October 3, 2019

eResearchTechnology
Mingzi Deng
Senior Regulatory Affairs Specialist
500 Rutherford Avenue
Boston, Massachusetts 02129

Re: K183479
Trade/Device Name: Asthma Monitor AM3 G+
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: August 29, 2019
Received: September 3, 2019

Dear Mingzi Deng:

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,

Michael Ryan
Division 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)*
K183479

Device Name
Asthma Monitor AM3 G+

Indications for Use *(Describe)*

The Asthma Monitor AM3 G+ is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever there is a need of. The AM3 measures the flow during expiration serving for the calculation of further parameters as FEV1.

The AM3 is used to monitor the respiratory status of human beings (adults and children 5 years and older) in the areas of asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.

The patient is informed of the results by numeric values for the selected parameters (e.g. PEF, FEV1). Furthermore, a visual control unit, displayed in the form of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician.

The device saves the results of a measurement (always with date and time) automatically in an internal database. In addition, (symptom and medications) questionnaire functionality can be called up by the use of a software (AMOS) to record e.g. the "Quality of Life"status.

When enabled, the AM3 can be programmed with a couple of questions, where the patient can then select from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation using the software AMOS.

The AM3 is designed to replace an ordinary peak flow meter, diary and pencil by a single system. The asthma monitor AM3 is intended to be used in health care, clinical and home use 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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GENERAL INFORMATION

1 Type of Submission

Special 510(k) Submission

Date 510(k) summary prepared: 10/03/2019

2 Submitter

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3 Establishment Registration Number

3008505660

4 Common Name or Classification Name

Diagnostic Spirometer (21 CFR 868.1840, Product Code BZG)

5 Trade Name

Asthma Monitor AM3 G+

6 Device Regulatory Classification

This is a Class II device

7 Classification Panel and Product Code

73 Anesthesiology Part 868 Code BZG

8 Reason for Premarket Notification

Modification of an existing device regarding “The New 510(k) Paradigm”

- Additional data transfer capabilities via TCP/IP
- Change in operating system of device accessory software AMOS

9 Legally predicate marketed device

Asthma Monitor AM3 GSM
K133722 Code BZG

10 Predicate Device Company

eResearchTechnology GmbH

11 Device Description

The Asthma Monitor AM3 G+ is a medical device (peak flow meter with symptom diary) providing following design and performance characteristics:

- Handheld device
- Battery operation
- Storing capacity of 1200 measurements
- Storing capacity of 400 sets of questionnaires (max. 20 questions each)
- Measurement Parameters: PEF and FEV1
- Accuracy Flow: ± 5% or ± 20 l/min
- Accuracy Volume: ± 3% or ± 0.05 litre
- Wireless communication with computer/mobile device/database via Bluetooth and mobile communication (3G, TCP/IP) by using accessory software AMOS
- Rotary Flow Sensor (single patient use)

The Asthma Monitor AM3 G+ is an instrument that combines a peak flow meter with a symptom and medication diary. This device displays questions concerning symptoms and medication to be answered twice a day and measures and evaluates the Peak Flow

(PEF = Peak Expiratory Flow [l/min]) and FEV1 (Forced Expiratory Volume in 1 second [l]).

The AM3 G+ keeps a diary of patient measurements by automatically recording all answers and PEF measurements with the date and time in its memory. Data can be collected for approximately 100 days. Every time the patient visits the centre, the data will be downloaded by using AMOS software. Additionally the data can be exchanged to a predefined database using the 3G mobile communication module (SMS, TCP/IP).

Scheduled sessions, including questionnaire and PEF measurements, can be configured wirelessly using AMOS software, performed and stored with the AM3 G+. Following the study protocol, the patient has to carry out scheduled sessions twice a day.

In the morning and the evening session, there is a set of questions to be answered before a scheduled PEF measurement can be performed. As soon as the patient switches on the AM3 G+ for the first time during one of the time windows, the first question of the appropriate questionnaire will be displayed.

AMOS is a stand-alone software for the professional user (physician/clinical staff) for configuration, parameter processing and data display. It does not provide a diagnosis or treatment suggestions. Diagnosis and appropriate therapeutic treatments are only made by the physician. The AMOS software allows to set and adjust individual thresholds which are based on international and national standards such as ATS and ERS. They are based on the patient's individual best value which is determined by the doctor.

12 Indications for Use Statement

The Asthma Monitor AM3G+ is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever there is a need of. The AM3 measures the flow during expiration serving for the calculation of further parameters as FEV1.

The AM3 is used to monitor the respiratory status of human beings (adults and children 5 years and older) in the areas of asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.

The patient is informed of the results by numeric values for the selected parameters (e.g. PEF, FEV1). Furthermore, a visual control unit, displayed in the form of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient’s physician.

The device saves the results of a measurement (always with date and time) automatically in an internal database. In addition, (symptom and medications)

questionnaire functionality can be called up by the use of a software (AMOS) to record e.g. the “Quality of Life” status.

When enabled, the AM3 can be programmed with a couple of questions, where the patient can then select from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation using the software AMOS.

The AM3 is designed to replace an ordinary peak flow meter, diary and pencil by a single system. The asthma monitor AM3 is intended to be used in health care, clinical and home use environments.

13 Required Components

AM3 G+ peak flow meter measurement device
Rotary Flow Sensor
AMOS software
User Manual

14 Comparison of technological characteristics with the predicate device

Comparison with Asthma Monitor AM3 GSM (K133722)

	Asthma Monitor AM3GSM (K133722)	**Asthma Monitor AM3 G+**
Indications for Use	The Asthma Monitor AM3 is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever there is a need of. The AM3 measures the flow during expiration serving for the calculation of further parameters as FEV1. The AM3 is used to monitor the respiratory status of *adult* human beings in the areas of asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management. The patient is informed of the	The Asthma Monitor AM3G+ is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever there is a need of. The AM3 measures the flow during expiration serving for the calculation of further parameters as FEV1. The AM3 is used to monitor the respiratory status of human beings (adults and children 5 years and older) in the areas of asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.

	results by numeric values for the selected parameters (e.g. PEF, FEV1). Furthermore, a visual control unit, displayed in the form of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician. The device saves the results of a measurement (always with date and time) automatically in an internal database. In addition, *questionnaire* functionality can be called up by the use of a software *package* (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM3 can be programmed with a couple of questions, where the patient can then select from a couple of different answers. This information is also stored in the internal database and can be transmitted for *evaluation to a standard PC* using the software *package* AMOS. The AM3 is designed to replace an ordinary peak flow meter, diary and pencil by a single system. *Easy handling, sturdy and handy design allow the Asthma Monitor AM3 to be used in healthcare, clinical and home use environments/settings.*	The patient is informed of the results by numeric values for the selected parameters (e.g. PEF, FEV1). Furthermore, a visual control unit, displayed in the form of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician. The device saves the results of a measurement (always with date and time) automatically in an internal database. In addition, (symptom and medications) questionnaire functionality can be called up by the use of a software (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM3 can be programmed with a couple of questions, where the patient can then select from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation using the software AMOS. The AM3 is designed to replace an ordinary peak flow meter, diary and pencil by a single system. The asthma monitor AM3 is intended to be used in health care, clinical and home use environments.
Patient population	The Asthma Monitor can be used for patients from 4 years on and older.	The Asthma Monitor can be used for patients from 5 years on and older.
Measurement principle	Determination of respiratory flow and volume via exchangeable infrared rotary flow sensor	**Identical**
Dimensions (housing)	Length x Width x Height: 112*82*37 mm Weight: 150 g (batteries included)	**Identical**
Display	LCD module Size: 54.0 x 33.5 mm 255 x 160 dots	TFT LCD module Size: 57.6 x 43.2 mm 320 x 240 dots
	Foil Key-panel (4 keys):	**identical**

Key-panel	- ESC (on/off) - UP-ARROW - DOWN-ARROW - OK	
Integrated mouthpiece (material)	Styrolution PS 454N, single patient use	**identical**
Housing of the device (material)	Cycoloy HC 1204HF, ROTEC ABS 1001 FR	**identical**
Performance (measurements)	Parameters: PEF FEV1 Accuracy: PEF: ± 5% or ± 20 l/min FEV1: ± 3% or ± 0.05 liter	**identical**
Interface	Serial RS 232 & USB & Blue-tooth & GSM	USB & Bluetooth & 3G
Energy type	LI-ION Polymer battery 3.7 V, 1700 mAh	**identical**
Operating Require-ments	PC software AMOS For standard PC with Windows OS	AMOS App Mobile application for Android OS higher 6.x and Windows 10
Bluetooth interface	WML-C46 (Mitsumi)	BT121 (Silicon Lab)
Mobile communicati on Interface	Sierra Wireless WISMO288	Sierra Wireless AirPrime HL8548
Expected operational lifetime	5 years	**Identical**

Differences

The subject device, AM3 G+ is equipped with a bigger screen; and it offers further advanced options for data transfer and exchange (3G/TCPIP instead of 2G). The previously integrated GSM and BT obsolete modules are replaced with the newer 3G module and a new Bluetooth module. In addition, RS-232 interface has been removed. Data was stored, exported and exchanged wirelessly with previously PC based software AMOS (cleared in K133722). The AMOS App is now modified to run on different operating systems and platforms (Windows10 and Android OS).

15 Performance Data - Summary of Device Testing

Performance Testing

The following standards and practices were followed for development of the Asthma Monitor AM3 G+ and accessory software AMOS:

- The device was developed and tested according to GMP Standard Operating Procedures for Medical Devices.
- Software verification and validation was done in accordance with IEC 62304:2006 + A1:2015.
- Risk analysis was performed according to ISO 14971:2007.
- Tests were performed to confirm that the Asthma Monitor meets the recommendations for accuracy and precision for Spirometry of the American Thoracic Society (ATS) according to ATS/ERS 2005 standards.
- The electrical safety testing was performed according to IEC 60601-1:2012 and IEC 60601-1-11:2015 to demonstrate conformance with the requirements for basic safety and essential performance.
- The Electro Magnetic Compatibility testing was performed according to IEC 60601-1-2:2014.
- The FDA Guidance “Radio Frequency Wireless Technology in Medical Devices” issued on August 14, 2013 was considered for the 3G/BT functions and all requirements are fulfilled.
- BT and 3G functions of the Asthma Monitor AM3 G+ were tested according to the Federal Communications Commission’s rules and regulation in Title 47 of the Code of Federal Regulations to demonstrate conformity with defined frequency bands and frequencies for the different spectrum allocations.
- The FDA Guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” from 2014 has been considered in the device design and all requirements are fulfilled.

The verification and validation activities for hardware and software were performed and the results demonstrated that the predetermined acceptance criteria were met.

Biocompatibility

There have been no changes in material and biocompatibility. All material used is identical to the predicate device. The manufacturing process is identical to the predicate device.

The Rotary Flow Sensor is exactly the same as already used in the predicate device and among all Asthma Monitor devices.

No new biocompatibility testing was done, as the biocompatibility testing for the predicate device remains effective for this submission.

Clinical Testing

No clinical testing is required.

Compliance with FDA-recognized Standards:

Standard	Description
IEC 60601-1:2012	Electrical Safety of Medical Devices
IEC 60601-1-2:2014	Electromagnetic Compatibility of Medical Devices
IEC 60601-1-11:2015	Electrical Safety of Medical Devices in the home healthcare environment
ISO 14971:2007	Risk Management
ISO 10993-1:2009	Biological evaluation of Medical Devices
IEC 62304:2006 + A1:2015	Medical Device Software - Software life-cycle processes

16 Conclusion

The modified device, AM3 G+ shares the same intended use but has different technological characteristics. Based on the intended use and the results of the performance testing provided in the 510(k), the device is found to be substantially equivalent to the predicate device AM3 GSM (K133722).