December 10, 2018

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

Re: K181405
Trade/Device Name: Hailie Sensor
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: October 31, 2018
Received: November 9, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181405

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 actuations of prescribed inhaler usage. This may be used in the following applications:

- In clinical trials, where researchers need to know when a patient has actuated their trial inhaler medication.
- In clinical practice, where specialists, general practitioners, nurses, and educators need to know if a patient has actuated 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 Bevespi Aerosphere® and is for use by adults. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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31 October 2018

510(k) SUMMARY

This summary of 510(k) information is submitted in accordance with requirements of 21 CFR 807.92:

(a)(1) Submitter Information

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

(a)(2) Name of the Device

Device Name:	**Hailie™ Sensor**
Model Number:	NF0096
Classification Name:	Nebulizer (Direct Patient Interface) Anesthesiology Devices, 21 CFR 868.5630, Class II, CAF

(a)(3) Identification of Legally Marketed Devices

The predicate device to which substantial equivalence is claimed is: K173310, SmartTouch™, manufactured by Adherium (NZ) Limited. The reference device which supports a substantial equivalence determination is: K133951, SmartTouch™, manufactured by Nexus6 Limited.

(a)(4) Description of the Device

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 Bevespi Aerosphere®.

The Hailie™ sensor is a clip-on device that attaches externally around the housing of the inhaler. Optical and mechanical 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 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 actuation and reminder setting data with a paired communications device and compatible mobile software applications.

(a)(5) Statement of the Intended 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 actuations of prescribed inhaler usage. This may be used in the following applications:

- In clinical trials, where researchers need to know when a patient has actuated their trial inhaler medication;
- In clinical practice, where specialists, general practitioners, nurses, and educators need to know if a patient has actuated 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 Bevespi Aerosphere® and is for use by adults. The Hailie™ sensor is not intended to indicate remaining quantity of medication in an inhaler and does not include a dose counting function.

(a)(6) Technological Characteristics Summary

Technological characteristics of the Hailie™ sensor are equivalent to the predicate and reference devices listed above. They are all electronic devices that clip on to an inhaler, using a combination of optical and mechanical 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:

- Clip-on attachment around the outside of an inhaler housing.
- Microprocessor control and use of an internal clock to log date and time of inhaler actuation.
- Provision of medication reminders.
- User interface controls design.
- Sensor technology used to detect inhaler presence.
- No interference with inhaler mechanism or operation.
- 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.
- Capability to provide inhaler usage data for further analysis using remote review software.

The Hailie™ sensor has equivalent technological characteristics to the reference device in terms of:

- Sensor technology used to detect inhaler actuation.

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

- User interface controls and indicators layout.
- Housing shape, which was modified to fit the Bevespi Aerosphere® inhaler.
- Use of a sensor to wake the device from transport mode.
- Some different materials and colorants are used.

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

(b)(1) Discussion of the Non-Clinical Tests

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).

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). 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. 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 Bevespi Aerosphere® according to requirements, covering:

- Optical inhaler presence detection - sensor performance testing.
- Pressure inhaler actuation detection - sensor performance testing.
- Bluetooth data transfer communications performance testing.
- General performance testing (shelf life, Bluetooth range).

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).

(b)(2) Discussion of the Clinical Tests

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.

(b)(3) Conclusions Drawn from Non-Clinical and Clinical Tests

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.