June 10, 2021

MeHow Innovative Ltd
% Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd
8-9th Floor, R&D Building, No.26 Qinglan Street,
Panyu District
Guangzhou, Guangdong 510006
China

Re: K201493
Trade/Device Name: Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: June 3, 2021
Received: June 7, 2021

Dear Olivia Meng:

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)*
K201493

Device Name
Spirometer

Indications for Use *(Describe)*
The spirometer (LA104, LA105) is a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (5 to 21 years) and adult (22 years and older) patients in hospitals, physician's offices, laboratories, and occupational health environments.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

MeHow Innovative Ltd

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Date Prepared:	06/2/2021

II. DEVICE

Name of Device:	Spirometer
Common or Usual Name:	Diagnostic Spirometer
Classification Names:	Spirometer, Diagnostic (21 CFR 868.1840)
Regulation Class:	II
Product Code:	BZG

III. PREDICATE DEVICE

Predicate device	CardioTech Spirometry System, Model GT-105: K090646

IV. DEVICE DESCRIPTION

The spirometer is used to detect the ventilatory conditions of patients using a flow sensor. Basic test items include: Forced Vital Capacity (FVC), Slow Vital Capacity (SVC), Maximum Ventilator Volume (MVV), and Minute ventilation (MV). The device also provides bronchial diastolic and bronchial provocation tests comparison before and after medication along with time-volume and time-flow curves of the above tests.

The device comes in two models: LA104 and LA105. There are no differences between the two models apart from a minor software function. LA104 includes software incentive animations to encourage children to follow breathing instructions. The spirometer (model: LA104, LA105) consists of the main body, handle, power adapter and a single-use flow sensor. In order to conduct simple spirometry testing, the spirometer is used with a commercially available single-use disposable filter with integrated mouthpiece. This device is compatible with 30mm diameter filters.

The fundamental technology to measure flow is differential pressure. While the patient breathes, the air flows through both ends of the flow probe and produces different pressures. Then the sensor detects the pressure gap between both ends and converts it to electrical signals. The electrical signals are converted into digital signals of the pressure gap. Then digital signals are input into the computer system, which outputs values of pulmonary function related parameters after digital signal processing and data analysis.

V. INDICATION FOR USE

The spirometer (LA104, LA105) is a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (5 to 21 years) and adult (22 years and older) patients in hospitals, physician's offices, laboratories, and occupational health environments.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The spirometer (LA104, LA105) is substantially equivalent to the cleared predicate device (K090646). The spirometer (LA104, LA105) has same indications for use,

patient population and technological characteristics with the predicate.

Differential pressure is the principle of spirometry testing for both the subject and predicate devices, in particular the same sensor technology is used for spirometry testing. Both the proposed device and predicated device comply with the ATS (American Thoracic Society) standards for measuring FVC, SVC, MVV, and MV (accuracy and repeatability).

Specification	Proposed Device	Predicate Device	Comparison
Device name	Spirometer (Model: LA 104, LA 105)	CardioTech Spirometry System, Model GT-105	
K number	K201493	K090646	
Indications for Use	The spirometer (LA104, LA105) is a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (5 to 21 years) and adult (22 years and older) patients in hospitals, physician's offices, laboratories, and occupational health environments.	The CardioTech Spirometry System, Model GT-105 is a diagnostic tool to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult patients in hospitals, physician's offices, laboratories, and occupational health environments.	Same
Product code	BZG	BZG	Same
Classification regulation	21 CFR 868.1840	21 CFR 868.1840	Same
Patient population	Pediatric (5 to 21 years) and adult (22 years and older) patients	Pediatric (4 to 17 years) and adult patients	Same
Environment of use	hospitals, physician's offices, laboratories, and occupational health environments	hospitals, physician's offices, laboratories, and occupational health environments	Same
Prescription use or not	Prescription use	Prescription use	Same
Technology for measure flow and volume	Differential pressure	Differential pressure	Same
Device type	Portable	Portable	Same
Flow range	±16 L/s	±14 L/s	Similar
Flow accuracy	Comply with ATS/ERS 2005: ATS/ERS Task Force	Comply with ATS/ERS 2005: ATS/ERS Task Force	Same

Flow resistance	<0.15 kPa/l/s	<0.15 kPa/l/s	Same
Volume range	0-16 L	0 -10 L	Similar
Volume accuracy	± 3% or ±50 ml, whichever is greater	± 3% or ±50 ml, whichever is greater	Same
Data Storage capacity	≥ 3000 patients data	More than 300 patient's data (HD)	Same
Communication	USB	USB and RS-232C	Same
Coaching	Display of volume-time and flow-volume curves	Display of volume-time and flow-volume curves	Same
Measurement parameters	SVC, FVC, MVV, MV + BD + Challenge	SVC, FVC, MVV, MV	Similar
Power source	Power adapter, battery	Power adapter, battery	Same
Display	8.4 inch touch screen (resolution 800x600)	8 inch TFT color LCD (640x480dots)	Similar
Printer	104 mm width, thermo-sensitive printer	112mm width, Thermal dot printer	Similar
Patient contact	Indirect contact with tissue less than 24h	Indirect contact with tissue less than 24h	Same
Biocompatibility contact duration	Less than 24 hours	Less than 24 hours	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance testing

The Spirometer meets the spirometry recommendations for accuracy and precision published by the American Thoracic Society (ATS). Testing demonstrated equivalence to the predicate device with regards to performance of forced vital capacity (FVC), slow vital capacity (SVC), maximum ventilator volume (MVV) and minute ventilation (MV) spirometry tests. Spirometer performance was tested according to:

- ATS/ERS 2005: ATS/ERS Task Force: Standardization of Lung Function Testing
- ISO 26782:2009: Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans

Biocompatibility testing

The device is an external communicating, non-sterile, with single use patient contacting

components (Flow sensor/Flow sensor head). The biocompatibility evaluation for the Spirometer was conducted in accordance with the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", June 16, 2016, 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 biocompatibility of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Also, the gas pathway testing has been conducted in accordance with ISO 18562-2 and ISO 18562-3.

- Particulate Matter
- Volatile Organic Compounds

Additionally, condensate testing was performed to show that no condensate is formed in the single-use flow sensor and mouthpiece. The flow sensor is considered to be tissue indirect contacting type for duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Spirometer. The device complies with the ANSI AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) for safety and the IEC 60601-1-2:2014 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “moderate” level of concern, since a failure of latent design flaw could directly result in minor injury to the patient or operator.

Clinical Testing

Based on the similarities of the device specifications, intended use, indications for use between the Spirometer and its predicate devices, no clinical studies were needed to support this 510(k) Premarket Notification.

VIII. CONCLUSION

The Spirometer and its application comply with standards as detailed the premarket notification. The non-clinical tests conducted on the device determined the Spirometer to be substantially equivalent to its predicate in terms of safety, effectiveness and performance.