August 18, 2021

Adherium (NZ) Ltd
Chris Mander
Head of Regulatory & Quality
Level 11, 16 Kingston Street
Auckland, 1010
New Zealand

Re: K211233
Trade/Device Name: Hailie Sensor NF0109
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: July 15, 2021
Received: July 19, 2021

Dear Chris Mander:

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, 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)*
K211233

Device Name

Hailie® Sensor

Indications for Use *(Describe)*

The Hailie® sensor is intended for single-patient use in the home environment as an electronic data capture accessory for monitoring and recording actuations, inspiratory flow, and inhaler shake, 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 Symbicort™ MDI inhaler. 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.

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."

Adherium (NZ) Limited
Level 11, 16 Kingston Street, Auckland 1010, New Zealand
PO Box 106-612, Auckland 1143, New Zealand
Phone +64 9 307 2771
contact@hailie.com
www.hailie.com

17 August 2021

510(k) SUMMARY

I. Submitter

Company Details:	Adherium (NZ) Ltd Level 11, 16 Kingston Street, Auckland 1010, New Zealand PO Box 106-612, Auckland 1143, New Zealand Phone +64 9 307 2771
Contact Person:	Chris Mander, Head of Regulatory & Quality

II. Device

Device Name:	**Hailie® Sensor**
Model Number:	NF0109
Classification Name:	Nebulizer Anesthesiology Devices, 21 CFR 868.5630, Class II, CAF

III. Predicate Device

The predicate device to which substantial equivalence claimed is: K173310 SmartTouch, manufactured by Adherium (NZ) Limited. The reference devices which support a substantial equivalence determination are: K183586 CapMedic, manufactured by Cognita Labs LLC; and K181405 Hailie® Sensor, manufactured by Adherium (NZ) Ltd.

IV. Device Description

The Hailie® sensor is a modification to the SmartTouch sensor, and is used to provide medication reminder, actuation monitoring, and shake 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 Symbicort™ MDI inhaler.

The Hailie® sensor is a clip-on device that attaches externally around the housing of the inhaler. Mechanical and 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 use in the home environment as an electronic data capture accessory for monitoring and recording actuations, inspiratory flow, and inhaler shake, 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 Symbicort™ MDI inhaler. 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 monitoring and recording and assessment of inhaler usage parameters for inspiratory flow and inhaler shake have been added. These features provide further information on inhaler use and technique and do 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 K183586.

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 which is logged to compile a usage history.

The Hailie® sensor has equivalent technological characteristics to the predicate device in terms of:

- Compatibility only with the Symbicort™ MDI inhaler to monitor medication usage.
- Clip-on attachment around the outside of an inhaler housing and secured by hinged door.
- Microprocessor control and use of an internal clock to log date and time of inhaler usage events.
- Provision of medication reminders.
- Sensor technology used to detect inhaler presence and actuation.
- No interference with inhaler operation, medication delivery, label visibility, or dose counter.
- Event storage capacity and memory management.
- Power supply from an internal non-rechargeable battery and shelf life / service life.
- Bluetooth communications technology for data upload.
- Interface to a communications device to upload inhaler usage data.
- Materials contacted by the user are the same as the Adherium reference device.
- Capability to provide inhaler usage data for further analysis using remote review software.

The Hailie® sensor has differing technological characteristics from the predicate device in terms of:

- Additional motion and flow sensor technology to detect inhaler usage technique parameters.
- Housing shape modified to relocate actuation detection sensor.
- User interface simplified to single button and LED indicator format.
- USB port and battery pull-tab removed to simplify device design.
- Device electronics, processor and PCB updated to current technology and to accommodate additional sensors.

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

VII. Performance Data

Non-clinical testing and evaluation of the Hailie® sensor has been carried out to cover 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 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 10993-1:2009 (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, A2:2010 (general safety), IEC 60601-1-11:2015 (home-use safety), and IEC 60601-1-2:2014 (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 Symbicort™ MDI inhaler according to requirements, covering:

- Optical inhaler presence detection - determined optical calibration limits and confirmed accurate detection of an installed inhaler, 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 shake detection to monitor inhaler shake duration before use, according to requirements from the inhaler manufacturer, while not detecting normal handling of the inhaler.
- General performance testing - confirmed acceptable performance over the specified 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 above.

VIII. Conclusions

Finished device testing carried out for the Hailie® sensor indicates it meets design, safety, and performance requirements. Inhaler detection, communications, shelf life, and user interface performance is equivalent to the predicate. Inhaler usage parameters are measured with sufficient accuracy for monitoring inhaler use, and the addition of the sensor 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 Hailie® sensor is substantially equivalent to the predicate device.