MAY 3 0 2012

SECTION 5: 510(K) SUMMARY

K112859

1. Submitter Information

Name:	PARI Respiratory Equipment, Inc.
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Contact Name:	James L. McIntire Jr.
Date Prepared:	September 29, 2011

2. Device Name

Common Name:	Nebulizer
Proprietary Name:	eRapid™ Nebulizer System
Classification Name:	Nebulizer (Direct Patient Interface)
Regulation No.:	868.5630
Class:	Class II
Panel:	Anesthesiology
Product Code:	CAF

3. Device Description

The eRapid Nebulizer System is a modified version of the predicate FDA-cleared eFlow® (now Trio®) Electronic Nebulizer, cleared in 510k Nos. K033833 and Special 510K No. K072670, and the Altera® Nebulizer System, cleared in 510(k) No. K100380. Its performance characteristics, however, are comparable to the predicates LC® Star, cleared in 510(k) No. K963924, and Micro Mist Nebulizer, cleared in 510(k) No. K930525.

Similarities are that both the eRapid and the predicate Trio and Altera devices are identical in purpose, function, core technology and method of operation. They are single-patient use, reusable electronic nebulizers, using micro-perforated vibrating membrane technology to aerosolize liquid medications. They are for adult and pediatric inhalation therapy in a home care, nursing home, sub-acute institution, or hospital environment. The devices are hand-held and portable, consisting of a controller and a nebulizer handset, connected with a connection cord. Power input for both devices is provided by either four AA batteries, or a DC or AC adapter. Alternate power cords, plugs and adapters allow their use in any country.

The eRapid incorporates three design modifications in comparison with the predicate eFlow Technology devices: (1) a larger capacity reservoir, and a smaller volume aerosol chamber; (2) for patient convenience, an accessory that aids in the cleaning of the aerosol

head, and; (3) also for patient convenience, added software user-interface functions that allow the device to pause in its operation, as well as to operate the cleaning aid.

Also, while the eRapid and the predicates Trio, LC Star and Micro Mist are for use with those medications prescribed by doctors for nebulization (i.e. general purpose) the Altera has a drug-specific application.

4. Intended Use

The eRapid™ Nebulizer System is a handheld nebulizer that is to be used with patients for whom doctors have prescribed medication for nebulization. It is intended for adult and pediatric patients, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.

5. Legally Marketed Predicate Devices

Manufacturer	Device	510(k) Number
PARI Innovative Manufacturers, Inc	eFlow Electronic Nebulizer	K033833, K072670
PARI Innovative Manufacturers, Inc	LC Star	K963924
PARI Respiratory Equipment, Inc.	Altera Nebulizer System	K100380
Hudson Respiratory Care, Inc.	Micro Mist Nebulizer	K930525

6. Technological Characteristics Compared to Predicate Devices

The eRapid, as with its predicates Trio and Altera, uses micro-perforated vibrating membrane technology to aerosolize liquid medications. This technology uses a wafer-thin plate of stainless steel, or membrane, perforated with numerous laser-drilled holes. This micro-perforated membrane vibrates at high frequencies against a body of fluid. The vibration source is the piezo-electric actuator that is activated by a simple electronic drive circuit. The actuator and the membrane form the atomizing head that is in contact with the liquid medication to be aerosolized. Liquid jets are created as an inertial response to the vibration of the membrane. Surface tension and hydrodynamic effects then cause these jets to disperse to produce a stream of precisely-controlled droplets.

In contrast to the above eFlow Technology devices the LC Star and Micro Mist operate on the principle of jet nebulization.

7. Summary of Testing

a. Biocompatibility

To improve the aerosol head manufacturing process three materials have been introduced as replacements to existing materials.

The complete aerosol head, incorporating these new materials, was subjected to an *In Vitro* Cytotoxicity Study. The results indicated that the aerosol head, under the parameters of the test, did not release substances in cytotoxic concentrations.

Since two of the new materials are indirectly in contact with the fluid and air paths they have undergone additional testing. Under the parameters of the tests it is concluded that they are biocompatible, and that there are no new issues of safety regarding their use as intended.

b. Software

Based upon the test results we conclude that the software performs within specifications, and is safe to the stated intended use. Since a permanent hazard analysis is implemented in the software development process, and due to the simple software architecture, we further believe that the test protocol sufficiently verifies the software's main functional operation.

c. Cleaning and Disinfection

Microbiological efficiency control tests were conducted previously on the predicate eFlow Technology devices in order to validate the nebulizer cleaning and disinfection methods in the IFU. Testing involved validation of a manual cleaning method as well as a chemical disinfection method. These are still valid. In addition to these previous validations, two nonchemical disinfection methods have been validated. All testing concluded that the nebulizer can be cleaned and disinfected effectively by use of the methods stated in the IFU.

d. Simulated Lifetime – Device

Simulated lifetime testing was conducted previously on the predicate eFlow Technology devices in order to validate the nebulizer cleaning and disinfection methods in the IFU. Testing involved validation of a manual cleaning method, and a chemical disinfection method. These are still valid with the eRapid device. In addition to the previous validations, simulated lifetime testing was done on the Easycare cleaning aid. All testing concluded that there were no deleterious effects encountered from the cleaning and disinfections methods used in with the eRapid device.

e. Simulated Lifetime – Aerosol Head

The eRapid's Aerosol Head was not tested for this submission because it is the same component in the predicate eFlow Technology devices, and was the subject of previous testing with those predicates.

f. Aerosol Characterization

PARI performed an aerosol characterization (particle size distribution) of the eRapid in comparison with the predicate devices eFlow and LC Star and Micro Mist. Testing was done by cascade impaction. With respect to aerosol performance the eRapid's: (1) MMAD is higher than or comparable to that of the predicates eFlow, LC Star and Micro Mist; (2) GSD is comparable to that of the eFlow, but lower than that of the LC Star and Micro Mist, and; (3) RM and TM is less than that of the eFlow and LC Star, but higher than that of the Micro Mist.

g. EMC and electrical safety

Performance testing has established that, with respect to EMC and electrical safety in its intended operational environment, the controller conforms to the applicable requirements of IEC 60601-1 and IEC 60601-1-2.

8. Conclusion

Based upon the above information the eRapid Nebulizer System is substantially equivalent to the predicate devices, and raises no new issues of safety and effectiveness.

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

MAY 30 2012

Mr. James L. McIntire Jr.
eFlow Regulatory
PARI Respiratory Equipment, Inc.
2943 Oak Lake Boulevard
Midlothian, Virginia 23112

Re: K112859
Trade/Device Name: eRapid™ Nebulizer System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: May 15, 2012
Received: May 16, 2012

Dear Mr. McIntire Jr.:

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):

Device Name: eRapid™ Nebulizer System

Indications For Use: The eRapid™ Nebulizer System is a handheld nebulizer that will be used with patients for whom doctors have prescribed medication for nebulization. It is intended for adult and pediatric patients, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.

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

510(k) Number: K112859

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 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)