Adherium (NZ) Ltd
Tara M. Creaven-Capasso
Vice President Quality, Regulatory and Clinical Affairs
Level 2, 63 Albert Street,
Auckland 1010
New Zealand

Re: K220622
Trade/Device Name: Hailie® Sensor NF0106
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: February 28, 2022
Received: March 3, 2022

Dear Tara M. Creaven-Capasso:

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 Blakely
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)*
K220622

Device Name
Hailie® Sensor

Indications for Use *(Describe)*
The Hailie® sensor is intended for single patient, multiple use, in the home environment, as an electronic data capture accessory for monitoring and recording actuations, inspiratory flow, and inhaler orientation, for prescribed inhaler usage.

The Hailie® sensor may be used in the following applications: in clinical practice or clinical trials, where specialists, general practitioners, nurses, and educators need to know if a patient has used their prescribed medication or assess inspiratory flow and inhaler technique; and in patient self-management including medication reminders.

The Hailie® sensor is compatible only with the following ELLIPTA® DPI inhalers: Breo™, Anoro™, Incruse™, Trelegy™ and Arnuity™. The Hailie® sensor is not intended to indicate remaining quantity of medication in an inhaler and does not include a dose counting function. The Hailie® sensor is not intended to provide spirometry measurements.

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.

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14 July 2022

510(k) SUMMARY

I. Submitter

Company Details:	Adherium (NZ) Ltd Level 2, 63 Albert Street, Auckland 1010, New Zealand PO Box 106-612, Auckland 1143, New Zealand Phone +64 9 307 2771
Contact Person:	Tara M. Creaven-Capasso, FRAPS, RAC, RQAP-GLP, MTOPRA Vice President Quality, Regulatory and Clinical Affairs

II. Device

Device Name:	**Hailie® Sensor**
Model Number:	NF0106
Classification Name:	Nebulizer Anesthesiology Devices, 21 CFR 868.5630, Class II, CAF
Classification:	Class II (performance standards)

III. Predicate Device

The predicate device to which Adherium claims substantial equivalence is: K211233 Hailie® Sensor (Model Number NF0109), manufactured by Adherium (NZ) Limited. The reference devices which support a substantial equivalence determination are: 510(k) cleared medical device (K203155) **BreatheSuite®** MDI Device, manufactured by Breathesuite Inc.; and 510(k) cleared medical device (K161454) **Propeller® Sensor Model 2015-E**, manufactured by Reciprocal Labs Corporation.

IV. Device Description

The Hailie® Sensor (Hailie® sensor) NF0106 model, is a modification to the Hailie® sensor NF0109 model, and is used to provide medication reminder, actuation monitoring, orientation and airflow recording functions, for use as an accessory to the inhaler specified on the device label. The Hailie® sensor is indicated for use only with the following ELLIPTA® DPI inhalers: Breo™, Anoro™, Incruse™, Trelegy™ and Arnuity™.

The Hailie® sensor is a clip-on device that attaches externally around the housing of the inhaler. Optical sensors are used to detect the inhaler presence and monitor actuation. Motion and flow sensors are used to record inhaler usage technique parameters. The Hailie® sensor contains an electronic clock and calendar that are used to log the date and time of inhaler usage events.

The user interface consists of a single Status Button and a multi-color LED indicator to check device status, initiate communications functions, and provide reminder features. The Hailie® sensor has a Bluetooth interface to wirelessly exchange medication usage data and reminder setting data with a paired communications device and compatible mobile software applications.

V. Indications for Use

The Hailie® sensor is intended for single patient, multiple use, in the home environment, as an electronic data capture accessory for monitoring and recording actuations, inspiratory flow, and inhaler orientation, for prescribed inhaler usage.

The Hailie® sensor may be used in the following applications: in clinical practice or clinical trials, where specialists, general practitioners, nurses, and educators need to know if a patient has used their prescribed medication or assess inspiratory flow and inhaler technique; and in patient self-management including medication reminders.

The Hailie® sensor is compatible only with the following ELLIPTA® DPI inhalers: Breo™, Anoro™, Incruse™, Trelegy™ and Arnuity™. The Hailie® sensor is not intended to indicate remaining quantity of medication in an inhaler and does not include a dose counting function. The Hailie® sensor is not intended to provide spirometry measurements.

The Indications for Use statement differs from the predicate device, in that the shape of the sensor is modified to fit the medication, and inhaler orientation has been added. This provides a better fit to the medication and additional information on inhaler use technique, which does not affect the safety or effectiveness of the device. The changes are within the scope of the cleared Indications for Use for the reference device K211233.

VI. Comparison of Technological Characteristics with the Predicate Device

Technological characteristics of the Hailie® sensor are equivalent to the predicate and reference devices listed above. They are both microprocessor-controlled electronic devices that clip on to an inhaler, using a combination of sensors to detect inhaler use data which is logged to compile a usage history.

The Hailie® sensor has equivalent technological characteristics to the predicate device, including intended use, device functionality and operating principles:

- Monitors medication usage of the inserted medication inhaler.
- Can be configured to provide medication reminders.
- Distributed as Over the Counter (OTC) devices.
- Single-patient, multiple home use, with no dose counting function.
- Attach externally around the compatible inhaler with similar size and shape.
- Does not interfere with inhaler operation, medication delivery, label visibility, or dose counter.
- Communicate inhaler usage information via Bluetooth connection to a paired smartphone.
- Include optical sensor to detect when an inhaler has been inserted.
- Can store up to 5120 event logs in the device memory before overwriting oldest events.
- Detect moisture to avoid spurious actuation signals due to water ingress.
- Powered by a non-rechargeable lithium coin cell battery, with service life of 12 months.
- Materials in contact with the user are the same as the reference device.
- The Hailie® sensor records inhaler usage parameters, specifically inspiratory flow rate and duration, and incorrect expiratory flow through the inhaler. This data is only available to a physician for optional assessment of inhaler usage technique.
- The user interface is one user button and one multi-color LED.
- Encryption for stored event logs is applied to the firmware.

- The means of power saving during transport before first use is electronic using the control button to wake the device.

The Hailie® sensor is an updated version of the predicate device, with a substantially equivalent intended use and differing technological characteristics. It can be considered a modification to the previous design, with the following key differences:

- The housing shape of the Hailie® sensor has been modified to accommodate the medication shape and its actuation for the following ELLIPTA® DPI inhalers: Breo™, Anoro™, Incruse™, Trelegy™ and Arnuity™.
- Device electronics and PCB layout have been modified to accommodate the medication shape and additional optical sensors added.
- Actuation detection modified according to the new sensor design.
- Accelerometer sensor is used to detect inhaler orientation.

The Hailie® sensor is substantially equivalent to the reference devices where the inhaler orientation detection feature is equivalent to FDA cleared device K203155 **BreatheSuite®** MDI Device, and where the medication sensor feature is equivalent to FDA cleared device K161454 **Propeller® Sensor Model 2015-E** intended for use with ELLIPTA® DPI inhalers. These design changes were verified by non-clinical testing to establish equivalent performance to the predicate device. These changes do not raise any safety and/or effectiveness concerns.

VII. Performance Data

Non-clinical testing and evaluation of the Hailie® sensor has been carried out to cover electrical safety and electromagnetic compatibility testing, biocompatibility evaluation, software verification and validation testing, performance testing, and usability evaluation.

Biocompatibility Evaluation

The biocompatibility evaluation for the Hailie® sensor 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 10993-1:2018 (biocompatibility), ISO 10993-5:2009 (cytotoxicity), ISO 10993-10:2010 (sensitization and intracutaneous irritation), and ISO 10993-12:2012 (sample preparation for biocompatibility testing). The materials used in the Hailie® sensor were evaluated according to requirements for a surface device contacting intact skin for limited duration ≤ 24 hours.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing was conducted by external laboratories on the Hailie® sensor. The device complies with the following standards: ANSI/AAMI ES60601-1:2005 +A1:2012, C1:2009, A2:2020 (general safety), IEC 60601-1-11:2020 (home-use safety), and IEC 60601-1-2:2020 (electromagnetic compatibility). General safety testing was conducted according to applicable requirements for a home use, battery-powered device. EMC testing was conducted according to applicable requirements for an internally powered, non-patient coupled, Bluetooth radio device. Information was provided according to FDA guidance *Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices* (11 Jul 2016), and *Radio-Frequency Wireless Technology in Medical Devices* (14 Aug 2013).

Software Verification and Validation Testing

Software verification and validation testing were conducted to ensure correct functionality for the Hailie® sensor software release, for all software modules. 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 Hailie® sensor with the following ELLIPTA® DPI inhalers: Breo™, Anoro™, Incruse™, Trelegy™ and Arnuity™, according to requirements, covering:

- Optical inhaler presence detection - determined optical calibration limits and confirmed accurate detection of the installed ELLIPTA® DPI inhalers, with equivalent performance to the predicate.
- Airflow detection sensor - confirmed performance of flow detection during inhaler usage across potential inspiratory flow range, to record flow rate and duration related to inhaler actuation and detect inhalation appropriately for the purpose of monitoring use of a medication inhaler.
- Airflow verification testing - confirmed the effect of the Hailie® sensor on flow impedance in the airflow path is negligible with respect to required airflow through the inhaler.
- Motion detection sensor - confirmed performance of orientation detection to monitor inhaler orientation, according to requirements from the inhaler manufacturer, while not detecting normal handling of the inhaler.
- General performance testing - confirmed acceptable performance over the specified Battery-life, Shelf-life and specified Bluetooth communications range, with equivalent performance to the predicate.
- User interface testing - confirmed visibility of device display and audibility of device buzzer, with equivalent performance to the predicate.

Usability Evaluation

Usability evaluation for the Hailie® sensor was carried out to evaluate impact on critical tasks indicated by the usability risk analysis for the updated design, 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).

Clinical Testing

Clinical testing was not required for a determination of substantial equivalence of the Hailie® sensor. The product functionality has been adequately assessed by non-clinical testing as outlined above.

VIII. Conclusions

Finished device testing carried out for the Hailie® sensor indicates it meets design, safety, and performance requirements. Inhaler detection, communication, Battery-life, Shelf-life, and user interface performance are equivalent to the predicate device. Inhaler usage parameters are measured with sufficient accuracy for monitoring inhaler use equivalent to the reference devices, and the addition of the sensor does not adversely affect normal 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 ELLIPTA® DPI inhalers: Breo™, Anoro™, Incruse™, Trelegy™ and Arnuity™.

This information indicates that the Hailie® sensor is substantially equivalent to the predicate device.