

MAY 02 2014

K140638

510(k) Premarket Notification
Reciprocal Labs Corporation Propeller System with Propeller Model 2
Sensor

510(k) Summary

Submission Date: April 16, 2014

Submitter: Reciprocal Labs Corporation
634 W. Main Street, Ste. 201
Madison, WI 53703

Submitter and Official Contact: Ms. Inger L. Couture
Chief Regulatory & Privacy Officer
Reciprocal Labs
634 W. Main Street, Ste. 102
Madison, WI 53703
+1 (608) 251-0470
+1 (608) 338-0883 (fax)
Inger.Couture@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: Asthmapolis K121609

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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 used under the care of a physician 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, 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.

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**Technology
Comparison:**

Technological characteristics of the Propeller System and the Asthmapolis System are largely equivalent. Similarities include the indications for use, basic principle of operation, data collection information, time of data recording via internal clock, utilization of software for varying types of data review and modification, dose counting characteristics and internal power source type.

The Propeller System employs these technological characteristics in a similar way as the predicate device.

Differences include power management: the Model 2 Sensor is not rechargeable; the method used to send the usage data from the sensor to the mobile device is Bluetooth, low energy. Expanded indications for use include software feature additions such as display of time between individual actuations of the MDI Propeller Sensor that can be used to assess technique (defined as the time between inhalations, or "puffs"). This was recorded previously, but not displayed, and a greater focus than previously labeled to include use of the system to reduce the frequency of symptoms and exacerbations through review of data recorded by the patient, and the data recorded by the patient's Propeller Sensor. By reviewing the recorded data displayed by the Propeller System, the physician or care provider can identify that a patient's state is worsening, and as a result, may choose to take action, such as contacting their patient. These aspects of the device have been verified and validated in order to establish equivalent performance to the equivalent device. This information indicates that the Propeller System is equivalent to the predicate device in terms of device safety and effectiveness.

Based upon this comparison of the predicate, and the accompanying testing results for the Propeller System, the Propeller System is substantially equivalent to the predicate device.

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**Performance
Testing Summary:**

Non-clinical testing has been carried out to cover functional verification and device performance. This included completion of software verification and validation procedures, with performance testing of the MDI actuation sensor system to ensure data is logged accurately for MDI usage. This established correct functionality of the Propeller System according to the requirements.

Third party testing of the Propeller System for compliance to IEC 60601 series standards for general safety and electromagnetic compatibility and ISO 10993 series standards for biocompatibility was completed by accredited laboratories prior to this submission. Cleaning instructions were validated by an accredited lab and testing in the applicable environments for wireless interference were completed. Complete, detailed reports are included in the application for clearance; summary information is included below where differences between the two devices use non-clinical test data to support equal safety and efficacy.

Software:

Software and Firmware for the Propeller System was designed and developed according to a robust software development process aligned with "*Design Control Guidance for Medical Device Manufacturers*", "*The Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*", "*Guidance for Off the Shelf Software Use in Medical Devices*", and verified and validated using guidance from the "*General Principles of Software Validation*" as recommended by FDA.

Test results indicate that the Propeller System complies with its predetermined specifications.

Electrical Safety:

The Propeller Sensor has successfully completed patient safety testing according to IEC 60601-1.

**Electromagnetic
Compatibility
Testing:**

The Propeller Sensor has successfully completed EMC testing according to IEC 60601-1-2.

**Performance
Testing – Bench:**

The Propeller System has successfully completed performance testing according to applicable standards and internal testing. Important to highlight in this summary, is the successful performance testing that was completed for wireless/Bluetooth technology in accordance with specifications and also with, "*FDA's Guidance on Radio-Frequency Wireless Technology in Medical Devices*". In addition, tests required for FCC licensing were successful.

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Conclusion:

Hardware testing carried out for the Propeller System indicates it meets design and performance functional requirements. Software verification demonstrates that device features are effective, and that the system configuration functions equivalently to the predicate device. The Propeller System also meets standard requirements for electrical safety, electromagnetic compatibility, biocompatibility, cleaning validation, and wireless technology in medical devices.

Based upon this comparison of the predicate, and the accompanying testing results for the Propeller System, the Propeller System is substantially equivalent to the predicate device.



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 2, 2014

Reciprocal Labs Corporation
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th St. NW
Buffalo, MN 55313

Re: K140638
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 17, 2014
Received: April 18, 2014

Dear Mr. Job:

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,

Tajashri Parikh-Sheth, M.D.
Clinical Deputy Director
DAGRIB/ODE/CDRH

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140638

Device Name
Propeller System

Indications for Use (Describe)

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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)

Anya C. Harry -S

2014.05.02

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