AUG 2 8 2006

K062158

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

The LC Sprint Star 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.

LC Sprint Star is a cosmetically and geometrically modified version of the LC Sprint nebulizer currently marketed by PARI. The LC Sprint Star has an inspiratory valve on the top component and an expiratory valve on the mouthpiece, allowing for breath-controlled aerosol output.

The LC Sprint Star will be available as a stand-alone item or a configuration component containing:

- LC Sprint Star nebulizer (consisting of nebulizer cup, top, and baffle insert)
- Mouthpiece
- Oxygen tubing (optional)
- Mask (optional)

Predicate devices referenced in this submission are:

Manufacturer	Device	510(k) Number
PARI Innovative Manufacturers, Inc.	PARI LC® Sprint Nebulizer	K060399
PARI Innovative Manufacturers, Inc.	PARI LC® Star Nebulizer	K963924
Westmed, Inc.	Vixone Nebulizer	n/a

Indications for Use

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

Comparison to Predicates

In **Section 12** we discuss the proposed device and compare it to the predicate devices. Rather than repeat this comparison in the Executive Summary we refer the reviewer to the appropriate sections of this submission. Below is a summary of the discussion.

Indications –

- Identical to predicate PARI LC Sprint – K060399

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2006

Pari Innovative Manufacturers, Incorporated
C/O Mr. Neil E. Devine
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K062158
Trade/Device Name: LC Sprint Star
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: August 16, 2006
Received: August 17, 2006

Dear Mr. Devine:

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.

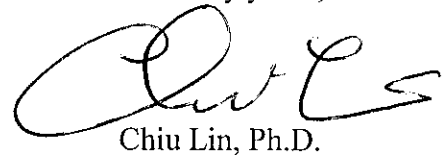
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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) 276-0120. 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 (240) 276-3150 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): N/A

Device Name: LC Sprint Star

Indications for Use:

The LC Sprint Star is a handheld nebulizer, designed to aerosolize medication approved for nebulization and prescribed by a physician. The LC Sprint Star is intended for pediatric and adult 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)

[signature]

...n Sign-Off)
...n of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number K062158