K033833

eFlow™ Electronic Nebulizer
510(k) Submission
510(k) Summary

MAY - 5 2004

Submitter Information

Name:	PARI Innovative Manufacturers, Inc.
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Date Prepared:	August 14, 2003

Device Name

Common Name:	Electronic Nebulizer
Proprietary Name:	eFlow™
Classification Name:	Nebulizer (Direct Patient Interface)

Legally Marketed Predicate Device

Manufacturer	Device	510(k) Number
AeroGen Inc	AeroNeb II™ Portable Nebulizer	K992381
AeroGen Inc	AcroNeb™ Portable Nebulizer	K003022/970010
PARI Innovative Manufacturers, Inc.	PARI LC Star® nebulizer	K963924

Device Description

The PARI eFlow™ 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 4 AA batteries, a DC adapter or an AC adapter. Alternate power cords/plugs/adapters allow use in any country.

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.

Technological Characteristics Compared to Predicate Device

eFlow, LC Star and Aeroneb are all nebulizers used to aerosolize medication for inhalation. LC Star is a compressor driven jet nebulizer while eFlow and Aeroneb use ultrasonic/piezoelectric vibration to generate the aerosol.

eFlow makes use of similar/identical materials for the nebulizer, as compared to the LC Star and also uses a similar two valve system to provide breath enhanced aerosol delivery.

Non-clinical Test Summary

EFlow was tested to compare performance to the predicate devices, including:

- MMAD: eFlow MMAD is comparable to or lower than predicate devices.
- RF: eFlow RF is comparable to or greater than predicate devices.
- TOR: eFlow TOR is comparable to or greater than predicate devices.
- Safety/EMC: eFlow meets the requirements of EN/IEC 60601-1, DIN EN 60601-2 and UL 1431.

Clinical Performance Summary

Clinical testing was not completed/is not required to show substantial equivalence.

Conclusions from Testing

eFlow meets performance requirements and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Pari Innovative Manufacturers
C/O Mr. Robert Mosenkis
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K033833
Trade/Device Name: eFlow Electronic Inhaler/Nebulizer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: April 20, 2004
Received: April 21, 2004

Dear Mr. Mosenkis:

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 (301) 594-5613. 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/dsma/dsmamain.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): K033833

Device Name: eFlowTM 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.

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K033833