October 26, 2018

Breathe me LTD
% Yoram Levy
KQsite General Manager
Qsite
31 Haavoda St.
Binyamina, 30500 Il

Re: K180487
Trade/Device Name: Peak.me
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter For Spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: September 20, 2018
Received: September 27, 2018

Dear Yoram Levy:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amy K. Levelle -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Peak.me

Indications for Use *(Describe)*
Peak.me is intended for monitoring FEV1 (Forced exhalation in the first second) and PEF (peak expiratory flow) for home use. The device is designed for adult users and pediatric children over 5 years of age with caregiver supervision.
Peak.me is not recommended for children under 5 years of age.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(K) SUMMARY

Peak.me

510(k) Number K180487

Applicant's Name: Breathe.me Ltd.
13 Zarchin st., Ra'anana 4366241,
P.O.B. 2219, ISRAEL
Tel: +972-76-889-9800
Fax: +972-76-889-9801

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***Peak.me***

Common Name: **Meter, Peak Flow, Spirometry**

510(k) Summary Preparation Date: October 25, 2018

Classification: **Name**: Peak-flow meter for spirometry
Product Code: BZH
Regulation No: 21 CFR 868.1860
Class: II
Panel: Anesthesiology

Device Description:

Peak.me is a hand-held Peak Flow Meter device that is intended for monitoring FEV1 (forced exhalation in the first second) and PEF (peak expiratory flow) for home use. The device is designed for pediatric to adult users. Peak.me is not recommended for children under 5 years of age.

Peak.me consists of a mechanical unit, which physically attaches to the user's smartphone, and a software application which analyzes the measurements and serves as a disease management platform. The device uses the smartphone's internal upper microphone as a sensor and does not include any electrical parts.

As the user exhales through the mechanical unit, it produces acoustic waves with a frequency proportional to the exhalation airflow rate, which then propagates to the smartphone's internal upper microphone.

Peak.me software application analyzes the sound and displays the results. Furthermore, the application includes a review of past measurements. It enables manual input of symptoms and medication usage and provides guidance for correct usage and more.

Intended Use Statement:

Peak.me is intended for monitoring FEV1 (Forced exhalation in the first second) and PEF (peak expiratory flow) for home use.
The device is designed for adult users and pediatric children over 5 years of age with caregiver supervision.
Peak.me is not recommended for children under 5 years of age.

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510(k) No.	Date of Clearance
Wing Smart FEV1 and Peak Flow Meter	K152276	June 3, 2016

Performance Standards:

Peak.me complies with the following voluntary standard:
American Thoracic Society, Standardization of Spirometry, 1994 Update for accuracy and precision.

A detailed description of additional bench performance tests performed appears in **Section 14**.

Summary of Technological Characteristics:

Peak.me device induces acoustic waves from airstreams, with a frequency proportional to the exhalation air flow rate. This enables to determine the respiratory flow using the smartphone's microphone as an acoustic sensor, in order to achieve the device intended use.
The device includes a mouthpiece, mechanical core, a holding mechanism and a SW application.

Principle of Operation

- The user activates the smartphone software application and sets it to initiate a test.
- The user physically attaches the mechanical unit to the smartphone.
- The user places the mouthpiece in his/her mouth and exhales forcefully - the software records the acoustic sound produced by the mechanical unit.
- Upon calculation of PEF and FEV1, the software displays and records the results, both numerically and graphically.

Comparison of the technological characteristics between the *Peak.me* and it's predicate device

	Peak.me	**Wing Smart FEV1 and Peak Flow Meter K152276**
Intended Use	***Peak.me*** is intended for monitoring FEV1 (Forced exhalation in the first second) and PEF (Peak Expired Flow) for home use. The device is designed for pediatric to adult users. Peak.me is not recommended for children under 5 years of age.	Wing is intended for monitoring FEV1 (Forced exhalation in the first second) and PEF (Peak Expired Flow Rate) for home use. The device is designed for pediatric to adult users. Wing is not recommended for children under 5 years of age.
Device Description	***Peak.me*** is a hand-held a Peak Flow monitor that measures the Peak Flow and FEV1. The device consists of a mechanical unit, which physically attaches to the user's smartphone and a software application, which analyzes the measurements and serves as a disease management platform. The device uses the smartphone's internal upper microphone as the sensor and does not include any electrical parts. As the user exhales through the mechanical unit, it produces acoustic waves with a frequency proportional to the exhalation air flow rate, which then propagates to the smartphone's microphone. ***Peak.me*** software application analyzes the sound and displays the results. Furthermore, the application includes past measurements' review, enables manual input of symptoms and medication usage, shows guidance for correct usage and more.	Wing® Smart FEV1 and Peak Flow Meter (Wing) is an electronic peak flow monitor that measures Peak Flow and FEV1. The Wing Sensor consists of a plastic shell and a detachable electronics module. The plastic shell includes a built-in mouthpiece and an acoustic transducer. The electronics module houses a PCBA with a microphone and a 3.5mm audio cable. The audio cable is plugged into the 3.5mm audio jack (headphone jack) of a smartphone to transmit audio data to the Wing Software. As the user blows through Wing Sensor, the acoustic Transducer induces oscillations in the airstream and an acoustic tone is created by the airstream and the microphone detects this acoustic tone. The frequency of the acoustic tone is proportional to flow rate of the air. Wing Software, which includes the Wing Mobile Application (Wing App), Wing Signal Processing Engine, and the Sparo Labs Data Management System, is used to collect, transmit, manage, store, and calculate FEV1 and Peak Flow measurements. When taking a lung function

	Peak.me	**Wing Smart FEV1 and Peak Flow Meter K152276**
		measurement, the user launches Wing App, which Serves as Wing's user interface, on his or her smartphone and connects the Wing Sensor by plugging it into the smartphone's headphone jack.
Device Class	Class II	Class II
Classification Panel	Anesthesiology	Anesthesiology
Product Code	BZH	BZH
Regulation Description	Peak-flow meter for spirometry	Peak-flow meter for spirometry
Regulation number	21 CFR 868.1860	21 CFR 868.1860
Intended user	The device is designed for pediatric to adult users. Peak.me is not recommended for children under 5 years of age.	The device is designed for pediatric to adult users. is not recommended for children under 5 years of age.
Method of Operation	As the user exhales through Peak.me, the rotor induces chopping of the airstream; an acoustic tone is created by the airstream and the microphone detects this acoustic tone. The frequency of the acoustic tone is proportional to air exhalation flow rate.	As the user blows through Wing Sensor, the acoustic Transducer induces oscillations in the airstream and an acoustic tone is created by the airstream and the microphone detects this acoustic tone. The frequency of the acoustic tone is proportional to flow rate of the air.
Principles of Operation	Following smartphone SW activation and exhalation into the connected device the PEF and FEV1 values are calculated by recording the acoustic tone.	Following smartphone SW activation and exhalation into the connected device the PEF and FEV1 values are calculated by recording the acoustic tone.
User Interface	Mobile application	Mobile application
Main SW application Features	Measure, view and store FEV1 and PEF values; includes Personal Best Peak Flow and Traffic Light Zone.	Measure, view and store FEV1 and PEF values; includes Personal Best Peak Flow and Stoplight Zone.
Measure Range	PEF: 50-900 L/min FEV1: 0.01-9.99 L	PEF: 50-900 L/min FEV1: 0.01-9.99 L
Parameters Accuracy	FEV1: ±0.1L or ±5% Peak Flow: ±20L/min or ±10%	FEV1: ±0.1L or ±5% Peak Flow: ±20L/min or ±10%
Measuring Resolution	FEV1: 0.01 [L] PEF: 1 [L/min]	FEV1: 0.01 [L] PEF: 1 [L/min]

	Peak.me	**Wing Smart FEV1 and Peak Flow Meter K152276**
Method of Connection to phone	Direct physical attachment.	3.5mm audio jack that plugged into the audio jack (headphone jack).
Home Use	Yes	Yes
Prescription/ Over the Counter (OTC) use	OTC	OTC
Wight	60 gr/0.13 lb.	70 gr/ 0.15 lb.
Dimensions	2 X 2 X 4.3 inches (50 X 50 X 110 mm)	3.2 X 2.4 X 1.5 inches (81 x 61 x 37mm)
Optional applications	Monitoring and management of asthma or COPD by measuring and recording PEF and FEV1 values.	Monitoring and management of asthma or COPD by measuring and recording PEF and FEV1 values.
Biocompatibility	All parts that are in contact with patient comply with the requirements of ISO 10993-1.	All parts that are in contact with patient comply with the requirements of ISO 10993-1.
Software	Verified and validated according to the FDA guidance.	Verified and validated according to the FDA guidance.
Standards	American Thoracic Society (ATS) Standardization of Spirometry, 1994 Update.	American Thoracic Society (ATS) Standardization of Spirometry, 1994 Update.

Performance Data:

The following Lab performance tests, design validation and software verification and validation tests were conducted:

Test Name	Purpose
Peak.me Accuracy and Precision PEF and FEV1 validation	Validation that the device meets the accuracy and precision requirements according to the ATS Standardization of Spirometry, 1994 Update.
Peak.me Resistance Validation	Validation that the device meets the Resistance requirements according to the ATS Standardization of Spirometry, 1994 Update.
Peak.me Lifetime Validation	Validation of Peak.me lifetime.

Test Name	Purpose
Peak.me Background Noise Validation	Validation of ***Peak.me***'s accuracy in the presence of potentially disruptive noises.
Peak.me Drop Test Validation	Essential performance tests were conducted following drop test according to IEC 60601-1. The tests were passed successfully.

Verification and testing have shown that ***Peak.me*** device performs according to its specifications.
The ***Peak.me*** device was tested and validated with the Samsung Galaxy S6, Samsung Galaxy S6 edge, Samsung Galaxy S7 and Samsung Galaxy S7 edge.

Summary of Clinical performance data:

No clinical study was conducted.

Peak.me has the same intended use, clinical indication and technology and no clinical studies were necessary to show substantial equivalency with its predicate device.

Human Factor (Usability) Study

A usability study was designed to address the usability concerns and clearness of the Instructions for Use (IFU) and Graphic User Interface (GUI) of Peak.me application and device, while operated by intended users - any person who wishes to monitor his/her lung function. All study participants (15 out of 15 - 100%) completed the scenario tasks alone with ease and confidence.

The study results of this usability study demonstrate that the ***Peak.me*** device and application are as safe and as effective as its predicate device.

Substantial Equivalence:

Peak.me and the predicate device have the same intended use. Both of them have the same clinical indication.
Peak.me device has the same technological characteristic and measuring principles as the Wing Smart FEV1 and Peak Flow Meter (K152276). Both devices induce acoustic waves from airstreams, with a frequency proportional to the exhalation air flow rate.
The design and components of ***Peak.me*** device are similar to those of the Wing Smart FEV1 and Peak Flow Meter. Both include a mouthpiece and a mechanical core. The only difference is the sensor's type. While ***Peak.me*** is a mechanical

device only that uses the smartphone's upper microphone as an acoustic sensor, in order to record the acoustic tone, the Wing also has an electronic module.
The differences in the design and configuration between the ***Peak.me*** and the Wing do not influence the core technology in achieving their intended use.
Both ***Peak.me*** device and Wing have a mobile application (App) as the user interface.
Any minor differences in the design do not raise any new types of safety and effectiveness issues. Therefore, ***Peak.me*** is substantially equivalent to its predicate device.

Conclusions:

As a result, ***Peak.me*** device is substantially equivalent to the Wing Smart FEV1 and Peak Flow Meter (K152276) predicate devices.