K060399

MAR 2 2006

LC Sprint Reusable Nebulizer
510(k) Submission
510(k) Summary

Submitter Information

Name:	PARI Innovative Manufacturers, Inc.
Address:	2943 Oak Lake Blvd. Midlothian, VA 23112
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Contact Name:	Michael Judge
Date Prepared:	November 22, 2005

Device Name

Common Name:	Nebulizer
Proprietary Name:	Multiple
Classification Name:	Nebulizer (Direct Patient Interface), 21 CFR 868.5630, Product Code CAF

Legally Marketed Predicate Device(s)

Manufacturer	Device	510(k) Number
Allegiance Healthcare Corporation	Airlife® Misty Max 10™ Nebulizer	K023602
PARI Innovative Manufacturers, Inc.	PARI LC® Star Nebulizer	K963924

Device Description

The LC Sprint is a small, single patient use, reusable air-powered nebulizer for the inhalation treatment of aerosolized medications. The device is non-sterile, prescription-use only, intended for use in hospital, clinic, or home environments.

Indications For Use

The LC Sprint is a handheld nebulizer, designed to aerosolize medication approved for nebulization and prescribed by a physician. The LC Sprint is intended for adult and pediatric patients consistent with the indications for the aerosol medication.

Technological Characteristics Compared to Predicate Device

LC Sprint, Misty Max 10, and LC Star are all nebulizers used to aerosolize medication for inhalation. All three devices are air compressor-driven jet nebulizers using the same aerosolization method.

LC Sprint employs similar materials compared to the LC Star nebulizer, has a similar breath-enhanced design, and utilizes a 2-way valve system similar to that used by the LC Star.

Non-Clinical Test Summary

LC Sprint was tested to compare performance to the predicate devices, including:

- MMAD: LC Sprint MMAD is comparable to the predicate devices
- RM: LC Sprint RM is comparable to the predicate devices
- Total Mass: LC Sprint Total Mass is comparable to the predicate devices

Clinical Performance Summary

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

Conclusions from Testing

LC Sprint 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

MAR 2 2006

Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K060399
Trade/Device Name: LC Sprint Reusable Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 14, 2006
Received: February 15, 2006

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.

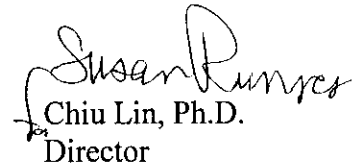
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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): K060399

Device Name: LC Sprint

Indications for Use:

The LC Sprint is a handheld nebulizer, designed to aerosolize medication approved for nebulization and prescribed by a physician. The LC Sprint is intended for adult and pediatric patients consistent with the indications for the aerosol medication.

Prescription Use XXX
(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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number: K060399

(Posted November 13, 2003)