June 19, 2019

Adherium (NZ) Ltd
Chris Mander
Head of Regulatory & Quality
Level 2, 204 Quay Street
Auckland, 1010 NZ

Re: K182638
Trade/Device Name: Hailie Sensor
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 16, 2019
Received: May 20, 2019

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,

James Lee
Assistant 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)*
K182638

Device Name
Hailie™ Sensor

Indications for Use *(Describe)*
The Hailie™ sensor is intended for single-patient use in the home environment as a medication reminder and electronic data capture accessory for recording usage of prescribed inhaler medication. This may be used in the following applications:
• In clinical trials, where researchers need to know when a patient has used their trial inhaler medication.
• In clinical practice, where specialists, general practitioners, nurses, and educators need to know if a patient has used their prescribed inhaler medication.
• In self-management, where patients need to track their medication use as part of their management plan.
The Hailie™ sensor is compatible only with the HandiHaler® inhaler and is for use by adults.

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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20 June 2019

510(k) SUMMARY

I. Submitter

Company Details:	Adherium (NZ) Ltd Level 2, 204 Quay 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:	NF0101
Classification Name:	Nebulizer (Direct Patient Interface) Anesthesiology Devices, 21 CFR 868.5630, Class II, CAF

III. Predicate Device

The predicate device to which substantial equivalence is claimed is: K180407, Smartinhaler™, manufactured by Adherium (NZ) Limited.

IV. Device Description

The Hailie™ sensor is used to provide a medication reminder and actuation recording function for use as an accessory to the inhaler specified on the device label. Under the current 510(k), the Hailie™ sensor is indicated for use only with the HandiHaler® inhaler.

The Hailie™ sensor is a clip-on device that attaches externally around the housing of the inhaler. Mechanical, optical and acoustic sensors are used to detect the presence and actuation of the inhaler. The Hailie™ sensor contains an electronic clock and calendar that are used to log the date and time of inhaler actuation.

The user interface consists of a single Status Button and dual multi-color LED indicators to check device status, initiate communications functions, and provide reminder features. The Hailie™ sensor has a Bluetooth interface to wirelessly exchange medication actuation 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 a medication reminder and electronic data capture accessory for recording usage of prescribed inhaler medication. This may be used in the following applications:

- In clinical trials, where researchers need to know when a patient has used their trial inhaler medication.
- In clinical practice, where specialists, general practitioners, nurses, and educators need to know if a patient has used their prescribed inhaler medication.
- In self-management, where patients need to track their medication use as part of their management plan.

The Hailie™ sensor is compatible only with the HandiHaler® inhaler and is for use by adults.

VI. Comparison of Technological Characteristics with the Predicate Device

Technological characteristics of the Hailie™ sensor are equivalent to the predicate device 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.

Device Feature	Proposed Device	Comparison to Predicate Device
Intended Use…		
Purpose and function:	Remind and monitor medication usage	Same
Type of use:	Over-the-counter use	Same
User population:	HandiHaler® users	Substantially equivalent. User population appropriate for intended inhaler.
Device usage:	Single-patient use	Same
Environment of use:	Home use	Same
Dose counting:	No dose counting function	Same
Features…		
Data collected:	Date and time for inhaler usage	Same
User notifications:	Audio/visual	Same
Medication reminders:	Configurable times	Same
Data transfer interface:	Automatic upload via Bluetooth	Same
User Interface…		
Controls:	Status button	Same
Display:	LED lights	Substantially equivalent. Proposed device LEDs located for better visibility.
Audio:	Buzzer	Same
Hardware…		
Size and weight:	Small and lightweight, suitable for use with inhaler	Substantially equivalent. Proposed device shape and attachment method modified to fit intended inhaler.
Configuration:	Attaches around outside of inhaler housing with clip-on fit	Same

Device Feature	Proposed Device	Comparison to Predicate Device
Sensor technology:	• Optical sensor for inhaler presence • Mechanical and acoustic sensors for inhaler usage	Same Substantially equivalent. Inhaler usage sensors appropriate to type of inhaler. Testing verifies functional performance.
Wireless technology:	Bluetooth	Same
Inhaler Interaction…		
Inhaler compatibility	Attaches to inhaler without affecting mechanism or operation	Same
Inhaler access:	Inhaler readily removed from device for cleaning and label access	Substantially equivalent. Usability testing verifies users understand instructions for review and removal of inhaler.
Electronics/Software		
Internal clock:	Yes	Same
Event record resolution:	1 second	Same
Event storage:	Non-volatile memory	Same
Limited event overwrite:	Yes	Same
Reject spurious events:	Yes	Same
Power source:	Rechargeable battery	Substantially equivalent. Proposed device only has rechargeable model.
Battery life:	2-3 months on full charge	Substantially equivalent. Proposed device only has rechargeable model. Both devices meet intended battery life.
Battery level indicator:	LED light color	Same
Power save before use:	Deep-sleep mode	Same
Materials…		
Device components:	Components tested to meet ISO 10993 cytotoxicity, sensitization, irritation	Substantially equivalent. Proposed device color matches intended inhaler. All materials and colorants are safe for intended use and pass biocompatibility testing.

The design changes described in the above table were verified by non-clinical testing to establish equivalent performance to the predicate device.

VII. Performance Data

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

Biocompatibility Testing

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: ANSI/AAMI/ISO 10993-1:2009 (biocompatibility), ANSI/AAMI/ISO 10993-5:2009 (cytotoxicity), ANSI/AAMI/ISO 10993-10:2010 (sensitization and intracutaneous irritation), and ANSI/AAMI/ISO 10993-12:2012 (sample preparation for biocompatibility testing). The

Hailie™ sensor was tested according to requirements for a surface device contacting intact skin for limited duration ≤ 24 hours.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted by external laboratories on the Hailie™ sensor. The device complies with the following standards and regulations: ANSI/AAMI ES60601-1:2005 +A1:2012, C1:2009, A2:2010 (general safety), IEC 60601-1-11:2015 (home-use safety), IEC 60601-1-2:2014 (electromagnetic compatibility), and ANSI C63.10:2013 / 47 CFR Part 15 (FCC regulations for radiofrequency (RF) devices). General safety testing was conducted according to applicable requirements for a home use, battery-powered device, that may be recharged via a USB connector. EMC testing was conducted according to applicable requirements for an internally powered, non-patient coupled, Bluetooth radio device that may be recharged from an AC adaptor. 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* (13 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 (real-time clock, user interface, power management, event recording, Bluetooth communications, USB power, non-volatile parameters, medication reminders, medication detection, and user functionality). 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* (9 Sep 1999), 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 HandiHaler® according to requirements, covering:

- Optical inhaler presence detection - determined optical calibration limits and confirmed accurate detection of an installed inhaler.
- Mechanical inhaler usage detection sensor - confirmed reliability of sensor over device lifetime.
- Acoustic inhaler usage detection sensor - confirmed accurate detection of inhaler usage and prevention of detection from other inputs.
- Spurious log prevention testing - determined circuit parameters and confirmed prevention of erroneous medication usage logs.
- General performance testing - confirmed acceptable performance over the specified shelf life and specified Bluetooth communications range.
- User interface testing - confirmed visibility of device display and audibility of device buzzer.

Usability Evaluation
Summative usability validation testing was carried out to evaluate critical tasks indicated by the usability risk analysis process. A description of the usability engineering process and the results obtained from the testing were provided 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 and performance functional requirements. Software verification demonstrates that device functions are substantially equivalent to the predicate device. The device meets standard requirements for biocompatibility,

electrical safety, electromagnetic compatibility, and wireless communications. The usability evaluation demonstrated that the Hailie™ sensor can be used successfully with the compatible inhaler.

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