

K072670

SECTION 5: PREMARKET NOTIFICATION 510(K) SUMMARY STATEMENT

1. Submitter Information

Name: PARI Innovative Manufacturers, Inc
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Contact Name: James L. McIntire Jr.
Date Prepared: August 2, 2007

DEC 13 2007

2. Device Name

Common Name: Nebulizer
Proprietary
Name: eFlow[®] Electronic Nebulizer
Classification
Name: Nebulizer (Direct Patient Interface)
Classification
Regulation No: 868.5630
Classification
Panel: Anesthesiology
Product Code: CAF

3. Device Description

The PARI eFlow[®] Electronic Nebulizer is a small, single-patient use, reusable electronic nebulizer for the inhalation treatment of aerosol medications. It is a hand-held device, containing a capped medication cup that can be filled by the user. Power input is provided by either four AA batteries or a DC or AC adapter. Alternate power cords/plugs/adapters allow its use in any country.

4. Intended Use

The eFlow[®] is a handheld nebulizer that will be used with patients for whom doctors have prescribed medication for nebulization. The eFlow[®] is intended for adult and pediatric patients.

5. Device Modification Summary

The device modification involves the addition of a new control unit and connection cord to those which are already part of the FDA-cleared device. These components will not replace the present control unit or connection cord. Rather, they represent additional device options.

The new control unit features a liquid crystal display (LCD) that visually displays the nebulization status and out-of-range parameters. It performs the same function as the audiovisual interfaces (light-

emitting diodes (LEDs) and audio tones) present in both the new and the FDA-cleared control units. All of these audiovisual interfaces, including the LCD, communicate one-way, and do not control any aspects of the nebulization process.

Modifications to the FDA-cleared device are thus confined to the new control unit and connection cord. However, incorporating the LCD in the new control unit has had a “snowball” effect, and resulted in the following: (1) added ergonomics of the LCD interface; (2) a redesigned control unit and connection cord connectivity, (3) software and firmware; and, (4) labeling.

6. Summary of Testing

The new, optional control unit underwent the following evaluations:

- Software verification and validation testing performed to the applicable requirements of PARI SOP PV 02 70014 Version 00 (Release Software 678*).
- Electromagnetic compatibility and electrical safety testing for the intended operational environment was performed to the applicable requirements of: IEC 60601-1-2; CAN/CSA C22.2 NO 601.1-M90; UL 1431, and;
- Stress testing for the intended operational environment was performed to the applicable requirements of IEC/EN/DIN 60068-2-3, 60068-2-6, 60068-2-14, 60068-2-29, 60068-2-64 and 60068-2-78.

Testing demonstrated that the modifications to the new, optional control unit do not affect the performance of the eFlow[®] Electronic Nebulizer, and raise no new issues of safety or effectiveness.

7. Substantial Equivalence

The new control unit and connection cord are an addition to the present eFlow[®]. Modifications to the device are confined to these new components, and involve the following: (1) added ergonomics of the device user interface (the LCD); (2) redesign of the control unit and the connection cord to accommodate the LCD, (3) software and firmware to accommodate the feature; and (4) labeling (IFU change to describe the LCD).

The addition of the modified unit does not affect the intended use, or alter the fundamental scientific technology of the legally-marketed PARI eFlow[®]. Additionally, there is no change to the legally-marketed device's: (1) materials; (2) performance specifications; (3) dimensional specifications; (4) environmental specifications; (5) energy sources; or; (6) packaging.

Based upon the criteria set forth in 21 CFR 807.87, and under the New 510(k) Paradigm, we believe that the modifications to the eFlow[®] device are substantially equivalent to the eFlow[®] Electronic Nebulizer, previously determined to be substantially equivalent on May 5, 2004 in 510k No. K033833.



DEC 13 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PARI Innovative Manufacturers, Incorporated
C/O Mr. Jay Y. Kogoma
Senior Staff Engineer
Intertek Testing Services
2307 East Eurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K072670
Trade/Device Name: eFlow[®] Electronic Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: November 30, 2007
Received: December 3, 2007

Dear Mr. Kogoma:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

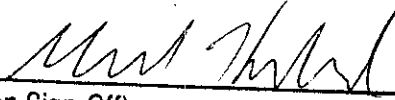
Enclosure

Indications for Use

510(k) Number (if known):

Device Name: eFlow[®] Electronic Nebulizer

Indications For Use: The eFlow[®] is a handheld nebulizer that will be used with patients for whom doctors have prescribed medication for nebulization. The eFlow is intended for adult and pediatric patients.



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072670

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)