February 21, 2024

Guangzhou Homesun Medical Technology Co., Ltd
℅ Tracy Che
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K231561
Trade/Device Name: Pulmonary Function Tester, Model: A9
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: BTY
Dated: January 17, 2024
Received: January 17, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of 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)*
K231561

Device Name
Pulmonary Function Tester, Model: A9

Indications for Use *(Describe)*
The Pulmonary Function Tester (Model: A9) is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent flow-volume measurements. Measurements shall be performed under the direction of a physician in the clinic, doctors' office or hospital. The Pulmonary Function Tester (Model: A9) is intended for use in patients from 4 years of age and older who can understand and perform instructions of the physician.

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, Tianxiang Business Building, No.28, Li Fu Road, Haizhu District, Guangzhou, GD. China
Contact person:	Suijie Huang
Phone number:	+86 13826204942
Email:	hsj@huxijia.com
Date of summary prepared:	February 20, 2024

(2) Proprietary name of the device

Trade name/Model:	Pulmonary Function Tester, model: A9
Regulation name:	Predictive Pulmonary Function Value Calculator
Regulation number:	21 CFR 868.1890
Product code	BTY
Review panel:	Anesthesiology
Regulation class:	Class II

(3) Predicate device

Sponsor	VIASYS HEALTHCARE GMBH
Device Name and Model	MASTERSCREEN PNEUMO & MASTERSCOPE
510(k) Number	K071753
Product Code	BTY
Regulation Number	21 CFR 868.1890
Regulation Class	II

(4) Description/ Design of device

The Pulmonary Function Tester (Model: A9) is a hand-held pulmonary function testing device which can be used by patients older than 4 years old under the direction of a physician in the clinic, doctors' office or hospital. The Pulmonary Function Tester (Model: A9) is comprised of the main unit (display screen, sensor and communication module), USB cable, application software (computer software, mobile software), and a power supply. The device use is very simple, it adopts mouth blowing method. The device uses a flow sensor to measure the air flow and volume of the

patient's exhaled or inhaled air. According to the volume-time curve and the flow-volume curve, the pulmonary ventilation indicators of human respiratory physiology, such as slow vital capacity, maximum minute ventilation and forced vital capacity, are estimated and reported on the LCD screen and computer/mobile software. The pulmonary Function Tester is powered by lithium battery (DC 3.7V, 1500mAh) or tablet/computer USB port, or the equipped power supply.

(5) Indications for Use

The Pulmonary Function Tester (Model: A9) is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent flow-volume measurements. Measurements shall be performed under the direction of a physician in the clinic, doctors' office or hospital. The pulmonary Function Tester (Model: A9) is intended for use in patients from 4 years of age and older who can understand and perform instructions of the physician.

(6) Technological characteristics and substantial equivalence

Item	Subject device	Predicate device	Remark
Trade name	Pulmonary Function Tester (Model A9)	MASTERSCREEN PNEUMO & MASTERSCOPE	
510 (k) number	K231561	K071753	
Regulation number	21 CFR 868.1890	21 CFR 868.1890	Same
Regulation description	Predictive Pulmonary Function Value Calculator	Predictive Pulmonary Function Value Calculator	Same
Product code	BTY	BTY	Same
Class	II	II	Same
Indications for use/ Intended use	The Pulmonary Function Tester (Model: A9) is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent flow-volume measurements. Measurements shall be performed under the direction of a physician in the clinic, doctors' office or hospital. The Pulmonary Function Tester (Model: A9) is intended for use in patients from 4 years of age and older	The Master Screen Pneumo & Masterscope is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent flow volume measurements. Mostly it will be used for COPD and Asthma patients. Measurements will be performed under the direction of a physician in the clinic, doctors office or hospital. It can be utilized for patients from 4 years of age and older	Similar

Item		Subject device	Predicate device	Remark
		who can understand and perform instructions of the physician.	as long as they can cooperate in the performance. The Master Screen Pneumo is powered from 100 - 240 V / 50 - 60 Hz wall outlets. No energy is transferred to the patient.	
Patient population		The device can be utilized for patients from 4 years of age and older as long as they can cooperate in the performance.	The device can be utilized for patients from 4 years of age and older as long as they can cooperate in the performance.	Same
Environment of use		Clinic, doctors' office or hospital	Clinic, doctors' office or hospital	Same
Prescription or OTC		Prescription	Prescription	Same
Basic unit specification				
Power supply		Internal battery: 3.7V, 1500mAh DC input: 5V, 1.2A Power supply: input：100-240V~,50-60Hz,0.3A；output：5V⎓1.2A	100 - 240 V / 50 - 60 Hz	Different
Dimensions		213*78*28mm	292 * 198 * 64 mm	Different
Components		Mainly composed of main unit, USB cable application software, and power supply.	Mainly composed of Handle with pneumotach and shutter, power unit and notebook (software).	Similar
Performance specification				
Technology for measure flow and volume		Differential pressure sensor	Differential pressure	Same
Flow (PEF)	Type	High Quality Pneumotach	High Quality Pneumotach	Same
	Range	0 – 16 L/s	± 20 L/s	Same
	Accuracy	<±5%	0.1 to 14 L/s: ± 5% or ± 0.2 L/s (whichever is greater)	Similar, conforms to ISO 23747
	Linearity	≤5%	Not known	Different but conforms to ISO 23747
	Frequency response	±0.25L/s or ± 12% (whichever is greater)	Not known	Different but conforms to ISO 23747
	Resolution	0.01 L/s	0.01 L/s	Same
	Resistance	< 0.15 kPa/(L/s) (not including filter)	<0.05kPa/L/s (<0.5cm H2O/ L/s) at 10 L/s	Different but conforms to ISO 23747

Item		Subject device	Predicate device	Remark
Volume (FEV1, FEV6 and FVC)	Type	Volume calculation through integration, from flow measurements	Volume calculation through integration, from flow measurements	Same
	Range	0 -10 L	±20 L	Different but conforms to ISO 26782
	Accuracy	< ±2.5%	0.5 to 8 L: ±3% or ±0.05 L (whichever is greater)	Similar, conforms to ATS 2019 and ISO 26782
	Linearity	< 2.5%	Not known	Different but conforms to ATS 2019 and ISO 26782
	Repeatability	<2.5%	Not known	Different but conforms to ATS 2019 and ISO 26782
	Resolution	1 mL	1 mL	Same
Operating mode		Spot checking	Spot checking	Same
Data transmission		Bluetooth/ USB	USB	Similar
Coaching		Display of volume-time and flow-volume curves	Display of volume-time and flow-volume curves	Same
Measurement parameters		FVC: VC、$FEV_{0.5}$、FEV_1、FEV_3、FEV_6、V backextrapol. ex、FIVC(FVC IN)、FIV_1、PEF、$FEF_{25\%}$、$FEF_{50\%}$、$FEF_{75\%}$、$FEF_{25\%-75\%}$（MMEF）、PIF、$FIF_{50\%}$、$FET_{100\%}$ 、FEV_1/FVC、FEV_3/FVC、FEV_1/VC max、V backextrapol.ex% FVC 、$FEF_{50\%}$/$FIF_{50\%}$、FEV_1/FIV_1 SVC: VC max、VC in、VC ex、IC、IRV、VT、ERV、MV、BF MVV: VT MVV、MVV、TIME MVV、BF MVV	FVC: VC、 FEV1、 FEV1、FEV3 、 FEV6 、 PEF 、FEF25%、FEF50%、FEF75%、FEF25%-75% （ MMEF ） 、PIF、 FEV1/FVC、 FEV1/VC max、 SVC: VC max、 VC in、 VC ex、 IC、IRV、VT、ERV、MV、 BF MVV :VT MVV、MVV、TIME MVV、BF MVV Rocc：ROCC、Palv、GOCC	Similar
Working conditions		Temperature: +10 - +34℃, Humidity: 15 -95% RH, Atmospheric pressure: 700 - 1060 hPa	Temperature: +10℃ - +34℃ (+50° F to 93.2° F), Humidity: 15 - 95% RH, non-condensing, Atmospheric pressure: 700 –	Same

Item	Subject device	Predicate device	Remark
		1060 hPa (525 to 795mmHg)	
Storage conditions	Temperature: -20 - +50 ℃, Humidity: 15 - 95% RH, Atmospheric pressure: 600 - 1200 hPa	Temperature: -20 - +50 ℃ (-4° F to 122° F), Humidity: 15 - 95% RH, non-condensing, Atmospheric pressure: 600 – 1200 hPa (450 to 900mmHg)	Same

(7) Non-clinical studies and tests

Non-clinical tests were conducted to verify that the Pulmonary Function Tester (Model: A9) meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results also demonstrate that the 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
- FDA's Guidance Document: Guidance Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff - 2013.
- The FDA "Guidance for Pre-Market Submissions and for Software Contained in Medical Devices- Guidance for Industry and Food and Drug Administration Staff issued 2023". The software documentation for this device was considered as Basic Documentation Level.
- The FDA "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions- Guidance for Industry and Food and Drug Administration Staff 2023.
- Standardization of Spirometry 2019 Update; An Official American Thoracic Society and European Respiratory Society: Technical Statement
- ISO 26782, Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans; 2009.
- ISO 23747, Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans; 2015.

Biocompatibility

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Pulmonary Function Tester main unit	ABS	Surface-contacting device: Intact skin	< 24hours

Flow sensor head	ABS, 304 stainless steel	Externally communicating tissue/bone/dentin	< 24hours

The body-contacting components of this device 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
- ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

Particulate and volatile organic compounds emission have been tested. The testing results demonstrate that the targeted device complies with the following standards:

- ISO 18562-1, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
- ISO 18562-2, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 18562-4, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate.

(8) Conclusion

Based on the above analyses and tests, it can be concluded that the Pulmonary Function Tester (Model: A9) is substantially equivalent to MASTERSCREEN PNEUMO & MASTERSCOPE and the noted differences do not raise different questions of safety and effectiveness.