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

November 1, 2016

Reciprocal Labs Corporation
Taylor Mahan-Rudolph
Regulatory & Quality Affairs Lead
634 W. Main Street, Suite 102
Madison, Wisconsin 53703

Re: K161454
Trade/Device Name: Propeller Sensor Model 2015-E
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: September 30, 2016
Received: October 3, 2016

Dear Ms. Mahan-Rudolph:

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

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
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Office of Device Evaluation
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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)*
K161454

Device Name
Propeller Sensor Model 2015-E

Indications for Use *(Describe)*
The Propeller System includes the Propeller Sensor Model 2015-E. 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 Ellipta 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 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.

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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510(k) Summary

Submission Date:	October 27, 2016
Submitter:	Reciprocal Labs Corporation 634 W. Main Street, Ste. 102 Madison, WI 53703
Submitter and Official Contact:	Taylor Mahan-Rudolph Regulatory & Quality Affairs Lead Reciprocal Labs 634 W. Main Street, Ste. 102 Madison, WI 53703 +1 (608) 251-0470 +1 (608) 338-0883 (fax) taylor@propellerhealth.com
Manufacturing Site:	Reciprocal Labs Corporation 634 W. Main Street, Ste. 102 Madison, WI 53703
Trade Name:	Propeller System
Model Name:	Propeller Sensor Model 2015-E
Common Name:	Nebulizer
Classification Name:	NEBULIZER (DIRECT PATIENT INTERFACE)
Classification Regulation:	21 CFR §868.5630
Product Code:	CAF
Substantially Equivalent Devices	K152882 Propeller Sensor Model 2014-D
Indications for Use:	The Propeller System includes the Propeller Sensor Model 2015-E. 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 Ellipta 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 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.

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.

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Device Description:

Dry Power Inhaler (DPI) / Ellipta Accessory that monitors a patient's inhaler usage. The portable, polycarbonate sensor clips on top of a DPI mouthpiece cover and passively records inhalation events when the inhaler is used using infra-red (IR) sensors. The sensor then sends the event information via Bluetooth to the mobile phone or wireless gateway.

Technology Comparison:

The Propeller Sensor Model 2015-E keeps track of medication use, with a record of when the dry-powder inhaler is used. The sensor is a small device that attaches to the existing inhaler. Both the subject device and the predicate devices use technology that includes bluetooth wireless connectivity which connects to the previously cleared Propeller Health software system together with a mobile phone or wireless gateway.

The Propeller Sensor Model 2015-E and the predicate (K152882) have similar technological characteristics. Both devices are bluetooth enabled sensors fixed to dry powder inhalers designed to detect medication use. The indications for use are similar for both devices, the only difference is the word “Diskus” which is replaced with“Ellipta”. No other changes were made to the indications for use.

Two primary differences are outlined in the technology comparison in the table below: battery and patient contact. The predicate device had two Li-ion batteries and the subject device has a single Li-ion battery. As this change for the subject device involves a lower voltage and fewer batteries, no new issues of safety and effectiveness of the device are found. The predicate device also had potential contact with breached skin (e.g. chapped lips) which is not possible with the subject device due to the location on the medication cover.

An additional minor difference is supported mobile versions. For the Propeller system, the supported mobile versions have changed to correspond with the versions supported by the operating systems.

All other listed characteristics are identical between the subject and predicate.These changes do not impact the safety and effectiveness of the device.

Technology Characteristic	<u>Predicate Device:</u> Propeller System, Propeller Sensor Model 2014-D 510k Number:	<u>Candidate Device:</u> Propeller System, Propeller Sensor Model 2015-E

	K152882	
Design - Attachment to Medication Dispenser	Physically attaches to DPI without inhibiting patient use	Same
Principle of Operation	The Propeller Health Sensor attaches to the medication canister and performs wireless uploading of usage history of the DPI	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 DPI usage by monitoring actuation of the DPI via sensors	Same
Mobile Platforms	● iOS versions 7 or higher ● Android operating system	● iOS versions 8 or higher ● Android operating system
Required Off the Shelf Hardware	● Apple smartphones or devices with Bluetooth, iOS 7 or higher ● Android smartphones or devices with	● Apple smartphones or devices with Bluetooth, iOS 8 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)	Bluetooth and operating system version of 4.3 and up for app ● Internet capable device; no processor or memory requirements (see Required Browser)
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 smart phone. In addition, the mobile application can be used to review the information captured when using a smart phone	Same
Software	The Propeller Health Web Application is software intended to allow users to review the collected information and characteristics of DPI use, to add detail	Same

	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 DPI 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	Single button interface	Same
Digital Display	No	Same
Power Source	2 internal 3V DC Li-ion Batteries	1 internal 3V DC Li-Ion battery
Battery Life	1 year	Same
Low Battery Indicator	Yes, light combination; software display of battery life.	Same
Environment	The Propeller System can be used both indoors and outdoors; home, work, and	Same

	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.	
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)	Lexan Polycarbonate	None

Test Summary: Test results indicate that the Propeller Sensor Model 2015-E

and its predicate Propeller Sensor Model 2014-D complies with predetermined specifications. Software verification and validation testing confirms this result. Software is listed as Moderate Concern, which is identical to the predicate device. Documentation was provided as recommended by the FDA's Guidance for Industry and FDA staff, "Guidance for Content of Premarket Submissions for Software Contained in Medical Devices."

Compliance to IEC 60601-1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-11:2015, ISO 10993:2010 Biocompatibility (Primary Skin Irritation, Patch Dermal Sensitization, Cytotoxicity) was confirmed. EMC testing was completed with test levels applicable to home use environment as recommended in the FDA guidance "Design Considerations for Devices Intended for Home Use". Wireless coexistence testing was performed with passing results.

Bench testing included battery performance testing and particle size distribution (PSD) testing.

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 between the candidate and predicate device. The overall testing confirms that the Propeller Sensor Model 2015-E is as safe and as effective as the predicate device.