

OCT 13 1998

510(k) Summary

K981841

RespirAid Ltd. BREATHE EASY

510(k) Number K981841

**Applicant's Name:**

RespirAid Ltd.  
POB 12, Katzrin 12900, Israel

**Contact Person:**

Shoshana Friedman  
Push-med Ltd.  
117 Ahuzah St. Ra'ananna 43373, Israel  
Telephone: 972-9-771-8130  
Fax: 972-9-771-8131

**Date Prepared:**

May 24, 1998

**Trade Name:**

BREATHE EASY (Models AD and CD)

**Classification Name:**

Medical Recirculating Air Cleaner

**Classification:**

The FDA has classified medical recirculating air cleaners as class II devices (product code 80 FRF, regulation no. 880.5045) and it is reviewed by General Hospital Devices.

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**Predicate Device:**

- Enviracaire EV-1 (Enviracaire, Co.) - K872359

**Indication for Use:**

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.

**Device Description:**

The BREATHE EASY is an adjustable, portable, personal system for treating air in a specified area of a room. The BREATHE EASY device contains an air treatment system, including a housing unit with an air inlet and a treated air outlet, a blower and a filter, for removing contaminants from the air flowing along the flow path.

The BREATHE EASY Model AD device contains also an air filtering system with a heater and humidifier for treating ambient air so as to bring it to a preselected respiratory comfort level. The BREATHE EASY device provides a method for guiding the treated air outflow so as to obtain a flow distribution in close proximity to the head of a user, thereby forming a treated air envelope surrounding his respiratory openings.

The BREATHE EASY device is supported on an adjustable support arm, adjustably mounted onto a household furniture (e.g., bed), wall, or wheeled support structure.

**Performance Standards:**

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the BREATHE EASY complies with the IEC 601-1.

**Substantial Equivalence:**

The BREATHE EASY device is substantially equivalent to Enviracaire EV-1 cleared under K872359 in respect to intended use, technological characteristics, performance, and labeling.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 13 1998

RespirAid Limited  
C/O Ms. Shoshana Friedman  
Push-med Limitd  
117 Ahuzah St. Ra'ananna 43373  
ISRAEL

Re: K981841  
Trade Name: BREATHE EASY, Models AD and CD  
Regulatory Class: II  
Product Code: FRF  
Dated: August 24, 1998  
Received: September 4, 1998

Dear Ms. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

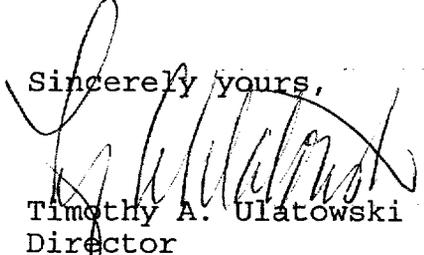
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

**510(k) Number (if known):** K981841

**Device Name:** **BREATHE EASY**

**Indications for Use:** 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.

*Chin S. Lim*

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

510(k) Number K981841

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)

Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number \_\_\_\_\_

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over the Counter Use X