K100380

SECTION 5: 510(K) SUMMARY

FEB 22 2010

1. **Submitter Information**

Name:	PARI Respiratory Equipment, Inc
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Contact Name:	James L. McIntire Jr.
Date Prepared:	February 9, 2010

2. **Device Name**

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

3. **Device Description**

The Altera™ Nebulizer System (hereinafter referred to as "Altera") is a drug specific version of the FDA-cleared eFlow Electronic Nebulizer, originally cleared in 510k No. K033833, and as modified in Special 510K No. K072670.

Both the Altera and the predicate eFlow are identical in purpose, function, core technology, basic design, materials and method of operation. They are single-patient use, reusable electronic nebulizers that employ 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. Both devices are hand-held and portable, consisting of a control, or base unit and a nebulizer handset, connected with a connection cord. Power input for both the Altera and the predicate eFlow 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.

However, unlike the predicate eFlow the Altera is drug-specific, intended for use only with aztreonam for inhalation solution.

4. **Intended Use**

The Altera™ Nebulizer System is intended specifically for the aerosolization of Cayston™ (aztreonam for inhalation solution) using vibrating membrane technology. The device is intended for adult and pediatric patients who have been prescribed Cayston, 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	PARI LC Star Nebulizer	K963924
Respironics® Inc.	I-Neb AAD System	K042991

6. **Technological Characteristics Compared to Predicate Devices**

The Altera, eFlow, LC Star and I-NEB AAD System are all nebulizers used to aerosolize medication for inhalation.

Altera and the predicate eFlow both use micro-perforated vibrating membrane technology to generate the aerosol. The predicate LC Star is a compressor-driven jet nebulizer, while the predicate I-neb® AAD® System uses vibrating mesh technology to generate its aerosol.

The Altera and the predicate I-neb® AAD® System have similar intended uses in the restrictive application of the devices to medications that are specifically approved for them.

The Altera and eFlow make use of identical materials and design for the nebulizer, as compared to the LC Star, and also use a similar two valve system to provide breath enhanced aerosol delivery.

7. **Summary of Performance Testing**

   a. **Simulated Lifetime Testing – Aerosol Head**

   PARI conducted simulated lifetime testing of the series' Aerosol Heads 25, 30, 35 and 45. The results of the testing were that Aerosol Heads 25, 30, 35 and 45 met TOR and MMD specifications of the different head sizes following a simulated lifetime use.

   b. **Simulated Lifetime Testing – Validation of Cleaning and Disinfection Methods**

   Microbiological efficiency control tests were conducted in order to validate the nebulizer cleaning and disinfection methods in the IFU. Testing involved validation of both manual and automated cleaning methods, and a chemical disinfectant as well as a home sterilizer disinfection method. The testing concluded that the nebulizer can be cleaned and disinfected effectively by use of the methods stated in the IFU.

   c. **Aerosol Characterization Testing**

   PARI performed an aerosol characterization (particle size distribution) of the Altera in comparison with the predicate devices eFlow and LC Star. Testing was done by two

methods: cascade impaction (Eight-Stage Anderson Cascade Impactor) and laser light scattering (Malvern MastersizerX). With respect to aerosol performance the Altera's MMAD, MMD and GSD is identical with or lower than the predicates eFlow and LC Star. The Altera's RF, TM and RM identical with or greater than the predicates eFlow and LC Star.

d. Drug-Specific Testing

The Altera's aerosol performance characteristics using aztreonam for inhalation solution were measured with the Andersen Cascade Impactor (ACI) method of eFlow® Model 678G1002 as the aztreonam for inhalation solution commercial delivery system. These data appear in the AZLI New Drug Application (NDA) 50-814, and in 000,6004,PDR,01,02 eFlow® Electronic Nebulizer USA Model 678G 1002 "Product Description, Comparability Analysis with eFlow Model 78G 1004, and Discussion Regarding use as the Aztreonam Lysine for Inhalation

e. Airpath Testing

Although Altera is not compressor-driven, airpath testing was nonetheless conducted to ensure there are no environmental safety issues with the series involving volatile organic compounds (VOCs), emitted particulates and CO/CO2/Ozone gases.

EMC and electrical safety validations were not performed for this submission because the Altera's controller is identical to that cleared in 510K No. K072670. Previous testing established that, with respect to EMC and electrical safety in their intended operational environment, the control unit met the applicable requirements of: IEC 60601-1-2; CAN/CSA C22.2 NO 601.1-M90, and; UL 1431. Further, they have been subjected to IEC/EN/DIN EN 60068-2-3, 60068-2-6, 60068-2-14, 60068-2-29, and 60068-2-64 with respect to stress testing.

8. Conclusion

Based upon the above information the Altera 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

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

FEB 22 2010

Re: K100380
Trade/Device Name: Altera™ Nebulizer System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 9, 2010
Received: February 16, 2010

Dear Mr. McIntire:

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,

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: Altera™ Nebulizer System

Indications For Use: The Altera™ Nebulizer System is intended specifically for the aerosolization of Cayston™ (aztreonam for inhalation solution) using vibrating membrane technology. The device is intended for adult and pediatric patients who have been prescribed Cayston, and may be used in hospitals, hospital-type facilities, nursing homes, sub-acute institutions and home environments.

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

510(k) Number: K100380

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)