity: <1%	Equivalent. Since DLco is computed by the ratio of CH4-in/CH4-out, the more important Gas Analyzer parameter is – linearity. That linearity was tested and verified by the OEM manufacturer and through extensive tests versus the DLco gas simulator [Hans Rudolf, Inc. The Gas Analyzer accuracy was also established by human measurements, based on internal repeatability measurements as well as versus the predicate device – the ZAN Function Lab [ZAN-500] concluded that MiniBox+ didn't adversely impact the substantial equivalence to ZAN 500 , the predicate device
Test gas	mixture of 0.3% Carbon monoxide (CO), 0.3% Methane (CH4), 21% Oxygen (O2) with balance Nitrogen (N2).	Not Applicable	mixture of 0.3% Carbon monoxide (CO), 0.3% Methane (CH4), 21% Oxygen (O2) with balance Nitrogen (N2).	Identical
Demand Valve	OEM by MSA	Not Applicable	OEM by MSA	Equivalent Same component as included with ZAN 500
Calculation and Displayed parameters	BHT , DLco, VA,VI, CO , CH4 and KCO	Not Applicable	BHT , DLco, VA,VI, CO , CH4 and KCO	Identical
LUNG VOLUME MEASUREMENT				
Measurements	Mouth pressure and mouth flow	Mouth pressure and mouth flow	Mouth pressure and mouth flow	Identical
Calculations	TLC, TGV (FRC), RV, VC, IC and ERV	TLC, TGV (FRC), RV, VC, IC and ERV	TLC, FRC, RV, IC, VC, TV, IRV, ERV	Identical
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	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	1) Pressure and flow are measured at the mouth 2) Pressure is measured in the body box 3) Equation based on Boyle's law is used to calculate total lung capacity	Identical to MiniBoxPFT™ 2.0

Specification	MiniBox+	MiniBoxPFT™ 2.0	ZAN LUNG-FUNCTION LAB (ZAN 500 Body Plethysmograph)	Differences discussion
	capacity	capacity		
Method of Operation	1) Patient seated at desk/table 2) 1-2 minutes normal breathing 3) 100 ms shutter closure per breath 4) Inspiration to TLC 5) Slow expiration to RV	1) Patient seated at desk/table 2) 1-2 minutes normal breathing 3) 100 ms shutter closure per breath 4) Inspiration to TLC 5) Slow expiration to RV	1) Patient seated in body box 2) 30 sec shallow panting (1 Hz) 3) 1-5 second shutter closure 4) Inspiration to TLC 5) Slow expiration to RV	Identical to MiniBoxPFT™ 2.0
Air Container	15L elliptic container	15L elliptic container	Body Box Chamber	Identical to MiniBoxPFT™ 2.0
SPIROMETRY MEASUREMENT				
Measurements	Mouth flow	Mouth flow	Mouth flow	Identical
Calculated Parameters	FEF25-75, FEV3, FEV3/FVC, FET, FEF 25, FEF50, FEF75, Evol, FIVC, FIV1, FIVC1/FIVC, PIF, IC, SVC, ERV, TV, IVC, EVC, MVV, MVV rate	FEF25-75, FEV3, FEV3/FVC, FET, FEF 25, FEF50, FEF75, Evol, FIVC, FIV1, FIVC1/FIVC, PIF, IC, SVC, ERV, TV, IVC, EVC, MVV, MVV rate	Flow-volume loop, FVC, FEV1, FEV1/FVC%, PEF, FEF25%, FEF50%, FEF75%, PIF	Identical to MiniBoxPFT™ 2.0
Displayed Parameters	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	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	Flow-volume loop, FVC, FEV1, FEV1/FVC%, PEF, FEF25%, FEF50%, FEF75%, PIF	Identical to MiniBoxPFT™ 2.0
Technical Specifications	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	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	Flow range: +/- 20 L/s Volume accuracy: <2% Flow accuracy: +/- 2% Dynamic resistance at 14 L/s: <0.8 cmH2O/(L/s) Dimensions: 100x50x50 mm Weight: 57 grams	Identical to MiniBoxPFT™ 2.0

5.5 UTILIZATION OF STANDARDS AND GUIDANCE'S:

The MiniBox+ met the following standards and guidance's:

IEC 60601-1:2005+A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

ASTM D4169-14, Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM D4332-14, Standard practice for conditioning containers, packages, or packaging components for testing

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

ATS/ETS :2005, Standardization of lung function testing

5.6 SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Summary of Non-Clinical Tests:

The MiniBox+ has been thoroughly tested through verification of Specifications and validation, including software validation. The following verification and validation testing were applied to the development of the system:

DLco performance verification against simulator [Hans Rudolf],DLco human comparative testing and DLco human reproducibility testing.

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 bench tests performed, the PulmOne MiniBox+ is substantially equivalent to the predicate devices.