December 6, 2019

Guangzhou Homesun Medical Technology Co., Ltd
℅ Tracy Che
Registered engineer
Feiying Drug & Medical Consulting Technical Service Group
B-3F 3005, Bldg.1, Southward Ruifeng Business Center, No. 22
Guimiao Rd.
Shenzhen, 518000 CN

Re: K191239
Trade/Device Name: Smart Peak Flow Meter (Model: B1)
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter For Spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: November 5, 2019
Received: November 8, 2019

Dear Tracy Che:

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,

for Michael Ryan
Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191239

Device Name
Smart Peak Flow Meter (Model: B1)

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.

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

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information

510 (k) owner's name:	Guangzhou Homesun Medical Technology Co., Ltd
Address:	Floor 7th, TianxiangBusiness Building, No.28, Li Fu Road, Haizhu District, Guangzhou, GD. China
Contact person:	Jinqun Li
Phone number:	+86 020 34003801
Fax number:	+86 020 34003801
Email:	ljq@huxijia.com
Date of summary prepared:	December 4, 2019

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/Model:	Smart Peak Flow Meter (Model: B1)
Regulation name:	Peak-flow meter for spirometry
Regulation number:	21 CFR 868.1860
Product code	BZH
Review panel:	Anesthesiology
Regulation class:	Class II

(4) Predicate and reference device

✧ Predicate device

Sponsor	Beijing M&B Electronic Instruments Co., Ltd.
Device Name and Model	MSA100BT Peak Flow Meter
510(k) Number	K170281
Product Code	BZH
Regulation Number	21 CFR 868.1860
Regulation Class	II

✧ Reference device 1

Sponsor	KORR MEDICAL TECHNOLOGIES, INC.

Device Name and Model	ACCUTRAX, MODEL EPF840 Electronic Peak Flow Meter
510(k) Number	K982995
Product Code	BZH
Regulation Number	21 CFR 868.1860
Regulation Class	II

✧ Reference device 2

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

(5) Description/ Design of device

Smart Peak Flow Meter (Model: B1) is a new type of hand-held pulmonary function testing device that measures peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV1). Regular measurement is beneficial to the controlling of pulmonary disease such as asthma. The accuracy meets American Thoracic Society (ATS) Standard 2005 Revision.

The Smart Peak Flow Meter (Model: B1) is mainly composed of the main unit and removable mouthpiece. The use of B1 is very simple, user can master it quickly after reading the product user manual. It adopts mouth blowing method. After mouthpiece installation and powering on, keep breath steady, take a deep breath, hold the breath while put the mouthpiece into mouth, then exhale quickly and forcefully, taking as much time as possible. The results will be shown on the display screen and smart phone App. The mouthpiece should be removed regularly for cleaning.

The device can store 100 sets of data which can be transmitted to smart phone App through Bluetooth transmission mode for permanent storage. User can check the previous measurement records on the smart phone App.

(6) Indications for 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 designed for adults and children over 5 years of age with caregiver supervision. The device is intended for monitoring respiratory conditions such as asthma.

(7) Technological characteristics and substantial equivalence

Item	Targeted device	Predicate device	Reference device 1	Reference device 2	Remark
Trade name	Smart Peak Flow Meter (Model: B1)	MSA100BT Peak Flow Meter	ACCUTRAX, MODEL EPF840 Electronic Peak Flow Meter	Mini-Wright Digital	/
510 (k) number	K191239	K170281	K982995	K053156	/
Regulation number	21 CFR 868.1860	21 CFR 868.1860	21 CFR 868.1860	21 CFR 868.1860	Same
Regulation description	Peak-flow meter for spirometry	Peak-flow meter for spirometry	Peak-flow meter for spirometry	Peak-flow meter for spirometry	Same
Classification name	Meter, Peak Flow, Spirometry	Meter, Peak Flow, Spirometry	Meter, Peak Flow, Spirometry	Meter, Peak Flow, Spirometry	Same
Product code	BZH	BZH	BZH	BZH	Same
Class	II	II	II	II	Same
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.	This device is intended for monitoring PEF (Peak Expired Flow Rate) and FEV1 (Forced Expiratory Volume in one second) for patient home use. The device is designed for pediatric to adult patients. The device is intended for monitoring respiratory conditions such as asthma.	This AccuTrax EPF80 device is intended for monitoring PEF and FEV1 for patient home and work use. The EPF840 is designed for pediatric to adult patients. When the EPF840 is used to watch lung conditions such as asthma, the user should be under the care of a licensed health care professional. A licensed health professional's advise is required to understand the meaning and	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	Similar

			importance of the measures reported by the AccuTrax 840, and how to decide on an appropriate treatment plan. This treatment plan will tell you what action to take when there are changes in your PEF/FEV1 numbers.	physician or licensed health care professional. The device is intended for use with pediatric and adult patients in both home and clinical settings.	
Patient population	Pediatric to adult patients.	Pediatric to adult patients.	Pediatric to adult patients.	Pediatric to adult patients.	Same
Prescription or OTC	OTC	OTC	Prescription	OTC	Same
Basic unit specification					
Power supply	3.7V-300mAh lithium polymer battery	AAA 1.5×2 alkaline batteries	Primary source: Alkaline 9-volt battery RTC backup: Lithium 3V battery CR2032	Lithium coin CR2032 (included, not changeable)	Different Note 1
Dimensions	111*39*40mm	126*54*28mm	88*112*48mm	29*44*114mm	Different Note 2
Weight	50g	120g (including batteries and mouthpiece)	184g with battery	54g	Different Note 2
Materials	PP (Mouthpiece)	PP (Mouthpiece)	ABS, Cycolac 2502 (GE Plastics) (flowhead)	/	Same
Components	Mainly composed of main unit and removable mouthpiece.	Mainly composed of main equipment, mouthpiece, turbine sensor.	Mainly composed of flowhead and unit body.	Mainly composed of meter and adapter	Similar
Compliance with voluntary standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11,	IEC 60601-1, IEC 60601-1-2, ATS 2005.	ATS standard	ATS 1994	Similar

	ATS 2005.				
Performance specification					
Measuring method	Flow: Pressure Sensor. Volume: Flow Integration	Flow: Turbine sensor Volume: Flow integration	Flow: Air pressure reducing mess in a flow head is applied to a pressure transducer Volume: Flow integration	Pressure sensor	Different Note 3
Measuring range of PEF	50-840L/min	50-900L/min	875L/min (max)	60-850L/min	Similar
Measuring range of FEV1	0.01-9.99L	0.01-9.99L	8.5L (max)	0.6-8L	Same
Accuracy	PEF: ±10% or ±18L/min (Take the larger one) FEV1: ±3% or ±0.05L (Take the larger one)	PEF: ±20L/min or ±10% of the reading; FEV1: ±0.05L or ±3% of the reading.	PEF: ±10% or ±24L/min whichever is greater FEV1: ±5% or ±0.100L whichever is greater	PEF: ±6% FEV1: ±3.5% (@25°1013mbar 50%HR)	Similar Note 4
Measuring resolution	PEF: 1L/min FEV1: 0.01L	PEF: 1L/min FEV1: 0.01L	/	PEF: 5L/min FEV1: 0/05L	Same
Memory	100 historical data	250 recordings	480 tests	240 FEV1and 240 PEF	Different Note 5
Data safety	Data rememorized by flash memory.	Data rememorized by flash memory.	/	/	Same
Data transmission	Bluetooth wireless transmission	BLE wireless transmission	/	/	Same
Working conditions	Temperature: 10℃～+40℃, Humidity: 0％RH～80％RH, Atmospheric pressure:	Temperature: 10℃～+40℃, Humidity: 25 ％RH～85％RH, Atmospheric pressure:	Temperature: 15℃～35℃	Temperature: 15℃～35℃	Similar

	70KPa ～ 106KPa	86KPa ～ 106KPa			
Storage conditions	Temperature: -20℃ ～ +55℃, Humidity: 0％ RH～80％RH, Atmospheric pressure: 70KPa ～ 106KPa	Temperature: -10℃～+55℃, Humidity: 15 ％ RH～93％RH, Atmospheric pressure: 50KPa ～ 106KPa	/	Temperature: -10℃～+50℃, Humidity: 15 to 95%	Similar
Biocompatibility	Passed the tests as per ISO 10993-1	Passed the tests as per ISO 10993-1	/	/	Same
Electrical safety	Passed the tests as per IEC 60601-1 and IEC 60601-1-11	Passed the test as per IEC 60601-1	/	/	Similar
EMC	Passed the test as per IEC 60601-1-2	Passed the test as per IEC 60601-1-2	/	/	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same

- Note 1:

The targeted device uses lithium battery for power supply which is different from the predicate device, but the lithium battery has been tested according to IEC 62133, so this difference should not raise any problems. And the reference devices also use lithium battery for power.

- Note 2:

Although the appearance, weight and dimensions are different between the targeted and predicate device, these differences are insignificant and do not raise any problems.

- Note 3:

The targeted device adopts pressure sensor to transform air flow into electrical signal, while the predicate device adopts turbine sensor to transform air flow into pulse signal. Although the measuring method is different, the difference will not raise any problems, as both devices were demonstrated to have electromagnetic compatibility, electrical safety and measurement accuracy by testing. And the reference devices also adopt pressure sensor/transducer, so this measuring method is similar.

- Note 4:

The accuracy of the targeted device's PEF is similar to that of the predicate device.

- Note 5:

The difference in memory does not raise any problems.

Conclusion:

Based on the above analysis, the Smart Peak Flow Meter (Model: B1) is substantially equivalent to

the predicate device.

(8) Non-clinical studies and tests performed

Non-clinical testings have been conducted to verify that the Smart Peak Flow Meter (Model: B1) 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
- Wireless testing was conducted on the Smart Peak Flow Meter (Model: B1). The device complies with FDA's guidance: Guidance Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff.

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 in the comparison testing, so it is concluded that the targeted device is substantially equivalent to the predicate device.
- Human Factor Engineering Study

A HFE study was designed to address the use-related risks, usability concerns and clearness of the Instructions for Use (IFU) and Graphic User Interface (GUI) of Smart Peak Flow Meter application and device, while operated by intended users. All study participants (20 out of 20 -100%) completed the critical tasks with ease and confidence.

The study results of this human factor engineering study demonstrate that the Smart Peak Flow Meter device and application are as safe and as effective as its predicate device.

(10) Conclusion

Based on the above analysis and tests performed, it can be concluded that the performance and function of Smart Peak Flow Meter (Model: B1) are Substantially Equivalent to the predicate device.