K133951

APR 2 5 2014

Nexus6 Limited
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20 December 2013

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) Submitter Information

Company Details:	Refer to information above
Contact Person:	Garth Sutherland, Chief Executive Officer

(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

K091803, SmartTrack System, Nexus6 Limited

(a)(4) Description of the Device

SmartTouch is used to provide a compliance monitoring function for use of a Metered Dose Inhaler (MDI).

SmartTouch is a clip-on device that attaches externally around the enclosure of an MDI. Optical and pressure sensor methods are used to detect MDI presence and actuation, and the device logs the usage history of the MDI. The device includes an LED indicator and control button to check device status and manually initiate communications functions. The SmartTouch has a Bluetooth interface to wirelessly exchange data with a communications device.

(a)(5) Statement of the Intended Use

The SmartTouch is intended for single-patient use as an 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 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 largely equivalent to the predicate device listed above. Equivalent features between the devices include: configuration in attaching to the outside of an MDI enclosure; microprocessor control and use of an internal clock, to log date and time of MDI actuations; power supply from an internal battery; interface to a communications device to upload MDI usage data; and capability to provide compliance data for further analysis using remote review software.

The sensor technology used to detect MDI actuation is different from the predicate device, as is the communications technology. 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 and device performance. 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 of the SmartTouch according to requirements.

Review and testing of the SmartTouch for compliance to IEC 60601 series standards for electrical safety, electromagnetic compatibility, and environmental performance; and FCC regulations for radio frequency devices; has been completed by external laboratories.

(b)(2) Discussion of the Clinical Tests

Clinical testing was not required to demonstrate the safety and effectiveness of the SmartTouch. The product functionality has been adequately assessed by bench testing as above.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

Finished device testing carried out for the SmartTouch indicates it meets design and performance functional requirements. Software verification demonstrates that device features are effective, and 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 in terms of device safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Nexus6, Ltd.
Mr. Garth Sutherland
Chief Executive Officer
Suite 205
8 Commerce Street
Auckland, 1010 New Zeland

Re: K133951
Trade/Device Name: SmartTouch
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Nebulizer)
Regulatory Class: Class II
Product Code: CAF
Dated: April 22, 2014
Received: April 23, 2014

Dear Mr. Sutherland,

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.

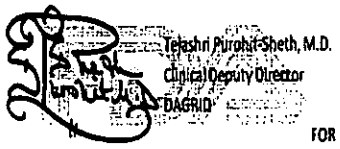
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number: K133951

Device Name: **SmartTouch**

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Prescription Use ✓ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Deepika A. Lakhani -A
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