September 25, 2020

TF Health Co.
% Roberta (Bobbi) Druyor-Sanchez
Regulatory Consultant
NDA Partners
1761 W. University Dr., Suite 140
Tempe, Arizona 85281

Re: K200076
Trade/Device Name: Breezing Med
Regulation Number: 21 CFR 868.1730
Regulation Name: Oxygen Uptake Computer
Regulatory Class: Class II
Product Code: BZL
Dated: August 28, 2020
Received: September 3, 2020

Dear Roberta (Bobbi) Druyor-Sanchez:

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,

Todd Courtney
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200076

Device Name
Breezing Med™ Metabolism Analyzer

Indications for Use *(Describe)*

Breezing Med™ Metabolism Analyzer measures metabolic functions including resting energy expenditure and respiratory quotient during resting conditions via direct measurement of oxygen uptake and carbon dioxide production to provide nutritional assessment, to optimize nutritional supplements, and to quantify substrate utilization. The nutritional assessment enables the healthcare professional to further assess energy expenditure and caloric intake for weight management, and to aid in the diagnosis of diseases related to abnormal metabolic parameters. Breezing Med is intended for use with adults breathing normally on their own in a sitting position in a healthcare environment. Since the device is designed for the patient to breathe ambient air, it is not intended for patients where supplementary oxygen is being provided. Breezing Med is not intended to use as sole means for any diagnosis, and ultimately will provide data for evaluation by the professional.

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
(21 CFR 807.92(C))

1. Applicant

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Primary Contact
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2. Device

- Trade Name: Breezing Med™ Metabolism Analyzer
- Common Name: Indirect calorimeter
- Classification Name: Computer, Oxygen Update (21 CFR 868.1730, product code BZL)

3. Predicate Device: Express Series (K070858)

4. Device Description

Breezing Med™ Metabolism Analyzer is a resting metabolic rate measurement system with an application installed on mobile devices that provides measurements of exhalation rate, oxygen uptake and carbon dioxide production. It is used to determine resting metabolic rates, teach energy balance, and pinpoint accurate caloric intake for weight management.

5. Intended Use

Breezing Med™ Metabolism Analyzer is intended for professional use, to determine resting metabolic rates, teach energy balance, and pinpoint accurate caloric intake for weight management.

6. Indications for Use

Breezing Med™ Metabolism Analyzer measures metabolic functions including resting energy expenditure and respiratory quotient during resting conditions via direct measurement of oxygen uptake and carbon dioxide production to provide nutritional assessment, to optimize nutritional supplements, and to quantify substrate utilization. The nutritional assessment enables the healthcare professional to further assess energy expenditure and caloric intake for weight

management, and to aid in the diagnosis of diseases related to abnormal metabolic parameters. Breezing Med™ is intended for use with adults breathing normally on their own in a sitting position in a healthcare environment. Since the device is designed for the patient to breathe ambient air, it is not intended for patients where supplementary oxygen is being provided. Breezing Med™ is not intended to use as sole means for any diagnosis, and ultimately will provide data for evaluation by the professional.

7. Technological Characteristics

Breezing Med™ is a stand-alone and fully integrated mask-like wearable metabolic analyzer based on the principle of indirect calorimetry, which is a gold standard for energy expenditure measurement. Breezing Med™ is designed for metabolic rate and respiratory quotient measurement and the main outputs include Resting Energy Expenditure (REE), Respiratory Quotient (RQ), Volume of Oxygen consumption (VO2), and Volume of Carbon Dioxide production (VCO2), where REE and RQ are calculated from measured parameters VO2 and VCO2.

Breezing Med™ measures the expiratory volume similar to the predicate device Medical Graphics Express® Series.

Breezing Med™ consists of five components: 1) a device body; 2) a mask; 3) headgear; 4) a sensor cartridge; and 5) an application.

8. Performance Data

A verification test of the Breezing Med™ to performance specifications derived from the predicate Medical Graphics Express series was conducted. The result of the test demonstrates substantial equivalence of the proposed to the predicate.

The summary of the Breezing Med™ test results are as follows:

- Both devices measured O2 volumes within the specified accuracy of +/-0.8%.
- Both devices measured CO2 volumes within the specified accuracy of +/-0.8%.
- Both devices measured Flow Rate within +/- 0.3 Lpm < 10 Lpm and +/-3% >= 10 Lpm.

We have also performed testing to ISO10993, IEC 60601-1 General requirements for basic safety and essential performance and IEC 60601-1-2 Electromagnetic disturbances.

9. Predicate Device Comparison

The Breezing Med™ Metabolism Analyzer is substantially equivalent to the Express Series (K070858). Both Breezing Med™ Metabolism Analyzer and its predicate device have a similar intended use. A summary comparison of technological characteristics is provided in **Table 5.1**.

Table 5.1 – Breezing Med™ Metabolism Analyzer and Predicate Comparative Analysis

Feature	Subject Device	Predicate Device
Device Name	Breezing Med™	Express® Series (indirect calorimeter)
Device Manufacturer	TF Health Co.	MGC Diagnostics Corporation
510(k) Reference	This submission	K070858
FDA Product Code	BZL	BZL
FDA Classification	Computer, Oxygen Uptake	Computer, Oxygen Uptake
FDA Regulation Number	868.1730	868.1730
Device Description	Breezing Med™ is a resting metabolic rate measurement system with an application installed on mobile devices that provides measurements of exhalation rate, oxygen uptake and carbon dioxide production.	The Express® Series is a cardiopulmonary exercise or resting metabolic rate measurement system with an integrated touch screen computer that provides breath by breath measurements of flow, oxygen uptake and carbon dioxide production.
Indications for use	Breezing Med™ Metabolism Analyzer measures metabolic functions including resting energy expenditure and respiratory quotient during resting conditions via direct measurement of oxygen uptake and carbon dioxide production to provide nutritional assessment, to optimize nutritional supplements, and to quantify substrate utilization. The nutritional assessment enables the healthcare professional to further assess energy expenditure and caloric intake for weight management, and to aid in the diagnosis of diseases related to abnormal metabolic parameters. Breezing Med™ is intended for use with adults breathing normally on their own in a	The Express® Series uses the direct measurement of oxygen uptake to objectively and noninvasively assess cardiac and pulmonary function during exercise. The system can be used to screen for early signs of cardiac and pulmonary dysfunction; differentiate heart and lung disease; assess dyspnea complaints; classify patients according to disease as a guide for patient management; establish an optimal exercise prescription and training program; evaluate the efficiency of prescribed therapy. The Express® Series uses the direct measurement of oxygen uptake and carbon dioxide production to provide nutritional assessment, to optimize nutritional supplements and quantify substrate utilization. The Express® Series can also provide direct Fick determination

Feature	Subject Device	Predicate Device
	sitting position in a healthcare environment. Since the device is designed for the patient to breathe ambient air, it is not intended for patients where supplementary oxygen is being provided. Breezing Med™ is not intended to use as sole means for any diagnosis, and ultimately will provide data for evaluation by the professional.	of cardiac output using real time oxygen uptake measurements.
Target population	Adults	Unspecified
Use Environment	Professional healthcare facilities	Professional healthcare facilities
Device Measurements	Metabolic functions during resting conditions	Non-invasive assessment of the cardiopulmonary response to exercise or measurement of energy expenditure using indirect calorimetry.
Measurement Mode(s)	Mixing chamber	Breath by breath
Output Parameters	Main outputs include resting energy expenditure (REE), respiratory quotient (RQ), oxygen consumption (VO_2), carbon dioxide production (VCO_2), and respiratory parameters.	Main outputs include resting energy expenditure (REE), respiratory quotient (RQ), oxygen consumption (VO_2), carbon dioxide production (VCO_2), and respiratory parameters.
Major Separate System Components	Device body, disposable mask, headgear, sensor cartridge, app in a mobile device	Express® Series indirect calorimeter, face tent/face mask, printer, mobile cart
Flowmeter Technology	Fixed-orifice differential pressure pneumotach	Bi-directional Pitot Tube Flow Sensor
O_2 Sensor Technology	Colorimetry	Galvanic
CO_2 Sensor Technology	Colorimetry	Non-dispersive infrared (NDIR)
User Interface	App on Mobile device	Touchscreen display
Software	Application	Intuitive icon-based software
Sterility	Non-sterile	Non-sterile

Feature	Subject Device	Predicate Device
Biocompatibility	All user contact components are biocompatible and used in already legally marketed devices with the same intended use	All patient contact components are biocompatible and used in already legally marketed devices with the same intended use
Mechanical Safety	No mechanical safety risk identified.	No mechanical safety risk identified.
Chemical Safety	No chemical safety risks identified.	No chemical safety risks identified.
Anatomical Sites	Patient's mouth and nose, through face mask	Patient's mouth and nose, through face tent/face mask
Human factors	Requires patient to keep mask sealed.	Requires patient to keep face tent/face mask sealed.
Energy used	External or internal power supply	External power supply
Energy delivered	No energy delivered to the patient.	No energy delivered to the patient.
Battery	Lithium-Ion, rechargeable	NA
Compatibility with environment	No known issues.	No known issues.
Compatibility with other devices	No known devices for compatibility issues.	No known devices for compatibility issues.
Standards Electrical safety	IEC 60601-1: class II / Internal Electric Power Source - type BF	Unspecified
Standards: EMC Testing	EN60601-1-2	Unspecified
Thermal Safety	No known thermal safety issues	No known thermal safety issues
Radiation Safety	No known radiation safety issues.	No known radiation safety issues.
Sensor cartridge	One-time use sensor cartridge for simultaneously O_2 and CO_2 sensing	O_2 and CO_2 sensors are for long time use (e.g. 1 year), and change during maintenance periods
Dimensions	80 x 110 x 160 mm	240 x 190 x 267 mm*
Weight	170 gm	9.2 lbs.*
Measurement Range	Flow: 0-150 l/min O_2: 10-21% CO_2: 0-10%	Flow: 0-40 l/min* O_2: 5-85%* CO_2: 0-10%*

Feature	Subject Device	Predicate Device
Measurement Accuracy Error/Resolution	Flow Accuracy: <3% or 10 ml/min O_2 Accuracy: <1% O_2 Resolution: ±0.1% CO_2 Accuracy: <1% CO_2 Resolution: ±0.1%	Flow Accuracy: <3% or 10 ml/min* O_2 Accuracy: <1%* O_2 Resolution: ±0.1%* CO_2 Accuracy: N/A CO_2 Resolution: ±0.1%*

*Note: Data from CCM Express Indirect Calorimeter's specification sheet provided on the product web page:
https://mgcdiagnostics.com/images/uploads/CCMexpress_sellsheet_060065rF_web.pdf

10. Substantial Equivalence Conclusion

Breezing Med™ Metabolism Analyzer is substantially equivalent to the predicate Express Series in terms of intended use and technical characteristics. Breezing Med™ Metabolism Analyzer successfully underwent bench testing, which includes safety testing (IEC 60601-1), EMC (IEC 60601-1-2), and biocompatibility (ISO 10993-1) compliance. A study was performed to simulate clinical use showing that the device works according to its intended use, in addition to its indications for use. There were no new issues of safety and effectiveness, and performance data. Verification and validation results demonstrate that the Breezing Med™ Metabolism Analyzer is safe and effective. Based on the information provided in this 510(k), TF Health concludes that the Breezing Med™ Metabolism Analyzer is substantially equivalent to the predicate device identified in this submission and is safe and effective.