March 26, 2020

Reciprocal Labs Corporation
Greg Dunkelberger
Regulatory Affairs Project Manager
1 S. Pinckney St. Suite 610
Madison, Wisconsin 53703

Re: K192724
Trade/Device Name: Propeller Sensor for Symbicort
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: February 27, 2020
Received: February 28, 2020

Dear Greg Dunkelberger:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192724

Device Name
Propeller Sensor Model 2018-S

Indications for Use *(Describe)*
The Propeller System includes the Propeller Sensor Model 2018-S. The sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring the actuations of prescribed pMDI usage for the Symbicort device.

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

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.

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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:	February 24, 2020
Submitter:	Reciprocal Labs Corporation 1 S. Pinckney St., Ste. 610 Madison, WI 53703
Submitter and Official Contact:	Greg Dunkelberger Regulatory Affairs Project Manager Reciprocal Labs Corporation 1 S. Pinckney St., Ste. 610 Madison, WI 53703 +1 (608) 251-0470 +1 (844) 411-7475 (fax) greg.dunkelberger@propellerhealth.com
Manufacturing Site:	Reciprocal Labs Corporation 1 S. Pinckney St., Ste. 610 Madison, WI 53703
Trade Name:	Propeller System
Model Name:	Propeller Sensor Model 2018-S
Common Name:	Nebulizer
Classification Name:	NEBULIZER (DIRECT PATIENT INTERFACE)
Classification Regulation:	21 CFR §868.5630
Product Code:	CAF
Device Description:	Pressurized Metered Dose Inhaler (pMDI) / Symbicort Accessory that monitors inhaler usage. The portable sensor mounts to the back of the pMDI and records inhalation events when the inhaler is used.

Substantially Equivalent Devices:	K180770 Propeller Sensor Model 2017-B
Indications For Use:	The Propeller System includes the Propeller Sensor Model 2018-S. The sensor is an accessory device intended for single-patient use to assist physicians and patients in recording and monitoring the actuations of prescribed pMDI usage for the Symbicort device. 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 pMDI 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 pMDI 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 pMDI, 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 pMDI 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 pMDI 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 pMDI dose

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

Technology Comparison:

The Propeller Sensor Model 2018-S keeps track of medication use, with a record of when the pressurized metered dose 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 2018-S and the predicate (K180770) have the same technological characteristics, both devices are bluetooth enabled sensors fixed to inhalers designed to detect medication use. The changes below only reflect a change to support the Symbicort form factor.

Technology Characteristic	Predicate Device: Propeller System, Propeller Sensor Model 2017-B 510k Number: K180770	Candidate Device: Propeller System, Propeller Sensor Model 2018-S 510k Number: K192724
Design - Attachment to Medication Dispenser	Physically attaches to DPI without inhibiting patient use	Physically attaches to pMDI without inhibiting patient use
Principle of Operation	The Propeller Health Sensor attaches to the medication canister and performs wireless uploading of usage history of the DPI	The Propeller Health Sensor attaches to the medication canister and performs wireless uploading of usage history of the pMDI

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	Records date and time of pMDI usage by monitoring actuation of the pMDI via sensors
Mobile Platforms	● iOS versions 10 or higher ● Android operating system	● iOS versions 11 or higher ● Android operating system
Required Off the Shelf Hardware	● Apple smartphones or devices with Bluetooth, iOS 10 or higher ● Android smartphones or devices with Bluetooth and operating system version of 4.4 and up for app ● Internet capable device; no processor or memory requirements (see Required Browser)	● Apple smartphones or devices with Bluetooth, iOS 11 or higher ● Android smartphones or devices with Bluetooth and operating system version of 5.0 and up for app ● Internet capable device; no processor or memory requirements (see Required Browser)
Required	Firefox, Chrome,	Same

Browser	Safari , Internet Explorer	
Mobile Application	The Propeller Health Mobile Application records, stores, and transmits usage events from the Propeller Health Sensor via a feature or smartphone. In addition, the mobile application can be used to review the Information captured when using a smartphone	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 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.	The Propeller Health Web Application is software intended to allow users to review the collected information and characteristics of pMDI 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 pMDI 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	1 internal 3V DC Li-ion Battery	Same
Battery Life	1 year	Same
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	Makrolon Polycarbonate

Test Summary: Test results indicate that the Propeller Sensor Model 2018-S and its predicate Propeller Sensor Model 2017-B complies with predetermined specifications. Software verification and validation testing confirms this result.

Compliance to IEC 60601-1, IEC 60601-2, IEC 60601-6, IEC 60601-11, ISO 10993-5, and ISO 10993-10 was confirmed.

Bench testing included battery performance testing, usability testing, and electrostatic discharge testing (to verify the device does not affect particle size distribution of the medication).

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 2018-S is substantially equivalent to the predicate device.