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.
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
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)

- [x] 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.

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

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
### 5 SECTION 5 – 510(K) SUMMARY

#### 5.1 ADMINISTRATIVE INFORMATION

<table>
<thead>
<tr>
<th>Date:</th>
<th>15-October-2016</th>
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</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>Specification</th>
<th>MiniBox+</th>
<th>MiniBoxPFT™ 2.0</th>
<th>ZAN LUNG-FUNCTION LAB (ZAN 500 Body Plethysmograph)</th>
<th>Differences discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>510(k) Number</strong></td>
<td>Proposed Device</td>
<td>K141793</td>
<td>K052328</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Product Code / Classification</strong></td>
<td>BZC- Calculator, Pulmonary Function Data</td>
<td>BZC- Calculator, Pulmonary Function Data</td>
<td>BZC- Calculator, Pulmonary Function Data</td>
<td>Identical</td>
</tr>
<tr>
<td></td>
<td>BZG- Spirometer, Diagnostic Class II</td>
<td>BZG- Spirometer, Diagnostic Class II</td>
<td>BZG- Spirometer, Diagnostic Class II</td>
<td></td>
</tr>
<tr>
<td><strong>Intended Use and Indications for Use</strong></td>
<td>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</td>
<td>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.</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td><strong>Target Population</strong></td>
<td>Adult and Pediatric, 5 years and older</td>
<td>Adult and Pediatric</td>
<td>Adult and Pediatric</td>
<td>Identical to MiniBoxPFT™ 2.0</td>
</tr>
<tr>
<td><strong>Patient Contacting Parts</strong></td>
<td>Patient direct contact with the cleared disposable viral and bacterial filter, K051712</td>
<td>Patient direct contact with the cleared disposable viral and bacterial filter, K051712</td>
<td>Single-use, disposable FDA-cleared viral bacterial filter or a mouthpiece. Single-use, disposable nose clips</td>
<td>Identical to MiniBoxPFT™ 2.0</td>
</tr>
<tr>
<td><strong>User Interface and reports</strong></td>
<td>LCD display with touch panel; top table device</td>
<td>LCD display with touch panel; top table device</td>
<td>LCD display with keyboard and mouse</td>
<td>Identical to MiniBoxPFT™ 2.0</td>
</tr>
<tr>
<td><strong>Physical Dimension</strong></td>
<td>21 x 10.5 x 4.5 cm Weight: ~10 kg</td>
<td>21 x 10.5 x 4.5 cm Weight: ~300gr</td>
<td>Dimensions: 71 x 87 x 174 cm Volume: 980 L Weight: 145 kg</td>
<td>Equivalent. Additional Weight due to embedded DLco module</td>
</tr>
<tr>
<td><strong>DIFFUSING CAPACITY [Gas Analyzer]</strong></td>
<td>-Technology: Infrared absorption</td>
<td>Not Applicable</td>
<td>-Technology: Infrared absorption</td>
<td>Identical</td>
</tr>
<tr>
<td><strong>CO Analyzer</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
## PulmOne Advanced Medical Devices

### Traditional 510(k)

#### Section 5 – 510(k) Summary

<table>
<thead>
<tr>
<th>Specification</th>
<th>MiniBox+</th>
<th>MiniBoxPFT™ 2.0</th>
<th>ZAN LUNG-FUNCTION LAB (ZAN 500 Body Plethysmograph)</th>
<th>Differences discussion</th>
</tr>
</thead>
</table>
|               | -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% | -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 |
| 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 |
| 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 |
| 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** | **Identical** |
| | **Calculations** | TLC, TGV (FRC), RV, VC, IC and ERV | TLC, TGV (FRC), RV, VC, IC and 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 | **Identical to MiniBoxPFT™ 2.0** |
<table>
<thead>
<tr>
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<th>MiniBoxPFT™ 2.0</th>
<th>ZAN LUNG-FUNCTION LAB (ZAN 500 Body Plethysmograph)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>capacity</td>
<td>capacity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Method of Operation</strong></td>
<td>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</td>
<td>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</td>
<td>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</td>
<td>Identical to MiniBoxPFT™ 2.0</td>
</tr>
<tr>
<td><strong>Air Container</strong></td>
<td>15L elliptic container</td>
<td>15L elliptic container</td>
<td>Body Box Chamber</td>
<td>Identical to MiniBoxPFT™ 2.0</td>
</tr>
<tr>
<td><strong>SPIROMETRY MEASUREMENT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Measurements</strong></td>
<td>Mouth flow</td>
<td>Mouth flow</td>
<td>Mouth flow</td>
<td>Identical</td>
</tr>
<tr>
<td><strong>Calculated Parameters</strong></td>
<td>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</td>
<td>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</td>
<td>Flow-volume loop, FVC, FEV1, FEV1/FVC%, PEF, FEF25%, FEF50%, FEF75%, PIF</td>
<td>Identical to MiniBoxPFT™ 2.0</td>
</tr>
<tr>
<td><strong>Displayed Parameters</strong></td>
<td>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</td>
<td>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</td>
<td>Flow-volume loop, FVC, FEV1, FEV1/FVC%, PEF, FEF25%, FEF50%, FEF75%, PIF</td>
<td>Identical to MiniBoxPFT™ 2.0</td>
</tr>
<tr>
<td><strong>Technical Specifications</strong></td>
<td>Flow range: +/- 16 L/s Volume accuracy: +/- 3% or 50mL Flow accuracy: +/- 5% or 200 mL/s Dynamic resistance at 14 L/s: &lt;0.7 cmH2O/(L/s) Dimension: 210x105x45 mm Weight: 300 grams</td>
<td>Flow range: +/- 16 L/s Volume accuracy: +/- 3% or 50mL Flow accuracy: +/- 5% or 200 mL/s Dynamic resistance at 14 L/s: &lt;0.7 cmH2O/(L/s) Dimension: 210x105x45 mm Weight: 300 grams</td>
<td>Flow range: +/- 20 L/s Volume accuracy: &lt;2% Flow accuracy: +/- 2% Dynamic resistance at 14 L/s: &lt;0.8 cmH2O/(L/s) Dimensions: 100x50x50 mm Weight: 57 grams</td>
<td>Identical to MiniBoxPFT™ 2.0</td>
</tr>
</tbody>
</table>
5.5 **Utilization of Standards and Guidance's:**

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


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.