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

May 15, 2015

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

Re: K142516
Trade/Device Name: Propeller System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: Class II
Product Code: CAF
Dated: April 11, 2015
Received: April 15, 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 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.
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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)*

Device Name
Propeller System Model 2 OTC

Indications for Use *(Describe)*
The Propeller System includes the Propeller MDI Model 2 OTC 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 MDI 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 MDI 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 respiratory medication(s) 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 MDI, 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 MDI technique.

When used under the care of a physician with a prescribed MDI, or other inhaled medication, the system can be used to reduce the frequency of respiratory health symptoms and exacerbations by increasing adherence to MDI or other inhaled 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 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 MDI or other inhaled 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 MDI or inhaled medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI or inhaled medication.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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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:	May 15, 2015
Submitter:	Reciprocal Labs Corporation 634 W. Main Street, Ste. 201 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 System
Common Name:	Nebulizer
Classification Name:	NEBULIZER (DIRECT PATIENT INTERFACE)
Classification Regulation:	21 CFR §868.5630
Product Code:	CAF
Device Description:	Electronic MDI Accessory
Substantially Equivalent Devices:	Propeller System K140638

Intended Use:

The Propeller System includes the Propeller MDI Model 2 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 MDI 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 MDI 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 MDI 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 together with a prescribed MDI, 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 MDI technique.

When together with a prescribed MDI, the system can be used to reduce the frequency of respiratory health symptoms and exacerbations by increasing adherence to MDI 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 MDI 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 MDI dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI.
Note	Propeller System Model 2 OTC is the remarketing of the previously approved Propeller System Model 2 for OTC use.
Technology Comparison:	The device is identical to the predicate device.
Test Summary:	Test results indicate that the Propeller System Model 2 OTC and its predicate Propeller System Model 2 complies with predetermined specifications. Completed EMC, electrical, safety, mechanical durability, software verification and validation testing confirms this result.
Clinical Testing	No clinical testing was required
Validation Testing for OTC	Validation 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 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 MDI medication use, shares data with their physician/care team and obtains help & support with OTC labeling. No new concerns of safety with the proposed OTC indication were found.
Conclusion:	There are no new safety or effectiveness issues with classification as an over-the-counter medical device.