5 SECTION 5 – 510(K) SUMMARY

5.1 ADMINISTRATIVE INFORMATION

Date:	September 30, 2013
Submitter:	PulmOne Advanced Medical Devices, Ltd. 64 Asher Street Ra'anana, Israel 4355332 Tel: +972 77 5100 938 Fax: +972 77 5100 939
Official Correspondent:	Avi Lazar, CEO
Trade Name:	PulmOne MiniBoxPFT™
Classification Name: Classification Number: Product Code: Device Class:	Pulmonary-function data calculator 21 CFR 868.1880, 21 CFR 868.1840 BZC, BZG Class II
510(k) Number:	K133051
Predicate Devices:	*Lung Volume Measurement Module* ZAN Messgeräte GmbH ZAN Lung-Function Lab 510(k) Number – K052328 *Spirometry Module* MIR Medical International Research Minispir 510(k) Number – K122384

5.2 DEVICE DESCRIPTION

The MiniBoxPFT™ is a table-top pulmonary function testing (PFT) device that measures both spirometry and lung volumes. It is developed and manufactured by PulmOne Advanced Medical Devices, Ltd. The MiniBoxPFT™ is composed of two modules: an OEM 510(k) cleared Spirometry module and a Lung Volume Measurement (LVM) module. A single-use, disposable viral-bacterial filter separates the patient from the internal components of the modules. The MiniBoxPFT has the following measurement capabilities:

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
Slow vital capacity (SVC)	L
Forced expiratory volume in 1 second (FEV1)	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

5.3 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.

5.4 SUMMARY OF TECHNICAL CHARACTERISTICS

The MiniBoxPFT™ is comprised of two modules, each of which has its own predicate device:

1) The Lung Volume Measurement (LVM) module of the MiniBoxPFT™ is substantially equivalent to the nSpire ZAN Lung-Function Lab (K052328). While there are slight differences in the technology between the proposed device and the predicate device (described below), the clinical performance testing demonstrates that these differences do not raise new questions of safety or effectiveness and that the proposed device is substantially equivalent to the predicate device.

2) The Spirometry module of the MiniBoxPFT™ has been sourced from Medical International Research and is identical in all respects to Medical International Research's Minispir (K122384). No changes were made to this module to allow its incorporation into the MiniBoxPFT™.

In comparison to the ZAN 500 Plethysmograph, the LVM module of the MiniBoxPFT™ is technically similar in device construction (see *Device Construction* below) and methods of operation.

Device Construction: Both devices utilize well-recognized pressure sensors, flow sensors, and a valve in their operation. The MiniBoxPFT™ is technically simpler as it does not have a body chamber, which requires additional calibrations and can be influenced by the environmental surroundings.

Methods of Operation: The methods of operation for both devices require the subject to perform breathing maneuvers on a disposable viral-bacterial filter during flow interruptions while wearing disposable nose-clips. The MiniBoxPFT™ requires less time to perform the breathing maneuvers, has shorter duration flow interruptions, and only requires tidal breathing instead of panting.

The primary difference between the two devices is in their methods to calculate TLC from the measured data, as is described below.

Principles of Operation: The primary difference between the two devices is the equations used to calculate TLC. The ZAN 500 relies on pressure data obtained from the body box chamber to calculate TLC. Without a body box chamber, the MiniBoxPFT™ only uses pressure and flow data measured at the mouth to calculate TLC.

5.5 UTILIZATION OF STANDARDS

The MiniBoxPFT™ has met the following recognized standards:

IEC 60601-1 Ed.3 General Medical Device Safety

IEC 60601-1-1 Ed. 3 Medical Electrical Safety

IEC 60601-1-2 Ed.3 Electromagnetic Compatibility

ASTM D4332 – 01 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

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

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

5.6 SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Non-clinical bench tests were performed to establish substantially equivalent performance and included electrical safety, software validation, and environmental testing. In addition,

bench testing was conducted to verify that the MiniBoxPFT did not alter the spirometry values calculated by the OEM spirometer, and to demonstrate repeatability and reproducibility of the TLC measurement.

The spirometry bench test verified that spirometry values calculated by the OEM spirometer were correctly reported by the MiniBoxPFT. The device successfully passed this test.

The repeatability and reproducibility bench test found that both intra-device repeatability and inter-device reproducibility values (reported as coefficients of variation) fell within pre-defined thresholds, and the device successfully passed this assessment.

5.7 SUMMARY OF CLINICAL PERFORMANCE DATA

A feasibility study was conducted to determine the ability of the device to measure TLC and to develop the algorithm for measuring TLC.

The pivotal study was conducted to demonstrate that the TLC measured with the Lung Volume Measurement (LVM) module of the MiniBoxPFT™ is substantially equivalent to the TLC measured with the ZAN 500 Plethysmograph. The study was multi-centered and randomized subjects (healthy and non-healthy) of varying age, sex, and race. All subjects were measured on both the proposed device and the predicate device. The primary endpoint was total lung capacity (TLC). Pre-defined success criterion was established from scientific literature that reported on the accuracy of FDA-cleared devices that measure TLC and compared these devices to TLC measured with body plethysmography. The clinical data demonstrate that the MiniBoxPFT successfully met its primary success criterion for accuracy of the TLC measurement compared to the predicate device. In addition, no erroneous results were obtained and thus the MiniBoxPFT successfully met its primary success criterion for specified performance. Further, no adverse events occurred during the study. Therefore, the clinical data demonstrate that the performance of the MiniBoxPFT is substantially equivalent to the predicate device for measurement of TLC. Based on these results, the clinical data demonstrate that the MiniBoxPFT is substantially equivalent to the predicate device with respect to TLC measurement.

5.8 CONCLUSIONS

The differences between the MiniBoxPFT™ and the ZAN 500 Plethysmograph do not raise new questions of safety or effectiveness .and, therefore, based on its underlying technology and both non-clinical and clinical performance testing, the PulmOne MiniBoxPFT™ is substantially equivalent to the predicate device.

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

May 2, 2014

Pulmone Advanced Medical Devices, Limited
C/O Ms. Rhona Shanker
Z & B Enterprises, Incorporated
12154 Darnestown Road, #236
Gaithersburg, MD 20878

Re: K133051
Trade/Device Name: MiniBoxPFT
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-function Data Calculator,
Regulatory Class: II
Product Code: BZC, BZG
Dated: April 2, 2014
Received: April 2, 2014

Dear Ms. Shanker:

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" (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 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,

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

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)*
K133051

Device Name

PulmOnc MiniBoxPFT

Indications for Use *(Describe)*

The PulmOne MiniBoxPFT is intended to measure lung function in adult and pediatric patients while at rest (including spirometry and lung volumes). The PulmOne MiniBox PFT 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)*

James J. Lee

Digitally signed by James J. Lee
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=James J. Lee, 0.9.2342.19200300.100.1.1=2000954859
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Acting for Anya Harry MD PhD

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