February 8, 2023

Adherium (NZ) Ltd
Tara Creaven-Capasso
Vice President Quality, Regulatory and Clinical Affairs
Level 11, 16 Kingston Street
Auckland, 1010
New Zealand

Re: K222247
Trade/Device Name: Hailie Sensor NF0110
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: February 3, 2023
Received: February 6, 2023

Dear Tara 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,

Ethan L. Nyberg -S

for James Lee, Ph.D.
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)*
K222247

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 actuation, 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.

The Hailie® sensor is compatible only with the Teva HFA MDIs like ProAir, Albuterol Sulphate inhalers. 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 2, 63 Albert Street, Auckland 1010, New Zealand
PO Box 106-612, Auckland 1143, New Zealand
Phone +64 9 307 2771
contact@hailie.com
www.hailie.com

15 Jul 2022

510(k) SUMMARY

I. General Information

510(k) Sponsor	Adherium (NZ) Ltd
Address	Level 2, 63 Albert Street, Auckland 1010, New Zealand PO Box 106-612, Auckland 1143, New Zealand Phone +64 9 307 2771
Correspondence Person	Tara Creaven-Capasso, FRAPS, RAC, RQAP-GLP, MTPORA
Title	Vice President Quality, Regulatory and Clinical Affairs
Contact Information	Regulatory@adherium.com
Date Prepared	15 July 2022

II. Subject Device

Proprietary Name	Hailie®
Common Name	Hailie® Sensor
Model Number	NF0110
Classification Name	Nebulizer Anesthesiology Devices,
Regulation Number	21 CFR 868.5630
Product Code	CAF
Regulatory Class	II

III. Predicate Device

Predicate device	Hailie® Sensor NF0109 (for use with Symbicort® MDI), manufactured by Adherium (NZ) Limited. Cleared under K211233
Reference device	Smartinhaler™ NF0091 for use with (ProAir®) also manufactured by Adherium (NZ) Ltd. Cleared under K180407

IV. Device Description

The subject device Hailie® Sensor (Hailie® sensor) NF0110 model, is a modification to the Hailie® sensor NF0109 model (the predicate device) and is used to provide medication actuation monitoring, 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 following TEVA MDIs: ProAir® HFA & Albuterol Sulphate HFA.

The Hailie sensor NF0110 is a clip-on device that attaches externally around the housing of the inhaler. The optical sensor and induction coil sensor 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 and initiate communications functions. The Hailie sensor has a Bluetooth interface to wirelessly exchange medication usage 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 actuation, 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 usage technique; and in patient self-management.

The Hailie sensor is compatible only with the following TEVA MDI inhalers: ProAir® HFA & Albuterol Sulphate HFA. 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.

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 subject device NF0110 has substantially equivalent technological characteristics to the predicate device Hailie Sensor model NF0109, including intended use, indication for use, materials, design, device functionality, features and operating principles. Nonclinical testing results support the substantial equivalence claim.

The subject device NF0110 is substantially equivalent to the reference device, Adherium's Smartinhaler model NF0091, cleared under K180407, manufactured by Adherium (NZ) Ltd. which uses same ProAir®, TEVA MDI medication.

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, A2:2020 (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 with the following TEVA MDI inhalers: ProAir® HFA and Albuterol Sulphate HFA:

- Optical inhaler presence detection - determined optical calibration limits and confirmed accurate detection of the installed TEVA MDI inhalers.
- Airflow detection sensor - confirmed performance of flow detection during inhaler usage.
- Airflow verification testing - confirmed the effect of the Hailie sensor on the airflow path.
- Motion detection sensor - confirmed performance of shake detection before inhaler use.
- General performance testing - confirmed acceptable performance over the specified shelf life and specified Bluetooth communications range.
- User interface testing - confirmed visibility of device LED display and audibility of device Piezo buzzer.

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. Performance verification demonstrates that device functions, Inhaler detection, communication, Shelf life, Battery life and user interface are substantially equivalent to the predicate device. Inhaler usage parameters are measured with sufficient accuracy for monitoring inhaler

use equivalent to reference device, and the change 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 inhaler TEVA ProAir® HFA and Albuterol Sulphate HFA.

This information indicates that the subject device Hailie Sensor model NF0110 is substantially equivalent to the predicate device Hailie Sensor model NF0109. Non-clinical testing results are acceptable and support the substantial equivalence claim.