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

March 4, 2016

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

Re: k152482
Trade/Device Name: Propeller Sensor Model 2014-R
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: February 2, 2016
Received: February 3, 2016

Dear David 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 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith M.S.
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)*
K152482

Device Name
Propeller Sensor Model 2014-R

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

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 SMI 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 SMI 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 with a prescribed SMI, 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 SMI technique.

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 SMI 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 SMI dose counter, nor is it intended to indicate the quantity of medication remaining in an SMI.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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:	November 10, 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 Sensor Model 2014-R
Common Name:	Nebulizer
Classification Name:	NEBULIZER (DIRECT PATIENT INTERFACE)
Classification Regulation:	21 CFR §868.5630
Product Code:	CAF
Device Description:	Electronic Soft-Mist Inhaler (SMI) Accessory
Substantially Equivalent Devices:	K14 2960, Propeller Sensor Model 2014-R (Rx) K142516, Propeller Sensor Model 2 (OTC)
Intended Use:	The Propeller System includes the Propeller Sensor Model 2014-R. The sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring the actuations of prescribed SMI usage. 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 SMI 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 SMI 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 with a prescribed SMI, 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 SMI technique.

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 SMI 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 SMI dose counter, nor is it intended to indicate the quantity of medication remaining in an SMI.

Note:

This 510k is for expanded indications for use adding the over-the-counter indication to the previously cleared Propeller Sensor Model 2014-R (K142960).

Technology Comparison and Device Description:

The Propeller Sensor Model 2014-R keeps track of medication use, with a record when a soft mist inhaler is used. The sensor is a small device that attaches to the top an existing inhaler. Both the subject device and the predicate device use technology that includes bluetooth wireless connectivity which connects to the same previously cleared Propeller Health software system together with a mobile phone or wireless gateway.

The Propeller Sensor Model 2014-R is identical to the predicate (K142960), and therefore there are no technology differences.

Technology Comparison	Predicate Device: Propeller System, Propeller Sensor Model 2014-R 510k Number: K142960	Candidate Device: Propeller System, Propeller Sensor Model 2014-R (OTC)
Design - Attachment to Medication Dispenser	Physically attaches to SMI without inhibiting patient use	Same
Principle of Operation	The Propeller Health Sensor attaches to the top of the medication canister and performs wireless uploading of usage history of the SMI.	Same
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 SMI usage by monitoring actuation of the SMI via sensors	Same
Mobile Platforms	• iOS versions 7 or higher • Android operating system	Same
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	Same

	can be used to review the information captured 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 SMI 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 SMI medication(s) are prescribed.	Same
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	Single button interface	Same
Digital Display	No	Same
Power Source	2 internal 3V DC Li-ion Batteries	Same

Battery Life	1 Years	Same
Low battery indicator	Yes, light combination; software display of battery life.	Same
Patient Reminder	Yes	Enhanced audio reminder component which is louder than the predicate.
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

Test Summary:

Test results indicate that the Propeller Sensor Model 2014-R and its predicate Propeller Sensor Model 2014-R complies with predetermined specifications.

Compliance to IEC 60601-1, IEC60601-2, IEC60601-6, IEC60601-11, ISO 10993 Biocompatibility (primary skin irritation, dermal sensitization, cytotoxicity) was confirmed. Additional testing to ESD levels of 10V/m was performed to ensure safety in a home health environment.

Validation Testing for OTC

Validation testing including EMC, electrical, safety, mechanical durability, and functional testing has been completed and confirms that the device continues to meet the specified requirements for the change from "Prescription Use" to "OTC" status.

Hazard Analysis for OTC	Hazard Analysis for OTC was identical to the predicate (K142516) included a review of existing hazards as well as how the patient obtains and learns about the system, registers for the system, installs the sensor, uses the Propeller System to track SMI medication use, shares data with their physician/care team and obtains help & support with SMI labeling. No new concerns of safety with the proposed OTC indication were found.
Clinical Testing	No clinical testing was required
Conclusion:	There are no new safety or effectiveness issues with classification as an over-the-counter medical device.