November 20, 2024

Gostar Co., Ltd
Pei-Fen Yang
President
2F, No.65, Wuquan 7th Rd.
Wugu District
New Taipei City, 248020
Taiwan

Re: K241843
Trade/Device Name: TD-7301 Spirometer (TD-7301)
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: October 15, 2024
Received: October 15, 2024

Dear Pei-Fen Yang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241843

Device Name
TD-7301 Spirometer (TD-7301)

Indications for Use *(Describe)*
TD-7301 Spirometer is intended to monitor Peak Expiratory Flow (PEF), Forced Expiratory Volume (FEV) in home and professional healthcare environments.
The device is designed for use with children over 5 years old, adolescent and adult subjects.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with the requirements of 21 CFR 807.92, this summary is being provided to serve as basis for the substantial equivalence determination.

1) Submitter information

Manufacturer	GOSTAR Co., Ltd
Address	2F., No. 65, Wuquan 7th Rd., Wugu Dist., 248020 New Taipei City, TAIWAN
Date Prepared	November 19, 2024
Correspondent	GOSTAR Co., Ltd
Correspondent Contact	Pei-Fen Yang, Ph.D.
Title	President
Phone	+886-2-2298-1927
E-mail	ra.cert@gostarmed.com

2) Proposed Device Information

Proprietary name	TD-7301 Spirometer
Common name	Diagnostic spirometer
Product code	BZG
Classification panel	Anesthesiology
Classification	2
Regulation Number	21 CFR 868.1840

3) Predicate Device Information

K number	K073155
Proprietary Name	VITALOGRAPH MODEL 4000 (ASMA-1 AND COPD-6)
Regulation Description	Diagnostic spirometer
Review Panel	Anesthesiology
Device Class	2
Product Code	BZG
Regulation Number	868.1840

4) Reference Device Information

K number	K222810

Proprietary Name	TD-7301 Peak Flow Meter
Regulation Description	Meter, Peak Flow, Spirometry
Review Panel	Anesthesiology
Device Class	2
Product Code	BZH
Regulation Number	868.1860

5) Indications for use

TD-7301 Spirometer is intended to monitor Peak Expiratory Flow (PEF), Forced Expiratory Volume (FEV) in home and professional healthcare environments.

The device is designed for use with children over 5 years old, adolescent and adult subjects.

6) Device Description

The TD-7301 Spirometer is a portable and handheld electronic spirometer used to measure expired Peak Expiratory Flow (PEF), Forced Expiratory Volume in one second (FEV1), Forced Expiratory Volume in six second (FEV6) and their ratio (FEV1/FEV6).

The users can transfer their measurement results from the TD-7301 Spirometer to iFORA smart on their mobile devices via Bluetooth. The iFORA smart provide an overview of users record with historical data and trend graph.

The TD-7301 Spirometer hardware is identical to the TD-7301 Peak Flow Meter cleared under K222810 (reference device).

7) Principle of Operation

The TD-7301 Spirometer is equipped with a removable mouthpiece and turbine connected to the peak flow meter. As patient puts the mouthpiece in the mouth and vigorously blows the gas through it, the turbine flow meter utilizes a unidirectional rotating vane with flow sensor 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 and calculates the flow volume integration on time. Taking the volume in the first second is the forced expiratory volume of 1 second (FEV1). The results will then display on the LCD screen of the device. For each of these two parameters, the result is a number shown on the screen of the TD-7301 Spirometer or on the smartphone screen. PEF and FEV1 are also associated with a four-zone monitoring system that, according to the result, may be green, yellow, orange, or red. Combined with forced expiratory volume of 6 second (FEV6) values, five stages of COPD classification are indicated on the right sidebar of the spirometer, from normal to stage IV, with stage IV being the most severe.

8) Comparison of Technological Characteristics

The similarities and differences between the predicate and subject device are summarized in Table 1 below:

Table 1: Similarities between the Predicate and Subject Device

Device name	**VITALOGRAPH MODEL 4000 (ASMA-1 AND COPD-6)**	**TD-7301 Spirometer**	**Comparison**
510(k) number	K073155 (Predicate)	K241843	-
Indications for Use	The Vitalograph Model 4000 is a battery powered, handheld electronic spirometer used to measure Peak Flow (PEF) and forced expired volume (FEV).	TD-7301 Spirometer is intended to monitor Peak Expiratory Flow (PEF), Forced Expiratory Volume (FEV) in home environment. The device is designed for use with children over 5 years old, adolescent and adult subjects.	Similar
Type of Use	Prescription Use	Prescription Use	Same
Classification	BZG	BZG	Same
Size	113x63x48 mm	155x50x34 mm	Different
Weight	Incl batteries 83g net, packaged 125g	100g	Different
Memories	1000 memory sets	800 memory sets	Different
Technology	Rotor stator design	Rotor stator design	Same
Method of communication	Bluetooth Low Energy and or USB	Bluetooth Low Energy	Same
Measured Values	PEF , FEV1, FEV6, FEV1/FEV6	PEF , FEV1, FEV6, FEV1/FEV6	Same
Power source	2x Alkaline AAA Batteries	2x Alkaline AAA Batteries	Same
Flow and Volume Accuracy	FEV1 Accuracy: ± 3% FEV6 Accuracy: ± 3% PEF Accuracy: ± 5%	FEV1 Accuracy: ± 2.5% or ± 0.05 L FEV6 Accuracy: ± 2.5% or ± 0.05 L Repeatability: ±2.5% or 0.05 L Linearity: ±2.5% Impedance: within 0.15 kPa/(L/s).	Comply with the latest standards

		PEF Accuracy: ± 5% or ± 10 L/min, Repeatability: ±5% or ± 10 L/min Linearity: ±5 % Resistance to flow: under 0.36 kPa/l/s (0.006 kPa/l/min). Frequency response: 15 l/min (0,25 l/s), or 12 %,	
Maximum peak flow	14 L/s	16 L/s	Different
Maximum FEV1	9.99L	10L	Same
Wireless transmission	Bluetooth and/or USB	Bluetooth	Same
Test Feedback	Real time feedback and graphical representation of flow	Real time feedback and graphical representation of flow	Same
Display	LCD Display	LCD Display	Same

Sterility	Non-sterile	Non-sterile	Same
Working condition	Temperature: 17 ºC ~ 37 ºC Humidity: 30% ~ 75%	Temperature: 5 ºC ~ 40 ºC Humidity: 15% ~ 93%	Similar
Storage condition	Temperature: 0 ºC ~ 50 ºC Humidity: 10% ~ 95%	Temperature: -25 ºC ~ 70 ºC Humidity: 10% ~ 95%	Similar
Traffic light indicator	4 color zones Green: ≥80% Yellow: 50-79% Orange: 30-49% Red: ≤29%	4 color zones Green: ≥80% Yellow: 50-79% Orange: 30-49% Red: ≤29%	Same
COPD classification indicator	5 zones N: FEV1/FEV6> 0.7 I: FEV1/FEV6< 0.70 andFEV1 ≥ 80%Pred. II: FEV1/FEV6< 0.70 andFEV1 < 80%Pred. III: FEV1/FEV6< 0.70 andFEV1 < 50%Pred. IV: FEV1/FEV6< 0.70 andFEV1 < 30%Pred.	5 zones N: FEV1/FEV6> 0.7 I: FEV1/FEV6< 0.70 andFEV1 ≥ 80%Pred. II: FEV1/FEV6< 0.70 andFEV1 < 80%Pred. III: FEV1/FEV6< 0.70 andFEV1 < 50%Pred. IV: FEV1/FEV6< 0.70 andFEV1 < 30%Pred.	Same

9) Substantial Equivalent Discussion

Summary of the technological characteristics

- The following technological differences exist between the subject and predicate devices
  1. The predicate device dimensions are 63 (W) x 113(L) x 48 (H) mm while TD-7301 Spirometer dimensions are 50 (W) x 155 (L) x 34 (H) mm.
  2. The predicate device weight is 83g Incl batteries while the weight of TD-7301 Spirometer is 100 g.
  3. The predicate device store up to 1000 measurements while TD-7301 Spirometer can store more than 800 memory sets.
  4. Different in Flow and Volume Accuracy and Maximum peak flow and Maximum FEV1 rate.
  5. The TD-7301 Spirometer has different storage condition and operating condition than the predicate.

- Difference 1,2: 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.

- Difference 3: Electrical safety and electromagnetic compatibility are evaluated to make sure difference in memory does not raise new questions of safety and effectiveness.

- Difference 4: Comply with the American Thoracic Society (ATS) Document "Standardization of Spirometry -2019". The performances of PEF, FEV1 and FEV6 are evaluated and met ISO 23747 and ISO 26782 standards.

- Difference 5: Shelf life test has been performed to ensure device does not raise safety and effectiveness issues under storage condition. Accuracy test has been performed at extreme limits of the operating conditions to ensure no safety and effectiveness issues are raised.

Applicable standards

- ATS: 2019 ATS ERS Spirometry Standards (2019)

- ISO 23747:2015 Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

- ISO 26782:2009 Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans

Non-clinical studies and tests performed

- Non-clinical tests have been conducted to verify that the TD-7301 Spirometer meets all design specifications which supports the conclusion that it's substantially equivalent to the predicate device.

- Performance evaluation – A performance evaluation of the TD-7301 Spirometer was conducted to

demonstrate the performances of FEV1, FEV6 and PEF parameters complied with the American Thoracic Society (ATS) Document "Standardization of Spirometry -2019", ISO 26782 and ISO 23747 and are substantially equivalent to the predicate device.

Testing under ISO 26782 included assessments for accuracy, repeatability, linearity, and expiratory impedance for measurements of volume.

Testing under ISO 23747, included assessments for the system's error of measurement, repeatability, resistance to flow, frequency response and linearity for measurements of flow

- Shelf-Life – Device shelf life was demonstrated by subjecting test units to extreme conditions to simulate device usage through its shelf life of 3 years. Attributes related to device functionality, accuracy, and repeatability were evaluated before and after exposure to extreme conditions and all attributes met acceptance criteria.
- Electrical Safety - The basic safety and essential performance of the TD-7301 Spirometer System are leveraged from the reference device, which was previously tested and demonstrated compliance with ANSI/AAMI 60601-1:2005//(R)2012 &A1:2012, IEC 60601-1-6:2010, and IEC 60601-1-11:2015.
- Electromagnetic Compatibility – Electromagnetic compatibility (EMC) testing for the TD-7301 Spirometer System was leveraged from the reference device, which was previously demonstrated to comply with IEC 60601-1-2:2014 and Federal Communication Commission (FCC) Regulations Part 15B.
- Biocompatibility – The patient contacting materials are identical to the reference device. Biocompatibility testing was leveraged from the reference device to support substantial equivalence.
- Software Verification and Validation – Software verification and validation testing was conducted in accordance with established specifications and IEC 62304. 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 "basic" documentation level. Results of executed protocols met the acceptance criteria and therefore support that the System's embedded software is acceptable for its intended use.
- Cybersecurity – A cybersecurity risk management documentation for the System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the System accordance with FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions." For each identified threat and vulnerability risk event scenario, risk assessment of impact to confidentiality integrity, and availability was performed and documented within the cybersecurity risk management documentation. Appropriate risk mitigation controls have been implemented and tested.
- Reprocessing Evaluation – The reprocessing evaluation for the TD-7301 Spirometer System was leveraged from the reference device, which was previously demonstrated to meet the cleaning and disinfection efficacy requirements in accordance with AAMI ST98, TIR12, and TIR30. As there were no changes to the hardware or reprocessing materials, additional reprocessing testing was not required.

Conclusion

Based on the above analysis and tests performed, **the TD-7301 Spirometer is substantially equivalent to the predicate device**.