February 23, 2024

Taian Dalu Medical Instrument Co., Ltd.
% Liz Li
Counselor
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K230423
Trade/Device Name: Electronic Peak Flow Meter
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter For Spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: January 11, 2024
Received: January 19, 2024

Dear Liz Li:

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)*
K230423

Device Name
Electronic Peak Flow Meter

Indications for Use *(Describe)*
This device is intended for monitoring PEF (Peak Expiratory Flow) for patient home use. The device is designed for children 5 years of age or older, 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

1. Contact Details

1.1 Applicant information

Applicant Name	Taian Dalu Medical Instrument Co., Ltd.
Address	West Part of Yitianmen Street, Hi-tech Zone, Taian 271000, Shandong, P.R. China
Phone No.	+86-538-8931961-8006
Contact person	Wang Yuqin
Contact person's e-mail	mobilepef@163.com
Date Prepared	Feb.15. 2023

1.2 Submission Correspondent

Correspondent Name	Shenzhen Joyantech Consulting Co., Ltd.
Address	1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86 755-86069197
Contact person	Liz Li
Contact person's e-mail	liz@cefda.com; grace@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Electronic Peak Flow Meter
Device Class	Ⅱ
Classification name	Peak-flow meter for spirometry
Product code	BZH
Regulation No.	21 CFR 868.1860

3. Legally Marketed Predicate Device

Trade Name	MSA100BT Peak Flow Meter
510(k) Number	K170281
Product Code	BZH
Manufacturer	Beijing M&B Electronic Instruments Co., Ltd.

4. Device Description

The device is made up of two elements – the Electronic Peak Flow Meter and a Mobile Medical Application for smartphones that communicate via Bluetooth. The device is a portable device that can measure the Peak Expiratory Flow (PEF).
The Electronic Peak Flow Meter consists of the main unit, turbine, and blowing mouthpiece.
Electronic Peak Flow Meter software is embedded in the main control unit, which is used to control the whole system of operation. After compiling, the program is solidified into the hardware. The combination of software and hardware realizes the functions for electronic peak flow meter.
When Electronic Peak Flow Meter connected to APP of communication devices (such as a mobile) through Bluetooth. The changes of the patient's PEF data within one week can be monitored by APP, so that it is more convenient to monitor the respiratory health status.

5. Intended use

This device is intended for monitoring PEF (Peak Expiratory Flow) for patient home use. The device is designed for children 5 years of age or older, adolescent and adult subjects.

6. Substantial Equivalence Comparison

Item	Proposed Device	Predicate Device: (K170281)	Comments
Device name and model	Electronic Peak Flow Meter (DL-DF01)	MSA100BT Peak Flow Meter	
Regulation number	21 CFR 868.1860	21 CFR 868.1860	Same
Classification	II	II	Same
Product code	BZH	BZH	Same
Intended use/Indications for use	This device is intended for monitoring PEF (Peak Expiratory Flow) for patient home use. The device is designed for children 5 years of age or older, adolescent and adult subjects.	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.	Similar
Patient Population	The device is designed for children greater than five years of age, adolescent and adult subjects.	The device is designed for pediatric to adult patients	Similar
OTC or Rx	OTC	OTC	Same
Materials	Polypropylene (mouthpiece)	Polypropylene (mouthpiece)	Same

Measuring range	PEF from 50 to 900 L/min	PEF from 50 to 900 L/min FEV1 from 0.01 to 9.99 L	Same
Measuring method	Flow: Turbine sensor	Flow: Turbine sensor Volume: Flow Integration	Same
Accuracy	±10 L/min or ±10%, whichever is greater	PEF ± 20 L/min or PEF ± 10% of the reading; FEV1 ± 0.05 L or FEV1 ± 3% of the reading	Similar
Repeatability	＜5% or 10 L/min, whichever is greater	not known	Similar
Measuring resolution	PEF 1 L/min	PEF 1 L/min; FEV1 0.01 L	Same
Data transmission	BLE wireless transmission	BLE wireless transmission	Same
Memory volume	500 recordings	250 recordings	Different
Power source	AAA 1.5×2 alkaline batteries	AAA 1.5×2 alkaline batteries	Similar
Performance testing	Standardisation of spirometry (2005 Revision)	Standardisation of spirometry (2005 Revision)	Same
Electrical Safety and EMC	IEC 60601-1 and IEC 60601-1-2	IEC 60601-1 and IEC 60601-1-2	Same
Shelf-Life/Use-Life	3 years	not known	Similar

7. Summary of Non-clinical Performance Testing

1) Electrical Safety, Electromagnetic Compatibility

The subject device has passed safety testing in according to following standards.

- IEC 60601-1:2005, AMDI:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 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

- IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests

2) Performance testing

Performance testing was conducted on the Electronic Peak Flow Meter for the measurement of peak expiratory flow (PEF). Technical parameters of accuracy and repeatability were evaluated in the performance testing, according to ATS/ERS Task Force: Standardisation of lung function testing - Standardisation of spirometry 2005. Measurements of PEF meet the requirements in the standard.

Operational/Environmental Testing IEC TR 60721-4-7:2001 Standardisation of spirometry (2005 Revision)

Transport testing: ISTA-3A:2018 Standardisation of spirometry (2005 Revision)

3) Biocompatibility test

Biocompatibility testing was conducted in accordance with the 2020 FDA guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Device Part 1: Evaluation and Testing."

The subject device has passed biocompatibility testing in according to following standards.

- ISO 10993-5:2019 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

4) Shelf/Use Life and Reprocessing

Shelf/Use life and reprocessing methods were validated in accordance with the following Standards:

- ASTM F1980-21 Standardisation of spirometry (2005 Revision)
- AAMI TIR 12:2020 Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- ISO 17664-1:2021 Processing of Health Care products- Information to be provided by the medical device manufacturer for the processing of medical devices

5) Software Verification and Validation

The subject device contains an embedded software system and an APP software. Software verification and validation testing were conducted 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 "moderate" level of concern.

6) Cybersecurity Management

The device was evaluated for cybersecurity according to the following guidelines and standards

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- IEEE/ANSI C63.27:2017

7) Human Factors

The device was evaluated for human factors and usability engineering.

8. Conclusion

The subject device, Electronic Peak Flow Meter (model DL-DF01), manufactured by Taian Dalu Medical Instrument Co., Ltd. is substantially equivalent to the predicate device (MSA100BT Peak Flow Meter) manufactured by Beijing M&B Electronic Instruments Co., Ltd. (K170281). This conclusion is based upon comparison on intended use, technological characteristics, and performance testing.