510(k) Summary

Submitter: Airsonett Inc
1171 Market Street, Suite 113
Fort Mill, SC 29708

Contact Information:
Constance G. Bundy
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6470 Riverview Terrace
Fridley, MN 55432
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Fax: 763-571-2437
E-mail: cgbundy@attglobal.net

Submission Date:
April 9, 2008

Proprietary Name:
Airsonett Airshower Air 3 Mobile Medical Air Cleaner

Device Name and Classification:
Sec. 880.5045 Medical Recirculating Air Cleaner.

Equivalent Device Identification:
BREATHE EASY (Models AD and CD) by RespirAid Ltd (K98 1841)

Device Description:
The Airsonett Airshower Air 3 Mobile Medical Air Cleaner is an adjustable, portable, personal system for use in providing a controlled environment for medical applications that require a high degree of airborne particulate control. The system is controlled by embedded firmware and runs on standard 115 volt, 1.7 ampere power. Pushbutton controls include airflow and cooling capacity. Manual controls include tilt/angle of air outflow.

The Airsonett Airshower Air 3 Mobile Medical Air Cleaner device provides a method, using air cooling, for guiding the treated ambient air so as to obtain an air flow distribution directly to the users breathing zone, thereby forming a treated air zone surrounding the user.

The Airsonett Airshower Air 3 Mobile Medical Air Cleaner has been designed to meet the following product safety standards:
**Intended Use**

The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

**Comparison Table:**

<table>
<thead>
<tr>
<th>Element of Comparison</th>
<th>Subject Device</th>
<th>Claimed SE Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Medical Recirculating Air Cleaner</strong></td>
<td>Airsonett AB</td>
<td>RespirAid Ltd.</td>
</tr>
<tr>
<td><strong>Intended use</strong></td>
<td>Mobile Air Filtration system</td>
<td>Mobile Air Filtration system</td>
</tr>
<tr>
<td></td>
<td>The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.</td>
<td>The BREATHE EASY device is a medical recirculating air cleaner designed to remove airborne particles and allergens, such as: dust, smoke, pollen, mold spores, animal hair and dander, dust mites and harmful fibers, that may lead to allergic reactions.</td>
</tr>
<tr>
<td><strong>Type of device</strong></td>
<td>Over the counter use</td>
<td>Over the counter use</td>
</tr>
<tr>
<td><strong>Labeling</strong></td>
<td>Airsonett Airshower Air-3</td>
<td>BREATHE EASY</td>
</tr>
<tr>
<td>Housing Unit</td>
<td>Housing Unit</td>
<td>Housing Unit</td>
</tr>
<tr>
<td>Air Inlet and Treated Air Outlet</td>
<td>Air Inlet and Treated Air Outlet</td>
<td></td>
</tr>
<tr>
<td>Blower</td>
<td>Blower</td>
<td></td>
</tr>
<tr>
<td>HEPA filter</td>
<td>HEPA filter</td>
<td></td>
</tr>
<tr>
<td>Air Warming Unit</td>
<td>Air Warming Unit</td>
<td></td>
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<tr>
<td>Air Cooling Unit</td>
<td>Air Cooling Unit</td>
<td></td>
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<tr>
<td>Humidifier</td>
<td>Humidifier</td>
<td></td>
</tr>
<tr>
<td>Adjustable Air Guidance Arm</td>
<td>Adjustable Support Arm</td>
<td></td>
</tr>
<tr>
<td>Control Panel</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Airsonett

<table>
<thead>
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<th>Element of Comparison</th>
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<th>Claimed SE Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient’s breathing zone.</td>
<td>The Breathe Easy uses a flow guide to isolate the respiratory passages of a user from ambient air. Method for guiding the treated air outflow so as to obtain a flow distribution in close proximity to the head of the user, thereby forming a treated air envelope surrounding his respiratory openings.</td>
</tr>
<tr>
<td>Power Requirements</td>
<td>115 Volts (60Hz), 1.7 Amps</td>
<td>115 Volts</td>
</tr>
<tr>
<td>Standard</td>
<td>IEC 60601-1</td>
<td>IEC 601-1</td>
</tr>
<tr>
<td>Air Flow</td>
<td>Airflow in clean air zone (cool side): Approx. 150 m³/h&lt;br&gt;Airflow warm side: Approx. 80 m³/h&lt;br&gt;Total airflow: Approx. 230 m³/h</td>
<td>20-40 m³/h</td>
</tr>
<tr>
<td>Air Quality in treated air envelope (referred as clean zone in appendix 1.7)</td>
<td>Class 100-1000 according to FED STD 209E</td>
<td>Class 100-1000 according to FED STD 209E</td>
</tr>
<tr>
<td>Rate of Air Changed</td>
<td>~1500 changes per hour</td>
<td>400-600 changes per hour</td>
</tr>
<tr>
<td>Sound Level</td>
<td>~38 dB(A)</td>
<td>Maximum 50 dBA or less</td>
</tr>
</tbody>
</table>

**Summary of Testing:** The device was tested for filter functionality and efficiency. Software functions were verified and validated. The device was EMC and safety tested according to relevant standards. The device functioned according to specifications.

**Conclusion:** Airsonett Airshower Air-3 is substantially equivalent to Breathe Easy regarding technology, intended use and performance.
Airsonett, Incorporated
C/O Ms. Constance G. Bundy
C.G. Bundy Associates, Incorporated
6470 Riverview Terrace
Findley, Minnesota 55432

Re: K081062
Trade/Device Name: Airsonett Airshower Air 3
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: II
Product Code: FRF
Dated: October 13, 2008
Received: October 21, 2008

Dear Ms. Bundy:

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 Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

[Signature]
Chiu S. Lin, Ph. D
Division 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): **K081062**

Device Name: Airsonett Airshower Air 3

Indications For Use:

The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

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Prescription Use __________ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: **K081062**