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

June 19, 2015

Reciprocal Labs Corporation
David Hubanks
VP Operations
634 W. Main Street, Suite 102
Madison, WI 53703

Re: K143671
Trade/Device Name: Propeller Sensor Model 2014-D
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: May 20, 2015
Received: May 21, 2015

Dear Mr. Hubanks:

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" (21CFR 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,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
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Erin I. Keith, M.S.
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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)*
K143671

Device Name
Propeller Model 2014-D Sensor

Indications for Use *(Describe)*
The Propeller System includes the Propeller Model 2014-D Sensor. The sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring the actuations of prescribed DPI usage for the Diskus devices.

The Propeller Mobile Application records, stores, and transmits usage events from Propeller Sensors, or via manual user entry, to a remote storage system. With the Propeller Mobile Application the user can review information collected from the DPI sensor, and report and review symptoms and other information about their disease management and its impact. The user may also share their information with their caregivers, physician, and healthcare providers.

The Propeller Web Application is software that, like the Propeller Mobile Application, is intended to allow users to review the collected information and characteristics of their DPI and its use, to capture other patient-reported information and outcomes, and to allow that information to be shared with their caregivers, physicians, and health care providers.

When used under the care of a physician with a prescribed DPI, the system can report on information captured during the normal course of use, such as the time between actuations that can be helpful in assessing DPI technique.

When used under the care of a physician with a prescribed DPI, the system can be used to reduce the frequency of respiratory health symptoms and exacerbations by increasing adherence to DPI medications through the use of feedback such as reminders and notifications, and self-management education.

The Propeller System is intended to be used in populations from Child (>2 years) to Adult.

The Propeller System can be used both indoors and outdoors; home, work, and clinical settings, as well as on aircraft.

The Propeller System may also be used in clinical trials where researchers need to know information about the use of DPI medication(s) by a participant.

The output of the Propeller System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The Propeller System is not intended for use as an DPI dose counter, nor is it intended to indicate the quantity of medication remaining in an DPI.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submission Date:	June 17, 2015
Submitter:	Reciprocal Labs Corporation 634 W. Main Street, Ste. 102 Madison, WI 53703
Submitter and Official Contact:	David Hubanks VP Operations Reciprocal Labs 634 W. Main Street, Ste. 102 Madison, WI 53703 +1 (608) 251-0470 +1 (608) 338-0883 (fax) david.hubanks@propellerhealth.com
Manufacturing Site:	Reciprocal Labs Corporation 634 W. Main Street, Ste. 102 Madison, WI 53703
Trade Name:	Propeller Model 2014-D Sensor
Model Name:	Propeller Model 2014-D Sensor
Common Name:	Nebulizer
Classification Name:	NEBULIZER (DIRECT PATIENT INTERFACE)
Classification Regulation:	21 CFR §868.5630
Product Code:	CAF
Device Description:	Dry Powder Inhaler (DPI) / Diskus Accessory
Substantially Equivalent Devices:	Propeller System K140638
Intended Use:	The Propeller System includes the Propeller Model 2014-D Sensor. The sensor is an accessory device intended for single-patient use to assist physicians and patients in recording

and monitoring the actuations of prescribed DPI usage for the Diskus devices.

The Propeller Mobile Application records, stores, and transmits usage events from Propeller Sensors, or via manual user entry, to a remote storage system. With the Propeller Mobile Application the user can review information collected from the DPI sensor, and report and review symptoms and other information about their disease management and its impact. The user may also share their information with their caregivers, physician, and healthcare providers.

The Propeller Web Application is software that, like the Propeller Mobile Application, is intended to allow users to review the collected information and characteristics of their DPI and its use, to capture other patient-reported information and outcomes, and to allow that information to be shared with their caregivers, physicians, and health care providers.

When used under the care of a physician with a prescribed DPI, the system can report on information captured during the normal course of use, such as the time between actuations that can be helpful in assessing DPI technique.

When used under the care of a physician with a prescribed DPI, the system can be used to reduce the frequency of respiratory health symptoms and exacerbations by increasing adherence to DPI medications through the use of feedback such as reminders and notifications, and self-management education.

The Propeller System is intended to be used in populations from Child (>2 years) to Adult.

The Propeller System can be used both indoors and outdoors; home, work, and clinical settings, as well as on aircraft.

The Propeller System may also be used in clinical trials where researchers need to know information about the use of DPI medication(s) by a participant.

The output of the Propeller System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The Propeller System is not intended for use as an DPI dose counter, nor is it intended to indicate the quantity of medication remaining in an DPI.

Technology Comparison and Device Description:

The subject device uses technology similar to the predicate device including Bluetooth wireless connectivity which connects to the same previously cleared Propeller Health software system together with a mobile phone or wireless gateway. The Sensor Model 2014-D is different from the Sensor Model 2 in that it contains enclosure size differences required to install on the DPI inhaler and electronic sensors to detect Propeller Sensor 2014-D use rather than a button which was used in the predicate device.

Technology Comparison	Predicate Device: Propeller System, Propeller Sensor Model 2 510k Number: K140638	Candidate Device: Propeller System, Propeller Sensor Model 2014-D
Design - Attachment to Medication Dispenser	Same	Physically attaches to dispenser without inhibiting patient use
Principle of Operation	The Propeller Health Sensor attaches to the top of the medication canister and performs wireless uploading of usage history of the MDI.	The Propeller Health Sensor securely encases the medication canister and performs wireless uploading of Diskus usage history.
Output port and Computer Interface	Wireless uploading to database; viewed by PC or other internet-capable device.	Same
Data Collection Technology	Records date and time of MDI usage with button press switch.	Records date and time of DPI usage by monitoring actuation of the DPI via sensors
Mobile Platforms	• iOS versions 7 or higher	Same

	• Android operating system	
Required Off the Shelf Hardware	• Apple smartphones or devices with Bluetooth, iOS 7 or higher • Android smartphones or devices with Bluetooth and operating system version of 4.3 and up for app • Internet capable device; no processor or memory requirements (see Required Browser)	Same
Required Browser	Firefox, Chrome, Safari , Internet Explorer	Same
Mobile Application	The Propeller Health Mobile Application records, stores, and transmits usage events from the Propeller Health Sensor via a feature or smart phone. In addition, the mobile application can be used to review the information captured	Same

	when using a smart phone.	
Software	The Propeller Health Web Application is software intended to allow users to review the collected information and characteristics of MDI use, to add detail associated with a recorded usage event, and to share that information with their physician in order to provide additional information associated with the condition for which their MDI medication(s) are prescribed.	The Propeller Health Web Application is software intended to allow users to review the collected information and characteristics of Diskus use, to add detail associated with a recorded usage event, and to share that information with their physician in order to provide additional information associated with the condition for which their Diskus medication(s) are prescribed.
Dose Counter	No	Same
Records Usage	Yes	Same
Records Location of Usage (GPS Coordinates)	Geographic coordinates can be captured by the wireless device if paired with a sensor.	Same
Keyboard/Input Interface	Dual button Interface: Primary button and secondary button.	Single button interface
Digital Display	No	Same
Power Source	Single 3V DC Li-ion Battery	2 internal 3V DC Li-ion Batteries
Battery Life	1.5 Years	1 year

Low battery indicator	Yes, light combination; software display of battery life.	Same
Patient Reminder	Yes	Same
Support	Yes	Same
Patient Data Storage with Software	Yes	Same
Patient Data Report Generation with Software	Yes	Same
Patient Data Graphs Generation	Yes	Same
Data Retrieval from Device w/ Software	Yes	Same
Case Material - Patient Contact by Intact Skin (hands)	Lexan Polycarbonate	Same
Case Material - Patient Contact by breached skin (lips)	N/A	Lexan Polycarbonate

Test Summary: Test results indicate that the Propeller Sensor Model 2014-D and its predicate Propeller System Model 2 complies with predetermined specifications. Software verification and validation testing confirms this result.

Compliance to IEC 60601-1, IEC60601-2, IEC60601-6, IEC60601-11, ISO 10993 Biocompatibility (primary skin irritation, dermal sensitization, ISO Agarose Overlay, ISO Guinea Pig Maximization Sensitization, ISO MEM Elution, ISO Intracutaneous Irritation, ISO MEM Elutiion Post-Cleaning) was confirmed.

Bench testing included air-flow and PSD Safety Assessment using Electrostatic Measurements and analysis of Electric Fields from the sensor on the Diskus medication. Insertion-removal measurements were performed to insure the device meets the performance specification for insertion and removal force and

does not damage the Diskus device or label. Co-existence testing to confirm in-home wireless compatibility.

The above testing confirms that the device is substantially equivalent to the predicate device as the minor differences between the predicate and the subject device were shown by the above testing that the subject device meets the predetermined performance specifications as was the case with the predicate device.

Clinical Testing No clinical testing was required

Conclusion: The technology differences are minor and validation through testing has demonstrated no impact to safety or effectiveness. The overall testing confirms that the Propeller Sensor Model 2014-D is as safe and effective and performs as well as the predicate device.