DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 30, 2017

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

Re: K163485
Trade/Device Name: SmartTouch
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: August 2, 2017
Received: August 4, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S

for
Lori Wiggins, MPT, CLT
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163485

Device Name
SmartTouch

Indications for Use *(Describe)*
The SmartTouch 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 SmartTouch is compatible only with the Symbicort MDI. The SmartTouch 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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K163485

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29 August 2017

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, Regulatory & Quality Manager

(a)(2) Name of the Device

Model Number / Name:	**SmartTouch**
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 that equivalence is claimed to is: K133951, SmartTouch, Nexus6 Limited.

(a)(4) Description of the Device

SmartTouch 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.

SmartTouch is a clip-on device that attaches externally around the housing of an MDI. SmartTouch is compatible only with the Symbicort MDI. Optical and mechanical sensor methods are used to detect MDI presence and actuation, and the device logs the usage history of the MDI. The SmartTouch contains an electronic clock and calendar that is used to log the date and time of MDI actuation.

The SmartTouch user interface consists of two LED indicators and three control buttons to check device status, initiate communications functions, and provide reminder features. The SmartTouch 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 SmartTouch 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 SmartTouch is compatible only with the Symbicort MDI. The SmartTouch 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 SmartTouch 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; 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 sensor technology used to detect MDI actuation, user interface design, and provision of reminder features are different from the predicate device. These aspects of the device have been 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 SmartTouch 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 MDI usage. This established correct functionality and compatibility of the SmartTouch with the Symbicort MDI according to requirements.

Review and testing of the SmartTouch for compliance to the following standards and regulations has been completed by external laboratories: AAMI/ANSI ES60601-1:2005 +A1:2012, C1:2009, A2:2010 (general safety), AAMI/ANSI HA60601-1-11:2015 (home-use safety), AAMI/ANSI/IEC 60601-1-2:2014 (electromagnetic compatibility); AAMI/ANSI/ISO 10993-1:2009, AAMI/ANSI/ISO 10993-5:2009, AAMI/ANSI/ISO 10993-10:2010, AAMI/ANSI/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 SmartTouch. 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 SmartTouch indicates it meets design and performance functional requirements. Software verification demonstrates that the device functions equivalently to the predicate device. The device meets standard requirements for wireless communications, electrical safety, electromagnetic compatibility, and environmental performance.

This information indicates that the SmartTouch is equivalent to the predicate device.