K062689

Section 5

FEB 16 2007

510(K) SUMMARY

Prepared: August 1, 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identification:

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Establishment Registration Number :0681154

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Respironics Medical Products (Shenzhen) Co., Ltd.
Tong Xi Chong Village, Boa on Districts
Shenzhen, People's Republic of China

Establishment Registration Number: 3003001596

Official Correspondent:
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2. **Name of the Device:**
Sidestream Plus Nebulizer
Common Name or Classification Name (21 CFR Part 807.87) of Device:
Nebulizer, 21 CFR Part 868.5630

3. **Predicate Device Information:**

Identification of legally marketed device which we claim substantial equivalence to:
Pari LC+
K935540
Pari Respiratory Equipment
2943 Oak Lake Boulevard
Mindlothian, Va 23112-3998

4. **Device Description:**

Sidestream Plus is a Class II device. It is a breath-enhanced reusable nebulizer to be used with a compressor that is capable of providing appropriate air pressure and flow to operate the device according to specification.

The Sidestream Plus is a breath-enhanced nebulizer and works utilizing the same operating principles as the Ventstream (K933535), the Pari LC Star (K963924) and the Pari LC + (K935540).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Respironics, Limited
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road
Twinsburg, Ohio 44087

FEB 16 2007

Re: K062689
Trade/Device Name: Sidestream Plus Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 5, 2007
Received: February 6, 2007

Dear Mr. Lehtonen:

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) 276-0120. 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): _____

Device Name: Sidestream Plus Nebulizer

Indications for Use:

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

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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