JUL 2 2012

510(k) Premarket Notification
Reciprocal Labs Corporation Asthmapolis System

510(k) Summary K121609

Submission Date:	March 8, 2012
Submitter:	Reciprocal Labs Corporation 612 W. Main Street, Ste. 201 Madison, WI 53703
Submitter and Official Contact:	Ms. Inger L. Couture Chief Regulatory Officer Reciprocal Labs 612 W. Main Street, Ste. 201 Madison, WI 53703 +1 (608) 251-0470 +1 (608) 338-0883 (fax) Inger.Couture@asthmapolis.com
Manufacturing Site:	Reciprocal Labs Corporation 612 W. Main Street, Ste. 201 Madison, WI 53703
Trade Name:	Asthmapolis 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:	SmartTrack System K091803

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Intended Use:

The Asthmapolis System includes the Asthmapolis Sensor which is an electronic accessory device intended for single-patient use to assist physicians and patients in recording and monitoring the actuations of prescribed MDI usage.

The Asthmapolis Mobile Application records, stores, and transmits usage events from the Asthmapolis Sensor to a remote storage system.

The Asthmapolis Web Application is software intended to allow users to review the collected information and characteristics of MDI 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 MDI medication(s) are prescribed.

The Asthmapolis System may also be used in clinical trials where researchers need to know information about use of a MDI Medication(s) by a participant.

The output of the Asthmapolis System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The Asthmapolis system is not intended for use as a MDI medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI.

Technology Comparison:

Technological characteristics of the Asthmapolis System and the SmartTrack 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 Asthmapolis System employs these technological characteristics in a similar way as the predicate device. Differences include the method used to detect sensor actuation, and the method used to send the usage data from the sensor to the database. 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 Asthmapolis 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 Asthmapolis System, the Asthmapolis 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 Asthmapolis System according to the requirements.

Third party testing of the Asthmapolis 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 Asthmapolis 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 Asthmapolis System complies with its predetermined specifications.

Electrical Safety:

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

Electromagnetic Compatibility Testing:

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

Performance Testing – Bench:

The Asthmapolis 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.

Conclusion:

Hardware testing carried out for the Asthmapolis 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 Asthmapolis System also meets standard requirements for electrical safety, electromagnetic compatibility, biocompatibility, cleaning validation, and wireless technology in medical devices.

This information indicates that the Asthmapolis 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 Asthmapolis System, the Asthmapolis 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 Room –WO66-G609
Silver Spring, MD 20993-0002

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

JUL 2 2012

Re: K121609
Trade/Device Name: Asthmapolis System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 18, 2012
Received: June 19, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121609

Device Name: Asthmapolis System

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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