May 26, 2021

Shanghai Sonmol Medical Equipment Co., Ltd.
% Raymond Luo
Technical Manager
Shanghai Sungo management Consulting Company Limited
14th F, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K203196
Trade/Device Name: Peak Flow Meter
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter For Spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: April 26, 2021
Received: April 26, 2021

Dear Raymond Luo:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203196

Device Name
Peak Flow Meter

Indications for Use *(Describe)*
This device is intended to monitor a patient's Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) at home. The device is designed for adults and children over 5 years of age with caregiver supervision. The device is intended for monitoring respiratory conditions such as asthma. The device is for Over-The-Counter Use.

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.

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510(K) Summary

Date of preparation: 5/25/2021

1. Applicant

Name: Shanghai Sonmol Medical Equipment Co., Ltd.
Address: Room 116-118, Building 21, No.500 Jiajian Road, Jiading District Shanghai, China

Official Contact Person Information

Shanghai Sungo Management Consulting Company Limited
Name: Raymond Luo
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2. Device

The proprietary name of the new device: Peak Flow Meter
The generic name of the device: Peak-Flow Meter For Spirometry
Classification regulation: 21 CFR 868.1860
Classification: Class II.
Product code: BZH

3. Predicate device and reference device

Predicate device

Sponsor	Guangzhou Homesun Medical Technology Co., Ltd
Device Name and Model	Smart Peak Flow Meter (Model: B1)
510(k) Number	K191239
Product Code	BZH
Regulation Number	21 CFR 868.1860
Regulation Class	II

Reference device

Sponsor	Clement Clarke Int. Ltd
Device Name and Model	Mini-Wright Digital (Model: 3120001)
510(k) Number	K053156
Product Code	BZH
Regulation Number	21 CFR 868.1860
Regulation Class	II

4. Intended use of the device:

This device is intended to monitor a patient's Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) at home. The device is designed for adults and children over 5 years of age. The device is intended for monitoring respiratory conditions such as asthma. The device is for Over-The-Counter Use.

5. Device Description:

5.1 Composition

The Peak flow meter is composed of Main Unit and Mouthpiece.
Mouthpiece: Mouth blowing.
Main Unit: Containing a segment LCD, a pressure sensor and a Microcontroller Unit.
The pressure sensor records the gas flow rate in real time and delivers to MCU for processing, to get the flow volume of gas and volume, after the measurement, LCD displays the measurement results.

5.2 Principle for working

Patient puts the mouthpiece in the mouth and vigorously blows the gas through it. The pressures sensor records the gas flow rate in real time and delivers to central processor for processing to estimate the flow volume of gas at the present time and the maximum value of the whole process which is the Peak Expiration Flow rate (PEF). At the same time, the central processor measures the time of the entire process using high-precision crystal from some to zero of the flow, and then calculates the flow volume integration on time. Taking the volume in the first second is the forced expiratory volume of 1 second (FEV1).

In the process of test, the buzzer gives a tone to indicate the beginning and end of the measurement, after the measurement, LCD displays the measurement results.

5.3 Model differences

The two models are identical except the following aspects.

ITEMS	SMPF-2S	SMPF-3A
Indications for use/ Intended use	Measuring forced expiratory volume of 1 second (FEV1), peak expiration flow rate （PEF）	Measuring peak expiration flow rate（PEF）
Measuring range of FEV1	0.5L ～ 8L	none
Accuracy	Volume：±3％ or ±0.05L (whichever is greater) Flow rate： ±10 ％ or ±18L/min (whichever is greater)	Flow rate： ±10 ％ or ±18L/min (whichever is greater)
Measuring resolution	Volume：0.01L Flow：1L/min	Flow：1L/min

6. Technological characteristics and substantial equivalence

ITEMS	Current Device	Predicate Device	Reference Device	Comparison
Trade name	Peak Flow Meter (SMPF-2S)	Smart Peak Flow Meter (Model: B1)	Mini-Wright Digital	
510 (k) number	K203196	K191239	K053156	
Regulation number	21 CFR 868.1860	21 CFR 868.1860	21 CFR 868.1860	identical
Regulation description	Peak-flow meter for spirometry	Peak-flow meter for spirometry	Peak-flowmeter for spirometry	identical
Classification name	Meter, Peak Flow, Spirometry	Meter, Peak Flow, Spirometry	Meter, Peak Flow, Spirometry	identical
Product code	BZH	BZH	BZH	identical
Class	II	II	II	identical
Indications for use/ Intended use	This device is intended to monitor a patient's Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) at home. The device is intended for monitoring respiratory conditions such as asthma. The device is for Over-The-Counter Use.	This device is intended to monitor a patient's Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) at home. The device is intended for monitoring respiratory conditions such as asthma.	The Mini-Wright Digital is a handheld, battery operated, electronic Peak Flow Meter and FEV1 monitoring device with an internal memory capable of storing 240 sets of readings. This product will be sold as an OTC device with appropriate instructions. When used to monitor conditions such as asthma, this device should be used under the direction of a physician or licensed health care professional. The device is intended for use with pediatric and adult patients in both home and clinical settings.	Identical to the predicate device
Patient population	Pediatric to adult patients.	Pediatric to adult patients.	Pediatric to adult patients.	identical

Prescription or OTC	OTC	OTC	OTC	identical
Basic Unit Specification				
Power supply	DC3V (2 AAA Alkaline batteries)	3.7V-300mAh lithium Polymer battery	Lithium coin CR2032 (included, not changeable)	Note 1
Dimensions	142*48*56mm	111*39*40mm	29*44*114mm	Note 2
Weight	52g	50g	54g	Note 2
Materials	ABS	PP (Mouthpiece)	/	Note 3
Components	Main Unit and Mouthpiece and the mouthpiece is unremovable.	Mainly composed of main unit and Removable mouthpiece.	Mainly composed of meter and adapter	Note 4
Compliance With voluntary standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, ATS 2005	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, ATS 2005	ATS 1994	Identical to the predicate device
Performance specification				
Measuring method	Flow: Pressure Sensor. Volume: Flow Integration	Flow: Pressure Sensor. Volume: Flow Integration	Pressure sensor	identical
Measuring range of PEF	60L/min ～ 840 L/min	50-840L/min	60-850L/min	Note 5
Measuring range of FEV1	0.5L ～ 8L	0.01-9.99L	0.6-8L	Note 6
Accuracy	PEF: ±10% or ±18L/min (Take the larger one) FEV1: ±3% or ±0.05L (Take the larger one)	PEF: ±10% or ±18L/min (Take the larger one) FEV1: ±3% or ±0.05L (Take the larger one)	PEF: ±6% FEV1: ±3.5% (@25°1013mbar 50%HR)	Identical to the predicate device
Measuring resolution	PEF: 1L/min FEV1: 0.01L	PEF: 1L/min FEV1: 0.01L	PEF: 5L/min FEV1: 0/05L	Identical to the predicate device

Memory	none	100 historical data	240 FEV1and 240 PEF	Note 7
Data safety	none	Data rememorized by flash memory.	/	
Data transmission	none	Bluetooth wireless transmission	/	
Working conditions	Temperature: 10℃～+40℃, Humidity: 0％ RH～80％RH, Atmospheric pressure:70KPa~106KPa	Temperature: 10℃～+40℃, Humidity: 0％ RH～80％RH, Atmospheric pressure:70KPa~106KPa	Temperature: 15℃～35℃	identical
Storage conditions	Temperature:-10℃ ～ +55℃； Humidity: ≤95%RH Atmospheric pressure: 500hPa～1060hPa	Temperature:-20℃ ～+55℃, Humidity: 0％RH～80％RH, Atmospheric pressure: 70KPa ～106KPa	Temperature: -10℃～+50℃, Humidity: 15 to 95%	Note 8
Biocompatibility	Passed the tests as per ISO 10993-1	Passed the tests as per ISO 10993-1	/	identical
Electrical safety	Passed the tests as per IEC 60601-1 and IEC 60601-1-11	Passed the tests as per IEC 60601-1 and IEC 60601-1-11	/	identical
EMC	Passed the test as per IEC60601-1-2	Passed the test as per IEC60601-1-2	/	identical
Sterility	Non-sterile	Non-sterile	Non-sterile	identical

Note 1: Although the power supply is different from the predicate device, the tests were conducted for electrical safety and EMC to ensure the conformity with standards.

Note 2: Although the appearance, weight and dimensions are different between the targeted and predicate device, these differences are insignificant and do not raise new questions of safety and effectiveness.

Note 3: Although the material used for the device is different, the test was done on patient contacting components to support biocompatibility.

Note 4: The mouthpiece of the current device is not removable. There is no new risk raised as this is reuse device for single user and the cleaning process is validated.

Note 5: The Maximum Measuring range of PEF is identical to the predicate device and the Minimum Measuring range of PEF is identical to the reference device.

Note 6: The FEV1 Measuring range of current device is similar to the reference device.

Note 7: The current device does not have the function of data memory or wireless transmission. So, there is no additional risk raised from cybersecurity standpoint.

Note 8: The storage condition is different, the test was done according to IEC60601-1-11 to provide conformance.

7. Non-clinical studies and tests performed

Non-clinical tests have been conducted to verify that the Peak Flow Meter (SMPF-2S, SMPF-3A) meets all design specifications which supports the conclusion that it's Substantially Equivalent to the predicate device. The testing results demonstrate that the targeted device complies with the following standards and guidance:
IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-11, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

The body-contacting components of this device are mouthpiece and main unit which have been demonstrated conformance to the following standards:
ISO 10993-1, Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process.

We have also conducted:
Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern. Software validation demonstrated that the software functions as specified in the software requirement specifications.

Performance test has also been conducted to verify the measurement accuracy, intra instrument repeatability, PEF inter instrument repeatability and performance of flow resistance of the device according to American Thoracic Society Standard of Spirometry (2005 Revision).

All of the tested parameters meet the requirements in the standards. The performance of the targeted device is demonstrated to be comparable with the predicate device, so it is concluded that the targeted device is substantially equivalent to the predicate device.

Human Factor Engineering Study was conducted according to IEC 62366. The study results of this human factor engineering study demonstrate that the Peak Flow Meter device and application are as safe and as effective as its predicate device.

8. Conclusion

Based on the above analysis and tests performed, it can be concluded that Peak Flow Meter (SMPF-2S, SMPF-3A) is substantially equivalent to the predicate device.