BreatheSuite Inc
Brett Vokey
Founder & CEO
Suite 301 – 215 Water Street
St. John's Newfoundland, Canada
A1C 6C9

Re: K203155
Trade/Device Name: BreatheSuite MDI Device
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: August 15, 2021
Received: August 17, 2021

Dear Brett Vokey:

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,

Brandon L. Blakely, Ph.D.
Acting 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)*
K201355

Device Name
BreatheSuite MDI Device

Indications for Use *(Describe)*
The BreatheSuite MDI Device is an electronic device intended for single-patient use of patients 5 years of age and older. It assists patients in recording and monitoring the actuations and technique of prescribed metered dose inhaler (MDI) usage. The BreatheSuite System is composed of the disposable, battery powered, portable BreatheSuite MDI Device and a mobile application.
The BreatheSuite MDI Device is an accessory designed to work with an MDI by attaching to the top of the canister of the inhaler. The BreatheSuite MDI Device does not interfere with regular MDI usage and can be removed and reattached with ease. The BreatheSuite MDI Device does not actuate the inhaler but rather gathers information based on manual MDI usage.
The BreatheSuite MDI Device measures the parameters of MDI use and records them for review by the patient. The BreatheSuite application records, stores, and transmits usage events from the BreatheSuite MDI Device to a remote storage system. Furthermore, BreatheSuite MDI reminds the patient of important steps of MDI use through visual feedback in the BreatheSuite application.
The output of the BreatheSuite System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The BreatheSuite system is not intended for use as a MDI medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI. The BreatheSuite MDI Device is not intended to replace a physician's advice or inhaler labels; patients are expected to always follow their doctor's advice and inhaler labels.
The BreatheSuite System can be used both indoors and outdoors as well as in home and work settings.
The BreatheSuite System may also be used in clinical trials where researchers need to know information about use of a MDI Medication(s) by a participant.

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
## As required by 21 CFR 807.92(c)
## for
## BreatheSuite MDI Device

**1. Submission Sponsor**

BreatheSuite Inc.
Suite 301 – 215 Water Street
St. John's, Newfoundland, Canada
A1C 6C9
Phone: 709-765-1002
Contact: Brett Vokey, Founder and CEO

**2. Submission Correspondent**

Brett Vokey
Founder and CEO
Phone number: 709-765-1002

**3. Date Prepared**

September 14th, 2021

**4. Device Identification**

| | |
|---|---|
| Trade or Proprietary Name: | BreatheSuite MDI Device |
| Common or Usual Name: | BreatheSuite MDI Device; BreatheSuite Device |
| Classification Name: | Nebulizer |
| Classification Regulation: | 868.5630 |
| Product Code: | CAF |
| Device Class: | Class II |
| Classification Panel: | Anesthesiology |

**5. Legally Marketed Predicate Device**

Primary Predicate Device: Propeller System Model 2 (K142516)
Reference Predicate Device: CapMedic (K183586)

**6. Device Description**

The BreatheSuite MDI Device is a Metered Dose Inhaler (MDI) accessory that monitors inhaler usage and inhaler technique metrics.

The BreatheSuite MDI Device mounts on top of an MDI to measure when and how patients use their inhalers. The device uses internal sensors to record parameters of MDI use and technique including date and time of usage; MDI shaking duration; orientation; coordination between MDI actuation and the start of inhalation; and inhalation duration.

By pairing with the BreatheSuite app via Bluetooth Low Energy (BLE) communications, the user receives reports on each inhaler dosage and on their inhalation technique. The user may share their use and technique information with their physicians and/or healthcare providers.

## 7. Intended Use

The BreatheSuite MDI Device is an electronic device intended for single patient use of patients 5 years of age and older. It assists patients in recording and monitoring the actuations and technique of prescribed metered dose inhaler (MDI) usage. The BreatheSuite System is composed of the disposable, battery powered, portable BreatheSuite MDI Device and a mobile application.

The BreatheSuite MDI Device is an accessory designed to work with an MDI by attaching to the top of the canister of the inhaler. The BreatheSuite MDI Device does not interfere with regular MDI usage and can be removed and reattached with ease. The BreatheSuite MDI Device does not actuate the inhaler but rather gathers information based on manual MDI usage.

The BreatheSuite MDI Device measures the parameters of MDI use and records them for review by the patient. The BreatheSuite application records, stores, and transmits usage events from the BreatheSuite MDI Device to a remote storage system. Furthermore, BreatheSuite MDI reminds the patient of important steps of MDI use through visual feedback in the BreatheSuite application.

The output of the BreatheSuite System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The BreatheSuite system is not intended for use as an MDI medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI. The BreatheSuite MDI Device is not intended to replace a physician's advice or inhaler labels; patients are expected to always follow their doctor's advice and inhaler labels.

The BreatheSuite System can be used both indoors and outdoors as well as in home, work and clinical settings.

The BreatheSuite System may also be used in clinical trials where researchers need to know information about use of an MDI Medication(s) by a participant.

## 8. Comparison of Technological Characteristics

Technological characteristics of the BreatheSuite MDI Device are equivalent to the primary and reference predicate device listed above. They are both microprocessor-controlled electronic devices that fit onto the top of an MDI, using a combination of sensors to detect inhaler use which is logged to compile inhaler usage history.

The BreatheSuite MDI Device has equivalent technological characteristics to the predicate device in terms of:

- Attachment to the top of a compatible MDI canister.
- Microprocessor control and use of an internal clock to log date and time of inhaler usage events.
- Power supply being an internal non-rechargeable battery and shelf life.
- Wireless data transmission through Bluetooth Low Energy.
- No interference with inhaler operation, medication delivery, label obstruction or dose counter.
- Application that records, stores and transmits usage events from the device to a remote storage system.

The BreatheSuite MDI Device has differing technological characteristics from the predicate device in terms of:

- Additional sensors to capture inhaler usage technique parameters.
- Unique housing shape to accommodate additional internal sensors to measure inhaler technique characteristics.
- Unique device electronics updated to current technology and to accommodate additional sensors to measure inhaler technique.

These design changes were verified by non-clinical testing to establish equivalent performance to the predicate device.

## 9. Non-Clinical Performance Testing

Non-clinical testing and evaluation of the BreatheSuite MDI has been completed to demonstrate substantial equivalence including biocompatibility evaluation, electrical safety and electromagnetic compatibility testing, software verification and validation testing, performance testing, and usability evaluation.

**Biocompatibility Evaluation**
The biocompatibility evaluation for the BreatheSuite MDI Device 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” (16 Jun 2016), to meet requirements from the following standards: ISO 10993-1:2009 (biocompatibility), ISO 10993-5:2009 (cytotoxicity) and ISO 10993-10:2010 (sensitization and intracutaneous irritation).

**Electrical Safety and Electromagnetic Compatibility (EMC) Testing**
Electrical safety and EMC testing was conducted by external laboratories on the BreatheSuite MDI Device. The device complies with the following standards: IEC 60601-1:2012 (general safety), IEC 60601-1-11:2015 (home-use safety), IEC 60601-1-2:2014 Ed 4.0 and FCC Part 15 Subpart B & ICES-003:2019 (electromagnetic compatibility). Information was provided according to FDA guidance Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (11 Jul 2016).

**Software Verification and Validation Testing**
Software verification and validation testing was conducted to ensure correct functionality for the BreatheSuite MDI software release, for all software components. Documentation was provided as recommended by FDA guidance Content of Premarket Submissions for Software Contained in Medical Devices (11 May 2005), Off-The-Shelf Software Use in Medical Devices (27 Sep 2019), and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (2 Oct 2014).

**Performance Testing**
Performance testing was conducted to establish correct functionality and compatibility of the BreatheSuite MDI inhaler according to requirements, including:

- Delivered Dose Uniformity (DDU) and Aerosol Particle Size Distribution (APSD) testing to confirm that the addition of the BreatheSuite MDI Device does not have an effect on medication delivery for compatible MDIs.

- Battery performance (Shelf Life) testing to confirm substantial equivalence to the shelf life of the predicate.
- MDI Compatibility testing to confirm substantial equivalence to the predicate in terms of compatible MDIs.
- Dose counting testing to confirm the BreatheSuite MDI Device does not inhibit the dose counter on any compatible metered dose inhaler.
- Depression Force Testing to confirm the BreatheSuite MDI Device does not change the force required to actuate any compatible metered dose inhaler.
- Device Fit and Label Obscuration testing to confirm the BreatheSuite MDI Device does not permanently obscure the MDI label.
- Technique Measurement testing to confirm the BreatheSuite MDI Device obtains and records correct technique information including inhaler shaking, orientation, actuation timing and inhalation duration for all compatible MDIs according to requirements.

**Usability Testing**

Usability evaluation of the BreatheSuite MDI Device was carried out to evaluate use scenarios and critical tasks indicated by the usability risk analysis for the BreatheSuite MDI Device, and established validity of the results obtained from testing carried out in accordance with the FDA guidance Applying Human Factors and Usability Engineering to Medical Devices (3 Feb 2016).

## 10. Clinical Testing

No clinical testing was required for a determination of substantial equivalence of the BreatheSuite MDI Device. The product functionality has been adequately assessed by non-clinical testing as above.

## 11. Validation Testing for OTC:

Validation testing was completed to ensure that the device and it's provided OTC labelling provided all of the necessary information to support over the counter use.

## 12. Hazard Analysis for OTC:

Hazard Analysis for OTC was completed to specifically identify any issues that could arise related to how the patient obtains and learns about the system, registers for the system, installs the sensor, uses the BreatheSuite MDI device during MDI medication use, reviews their data and obtains help & support. No new concerns of safety with the proposed OTC indication were found.

## 13. Conclusion - Statement of Substantial Equivalence

Completed testing carried out for the BreatheSuite MDI Device indicates it meets design, safety, and performance requirements. Device fit, depression force, shelf life, MDI compatibility and DDU/APSD performance is equivalent to the predicate. Inhaler usage parameters are measured with sufficient accuracy for monitoring inhaler use, and the addition of the new sensors does not adversely affect use of the inhaler. Software verification demonstrates that the device should perform as intended in the specified use conditions, and equivalently to the predicate for common software functions. The device meets standard requirements for biocompatibility, electrical safety, and electromagnetic compatibility. The usability evaluation indicates there are no issues for successful use with the compatible inhaler.

This information indicates that the BreatheSuite MDI Device is substantially equivalent to the predicate device.