June 7, 2019

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

Re: K182573
Trade/Device Name: Hailie Sensor
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 6, 2019
Received: May 7, 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 J. Lee Ph.D.
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)*
K182573

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 Advair® Diskus® and Flovent® Diskus® inhalers. The Hailie™ sensor is not intended to indicate remaining quantity of medication in an inhaler and does not include a dose counting function.

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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7 June 2019

510(k) SUMMARY

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

Device

Device Name:	**Hailie™ Sensor**
Model Number:	NF0100
Classification Name:	Nebulizer (Direct Patient Interface) Anesthesiology Devices, 21 CFR 868.5630, Class II, CAF

Predicate Device

The predicate device to which substantial equivalence is claimed is: K180407 Smartinhaler™, manufactured by Adherium (NZ) Limited. The reference devices which support a substantial equivalence determination are: K091803 SmartTrack™ System, manufactured by Nexus6 Ltd; and K152882 Propeller Sensor Model 2014-D, manufactured by Reciprocal Labs.

Device Description

The Hailie™ sensor is used to provide a medication reminder and usage recording function as an accessory to the inhalers specified on the device label. Under the current 510(k), the Hailie™ sensor is indicated for use only with the Advair® Diskus® (100/50, 250/50, 500/50 mcg) and Flovent® Diskus® (50, 100, 250 mcg) inhalers.

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

The user interface consists of a three control buttons and three LED indicators to check device status, initiate communications functions, and provide reminder features. The Hailie™ sensor has a Bluetooth interface to wirelessly exchange medication usage and reminder setting data with a paired communications device and compatible mobile software applications.

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 Advair® Diskus® and Flovent® Diskus® inhalers. The Hailie™ sensor is not intended to indicate remaining quantity of medication in an inhaler and does not include a dose counting function.

Comparison of Technological Characteristics with the Predicate Device

Technological characteristics of the Hailie™ sensor are equivalent to the predicate and reference devices listed above. Features that are the same between the devices include: attachment to the outside of an inhaler housing; microprocessor control and use of an internal clock to log the date and time of inhaler usage; power supply from an internal rechargeable battery; sensor technology used to detect inhaler usage; provision of reminder features; Bluetooth communications technology; interface to a communications device to upload inhaler usage data; and capability to provide inhaler usage data for further analysis using remote review software. Like the predicate device, the Hailie™ sensor is intended for OTC sale, for which a review of the product life cycle, labeling, and risk analysis was conducted to ensure the device meets requirements for OTC sale.

The Hailie™ sensor differs from the predicate devices in the housing shape and the method of medication usage detection, which were modified to fit the Diskus® and the user interface layout. Differences between the proposed and predicate device were verified by non-clinical testing to establish equivalent performance.

Performance Data

Non-clinical testing of the Hailie™ sensor has been carried out to cover functional verification, device performance, and usability of the user interface. This included completion of software and device verification procedures, with performance testing of the inhaler presence and usage sensor system to ensure data is logged accurately for inhaler usage. This established correct functionality and compatibility of the Hailie™ sensor with the Diskus® inhaler according to requirements.

Review and testing of the Hailie™ sensor for compliance to the following standards and regulations has been completed by external laboratories: 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); ANSI/AAMI/ISO 10993-1:2009 (biocompatibility), ANSI/AAMI/ISO 10993-5:2009 (cytotoxicity), ANSI/AAMI/ISO 10993-10:2010 (sensitization and intracutaneous irritation), ANSI/AAMI/ISO 10993-12:2012 (sample preparation for biocompatibility testing); and ANSI C63.10:2013 / 47 CFR Part 15 FCC regulations for radiofrequency (RF) devices.

Clinical testing was not required for a determination of substantial equivalence of the Hailie™ sensor. The product functionality has been adequately assessed by bench testing as above.

Conclusions

Finished device testing carried out for the Hailie™ sensor indicates it meets design and performance functional requirements. Software verification demonstrates that the device functions are substantially equivalent to the predicate device. The device meets standard requirements for wireless communications, electrical safety, electromagnetic compatibility, and environmental performance.

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