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

June 3, 2016

Sparo Inc.
Ms. Mona Dean
Consultant, Regulatory Affairs
911 Washington Ave, #809
Saint Louis, Missouri 63101

Re: K152276
Trade/Device Name: Wing Smart FEV1 and Peak Flow Meter
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: August 8, 2015
Received: May 5, 2016

Dear Mona Dean:

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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

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)*
K152276

Device Name
Wing Smart FEV1 and Peak Flow Meter

Indications for Use *(Describe)*
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.

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

Manufacturer: Sparo Inc. (d.b.a Sparo Labs)

Contact: Mona Dean
Consultant, Regulatory Affairs
913-638-1954 (phone)
monadeans@gmail.com

Date Prepared: June 2, 2016

Product Code: BZH
Device Trade Name: Wing Smart FEV1 and Peak Flow Meter
Regulation Description: Peak-flow meter for spirometry
Classification: 21 CFR 868.1860
Class: II

Indications for Use:
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:
The Wing® Smart FEV1 and Peak Flow Meter (Wing) is an electronic peak flow monitor, that measures Peak Flow and FEV1. Wing is not recommended for children under 5 years of age.

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. The Wing Software, which includes the Wing Mobile Application (Wing App), the 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 measurement, the user launches the 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. The Wing App prompts the user to perform the lung function test after the user has indicated that they would like to take a lung function measurement. As the user blows through Wing Sensor, the acoustic transducer induces oscillations in the airstream and an acoustic tone is created by the airstream. The microphone, located in the electronics module, detects this acoustic

tone. The frequency of the acoustic tone (i.e. the number of oscillations) is proportional to flow rate of the air as it passes through the acoustic transducer. With flow rate and correspondent time, the FEV1 can be calculated. Wing is provided non-sterile.

Predicate Device:
Wing was shown substantially equivalent to the previously cleared device: Microlife Electronic Peak Flow Monitor, with PEF and FEV1, Models PF-100 and PF-100-1 (with software) – K040723.

Substantial Equivalence
Technological Characteristics:
The Wing Sensor measuring principle is determination of respiratory flow using acoustic sensor (meeting ATS accuracy & precision testing) whereas the predicate device uses a infrared rotary flow sensor. Both technologies measure frequency of oscillation (or rotation) caused by the airstream to calculate FEV1 and PEF. Both devices meet ATS accuracy & precision recommendations. The Wing Sensor also uses a 3.5mm audio jack (headphone jack) to transmit data to the Patient Mobile Device (e.g. an iPhone), whereas the predicate device uses a mini-USB port to transmit data to a computer and associated tracking software. The Wing Sensor contains no battery and draws power directly from the Patient Mobile Device via the 3.5mm audio jack, whereas the predicate device is powered by 2 AAA batteries.

Performance Testing:
The following performance data were provided in support of the substantial equivalence determination: Bench testing, biocompatibility testing, applicable electrical safety testing, and software validation & verification testing.

Bench Testing:
Wing was tested to and passed the American Thoracic Society (ATS) 24 and 26 Standard Waveforms using a pulmonary waveform generator, meeting ATS accuracy and precision recommendations for measuring FEV1 and Peak Flow.

Biocompatibility Testing:
The biocompatibility evaluation for the Wing device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The test articles were prepared in accordance with ISO 10993-12, Cytotoxicity testing was completed in accordance with ISO 10993-5, and Sensitization and Irritation testing were completed in accordance with ISO 10993-10.

Electrical Safety Testing:
Electrical safety testing was conducted on the Wing Sensor, showing the system complies with the IEC 60601-1 standard.

Electromagnetic Compatibility (EMC) Testing:
Electromagnetic compatibility (EMC) testing was conducted on the Wing Smart FEV1 and Peak Flow Meter, showing the system complies with the IEC 60601-1-2 standard.

Software Validation & Verification Testing:
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.

Animal & Clinical Testing:
The subject of this premarket submission, Wing, did not require animal or clinical studies to support substantial equivalence.

Conclusion:
Wing was shown to be substantially equivalent to the Microlife Electronic Peak Flow Monitor, with PEF and FEV1, Models PF-100 and PF-100-1 (with software) with respect to intended use, indications for use, technological characteristics, performance characteristics, and biocompatibility.