August 1, 2018

MIR Medical International Research
% Mr. Dave Yungvirt
Official Third Party Correspondent
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K181666
Trade/Device Name: Smart One
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-flow meter for spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: July 30, 2018
Received: August 1, 2018

Dear Mr. Yungvirt:

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,

James J. Lee -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)*
K181666

Device Name
Smart One

Indications for Use *(Describe)*
Smart One is intended for home use by patients to monitor PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in one second). The device is designed for children greater than five years of age, adolescent and adult subjects.

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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MEDICAL INTERNATIONAL RESEARCH

510(k) Summary

1. Applicant Information

Date Prepared:	July ,27th 2018
Submitter:	MIR Medical International Research
Address:	Via del Maggiolino, 125 00155 Roma – Italy
Contact Person:	Gerda Van Houts
Phone Number:	+39 06.22.754.777

2. Device Information

Trade Name:	Smart One
Common Name:	Peak-Flow meter
Classification Name:	Meter, Peak Flow, Spirometry
Classification	Class II
Regulation Number	868.1860
Product Code	BZH

3. Identification of the legally marketed device to which the submitter claims equivalence:

Company Name:	MICROLIFE INTELLECTUAL PROPERTY GMBH
Trade Name:	MICROLIFE ELECTRONIC PEAK FLOW MONITOR, WITH PEF AND FEV1, MODELS PF-100 AND PF-100-1 (WITH SOFTWARE)
510(k) number:	K040723
Regulation Number	868.1860
Product Code	BZH

4. Description of the device:

Smart One is a pocket-sized system for monitoring the following respiratory parameters:

- PEF (Peak Expiratory Flow)
- FEV1 (Forced Expiratory Volume in 1 sec)

For each of these two parameters, the result is a number shown on the smartphone screen. PEF is also associated with a three zone monitoring system that, according to the result, may be green, yellow or red.

Smart One is made up of two elements – the device and a Mobile Medical Application for smart-phones (or tablets) that communicate via Bluetooth Smart 4.0.

Functions of the device

The device is equipped with a plastic mouthpiece connected to a turbine flow meter based on the

infrared interruption principle.

The device detects the signals generated by the turbine, measures the exhalation flow and then sends it the Mobile Medical Application. At the end of the expiration, the device calculates the PEF and FEV1 and sends them to the Mobile Medical Application.

Functions of the Mobile Medical Application
The Mobile Medical App is used to display the data and to compare PEF with the baseline value set when configuring the Mobile Medical Application.

In details, the Mobile Medical Application performs the following functions:

- sends the start test command to the device
- during expiration, displays a progressive numerical and graphical representation (similar to a histogram) of the exhalation flow values
- at the end of the expiration, displays the parameter measured and received by the device (PEF and FEV1) and adds it to the diary where the parameters are recorded and can be viewed at a later stage
- compares the PEF measured by the device with the baseline value set when configuring the Mobile Medical Application and displays a three zone system (green, yellow or red) that makes it easy to interpret the test result.
- can transfer a file with the data from the electronic diary to your doctor or other licensed health care practitioner for consultation.

5. Statement of Intended Use:

Subject device
Smart One is intended for home use by patients to monitor PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in one second).
The device is designed for children greater than five years of age, adolescent and adult subjects.

Predicate device
This device is intended for monitoring PEF (Peak Expired Flow Rate) and FEV1 (forced exhalation in the first second) for patient home use. The device is designed for pediatric to adult patients.

Comparison between the indication statements of the subject with the predicate device
Environment of use (home), function (Peak Flow Meter) and patient population (children greater than five years of age, adolescent and adult subjects) of the subject device are the same as the predicate device.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:
The principle of operation of both predicate device and subject device is the same: the air flow passes through the turbine and makes the blade of the turbine rotate. Rotation speed which is in linear relationship with the air flow rate is measured by photodetectors.
The subject and predicate devices are based on the following same technological characteristics:

- Use of a turbine sensor as a flowmeter
- Display, storage, and review of monitored data (PEF and FEV1)

- Possibility to set personal best value (for PEF)
- Use of a three zone monitoring system (green, yellow and red) for PEF

The following technological differences exist between the subject and predicate devices

1. The predicate device dimensions are 77 (W) x 144 (L) x 48 (H) mm while Smart One dimensions are 49 (W) x 109(L) x 21 (H) mm.
2. The predicate device weight is 150 g (including batteries) while the weight of Smart One is 60.7 g (including batteries).
3. Smart One has flow and volume accuracy and range equal or superior to the predicate device.
4. The predicate device uses a graphic marker displayed as a colored bar, while Smart One uses a graphic marker displayed as a colored circle.
5. The predicate device store up to 240 measurements while Smart One can store more than 1000 measurements.
6. Predicate device provides data transmission via USB while Smart One uses Bluetooth.
7. In the predicate measured data are shown on the display of the device while Smart One displays data on the smartphone.

The first five differences do not affect substantial equivalence of the device.

In order to evaluate the effects on substantial equivalence of the sixth difference, SmartOne has been qualified according to Bluetooth SIG. Smart One data transmission integrity has been thoroughly tested. Also Bluetooth transmission of test results is employed in another legally marketed device, considered as reference device (Spirotel, K130784). Thus Bluetooth transmission does not affect safety and effectiveness and Smart One is at least as safe and as effective as the predicate device.

In order to evaluate the effects on substantial equivalence of the seventh difference, the following reference device has been used: Spirotel manufactured by MIR (K130784). Spirotel can measure several parameters, including PEF and FEV1. When Spirotel is configured by choosing PEF (or FEV1) as measured parameter, it operates as a peak flow meter. Spirotel can operate completely autonomously as a standalone device or can be operated by a PC or a phone via USB or Bluetooth. Given that Smart One uses equivalent technology as Spirotel when Spirotel operates as peak flow meter via Bluetooth, the different technological characteristics between Smart One and the predicate device do not raise different questions of safety and effectiveness and Smart One is at least as safe and as effective as the predicate device.

7. Brief discussion of the clinical and nonclinical tests relied on for a determination of SE.

Non clinical tests

The following non-clinical testing was conducted to demonstrate substantial equivalence.

Electrical safety and electromagnetic compatibility (EMC) testing was conducted in accordance with IEC 60601-1:2005 and IEC 60601-1-2:2007. Mechanical durability and temperature/humidity testing have been completed. In addition, wireless transmission integrity as well as wireless co-existence tests were performed. The results demonstrate that the Smart One is in compliance with the guideline and standards referenced and that it performs within its specifications.

A performance test has been carried out on the bench according to the American Thoracic Society (ATS) Document "Standardization of Spirometry – 2005". The test has been conducted in MIR facilities using a Pulmonary Waveform Generator.
The results obtained show that accuracies of measured parameters are within the limits of the ATS standards.

Biocompatibility of the materials has been tested for cytotoxicity, irritation, and sensitization according to ISO 10993-1: 2009, following FDA's guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". Results of the tests show that materials are biocompatible.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", and the software for this device was considered as a "moderate" level of concern.

In addition, the following FDA guidance documents were also followed in this submission:

- Guidance For Labeling Peak Flow Meters For Over The Counter Sale, Version 1.0, 1993
- Radio Frequency Wireless Technology in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, August 4, 2013
- Design Considerations for Devices intended for home Use, Nov 24, 2014
- Postmarket management of Cybersecurity in Medical Devices, Dec 28, 2016

8. Conclusions

Based on these results, it is our determination that the device is substantially equivalent to the predicate device.