



July 25, 2018

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

Re: K180407

Trade/Device Name: Smartinhaler™
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: June 22, 2018
Received: June 25, 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

Indications for Use

510(k) Number (if known)
K180407

Device Name
Smartinhaler™

Indications for Use (Describe)

The Smartinhaler™ is intended for single-patient use in the home environment as a medication reminder and electronic data capture accessory for recording actuations of prescribed MDI usage. This may be used in the following applications:

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

The Smartinhaler™ is compatible only with the following MDIs: Ventolin® HFA, Advair® HFA, Flovent® HFA, ProAir® HFA, and QVAR® HFA. The intended MDI is specified on the product labeling. The Smartinhaler™ is not intended to indicate remaining quantity of medication in an MDI 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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20 July 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

Model Number / Name: **Smartinhaler™**
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: K133951, SmartTouch™, manufactured by Nexus6 Limited. The reference device which supports a substantial equivalence determination is: K173310, SmartTouch™, manufactured by Adherium (NZ) Limited.

(a)(4) Description of the Device

Smartinhaler™ is used to provide a medication reminder and actuation recording function for use as an accessory with a Metered Dose Inhaler (MDI) as part of normal daily use of the MDI.

Smartinhaler™ is a clip-on device that attaches externally around the housing of an MDI. The Smartinhaler™ comes in rechargeable and non-rechargeable models. Each Smartinhaler™ is compatible only with one of the following MDIs: Ventolin® HFA (90 mcg), Advair® HFA (45/21, 115/21, 230/21 mcg), Flovent® HFA (44, 110, 220 mcg), ProAir® HFA (90 mcg), QVAR® HFA (40, 80 mcg). The intended MDI is indicated on the device labeling. Optical and pressure sensors are used to detect MDI presence and actuation, and the device logs the usage history of the MDI. The Smartinhaler™ contains an electronic clock and calendar that is used to log the date and time of MDI actuation.

The Smartinhaler™ user interface consists of one LED indicator and one control button to check device status, initiate communications functions, and cancel medication reminders. The

Smartinhaler™ 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 Smartinhaler™ is intended for single-patient use in the home environment as a medication reminder and electronic data capture accessory for recording actuations of prescribed MDI usage. This may be used in the following applications:

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

The Smartinhaler™ is compatible only with the following MDIs: Ventolin® HFA, Advair® HFA, Flovent® HFA, ProAir® HFA, and QVAR® HFA. The intended MDI is specified on the product label. The Smartinhaler™ is not intended to indicate remaining quantity of medication in an MDI and does not include a dose counting function.

(a)(6) Technological Characteristics Summary

Technological characteristics of the Smartinhaler™ are equivalent to the predicate device listed above. Equivalent features between the devices include: configuration in attaching to the outside of an MDI housing; microprocessor control and use of an internal clock to log date and time of MDI actuation; power supply from an internal battery; sensor technology used to detect MDI actuation; user interface design; Bluetooth communications technology; interface to a communications device to upload MDI usage data; and capability to provide MDI usage data for further analysis using remote review software.

The Smartinhaler™ is intended for OTC use, which is a change from the predicate. A review of the product life cycle, labeling, and risk analysis was conducted to ensure the device meets requirements for OTC use and to confirm the difference does not affect substantial equivalence. Minor design changes include addition of medication reminders, spurious actuation log prevention improvements, enclosure modifications for MDI compatibility, and a non-rechargeable model, and 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 Smartinhaler™ 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 MDI presence and actuation sensor system to ensure data is logged accurately for usage with each of the compatible MDIs. This established correct functionality and compatibility of the Smartinhaler™ with the Ventolin® HFA, Advair® HFA, Flovent® HFA, ProAir® HFA, QVAR® HFA according to requirements.

Review and testing of the Smartinhaler™ 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), ANSI/AAMI HA60601-1-11:2015 (home-use safety), ANSI/AAMI/IEC 60601-1-2:2014 (electromagnetic compatibility); ANSI/AAMI/ISO 10993-1:2009, ANSI/AAMI/ISO 10993-5:2009, ANSI/AAMI/ISO 10993-10:2010, ANSI/AAMI/ISO 10993-12:2012 (biocompatibility); and ANSI C63.10:2013 / 47 CFR Part 15 FCC regulations for RF devices.

(b)(2) Discussion of the Clinical Tests

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

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

Finished device testing carried out for the Smart inhaler™ 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 Smart inhaler™ is substantially equivalent to the predicate device.