SMDA Non-confidential 510(k) Summary

K032849

(1) Submitter's name / Contact person:

Aerogen, Inc.
2071 Stierlin Court
Mountain View, CA 94043
USA

Contact person: Nancy E. Isaac
Vice President, Regulatory Affairs and Quality
Tel.: (650) 864-7493
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Date prepared: August 2003

(2) Name of device:

Trade name: Aeroneb® Go Nebulizer
Common name: Nebulizer
Classification name: Nebulizer, 21 CFR §868.5630

(3) Identification of predicate device:

Manufacturer	Device	510(k) Number
Aerogen, Inc.	Aeroneb® Portable Nebulizer System	K970010/ K003022
Pare Holding Co.	Pari LC Star™ Reusable Nebulizer	K963924
Omron Healthcare, Inc.	Omron MicroAir® Portable Ultrasonic Nebulizer	K923024

(4) Description of the device:

The Aeroneb Go nebulizer, for use by pediatric and adult patients, is intended to aerosolize physician-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer.

The Aeroneb Go nebulizer uses the OnQ™ Aerosol Generator, which is comprised of a unique dome shaped aperture plate containing over 1,000 precision-formed tapered holes surrounded by a vibrational element. When energy is applied, the aperture plate vibrates approximately 100,000 times per second. This rapid vibration causes each aperture to act as a micropump, drawing liquid through the holes to form consistently sized droplets.

The Aeroneb Go nebulizer is lightweight, compact and silent. The device can be powered with the AC Power Controller or with the Battery Powered Controller that uses three "AA" disposable batteries.

(5) A statement of the intended use of the device:

The Aeroneb Go nebulizer, for use by pediatric and adult patients, is intended to aerosolize physician-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer.

(6) Predicate device comparison:

The Aeroneb Go nebulizer is substantially equivalent to similar features in the predicate devices and has the same intended use and technological characteristics as the predicate devices.

Non-clinical performance tests were conducted comparing Aeroneb Go nebulizer to the Aeroneb Portable Nebulizer System, the Pari LC Star and the Omron MicroAir. Results demonstrated that the Aeroneb Go nebulizer was substantially equivalent to the other legally marketed devices in performance.

(7) Performance evaluations:

Evaluation of performance included nebulizer delivery characterization, electrical, mechanical, and EMC safety, were based on those suggested in the FDA CDRH - REVIEWER GUIDANCE FOR NEBULIZERS, METERED DOSE INHALERS, SPACERS AND ACTUATORS issued on: October 1, 1993.

The successful tests demonstrated the device consistently performed within its design parameters and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2003

Aerogen, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K032849
Trade/Device Name: Aeroneb Go Nebulizer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: November 6, 2003
Received: November 7, 2003

Dear Mr. Job:

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) 594-4646. 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

510(k) Number (if known): K032849

Device Name: Aeroneb® Go Nebulizer

Indications for Use:

The Aeroneb Go nebulizer, for use by pediatric and adult patients, is intended to aerosolize physician-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032849

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANTOHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the Counter Use_____

Optional Format 1-2-96)