JUN - 3 2004

Summary of Safety and Effectiveness

Air Safety Ltd.
NFC House, Vickers Industrial Estate
Mellishaw Lane
Morecambe, Lancaster LA3 3EN
England

Non-Confidential Summary of Safety and Effectiveness

1-June-04

Official Contact:	Steve Brown – Quality Manager
Proprietary or Trade Name:	Air Safety HEPA Model 3500 Filter
Common/Usual Name:	Inlet filter
Classification Name:	Accessory to a Continuous Ventilator (Respirator), MOD
Predicate Devices:	NPB Achieva ventilator – K990177 EMS filter – K013089

Device Description

Model 3500/01 is a replacement part for the ventilator. The Inlet Filter removes particles of 0.3 micron size (or larger) from entering the ventilator.

It is a HEPA grade particulate filter for the NPB Achieva or LP 10 ventilators, which is in the gas flow pathway.

HEPA particulate filtration testing was performed via standard DOP aerosol testing methods. There are no Bacterial or Viral filtration efficiency (BFE / VFE) claims made or required for this filter.

Intended Use and Environments

Intended Use --	Model 3500/01 is a replacement part for the ventilator. The Inlet Filter removes particles of 0.3 micron size (or larger) from entering the ventilator. It is a HEPA grade particulate filter for use with the NPB Achieva or LP 10 ventilators. The filter is in the gas flow pathway. It is changed during periodic maintenance of the ventilator.
Environment of Use --	Where the NPB Achieva and LP 10 ventilators are used, i.e., Home, Hospital, Sub-acute Institutions, Emergency services

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General Technical Characteristics

Attribute	Air Safety
Indications for use – As a HEPA particulate filter for the inlet air to be supplied to the patient from the ventilator.	Same
Intended for disposable, extended use – preventive maintenance	Yes
Prescription	Yes
Specific equipment	Only for use with the NPB Achieva and LP 10 ventilators
Intended Environment of Use	As specified by the ventilator
Design	
Screw-in cartridge to fit the inlet air filter port of the ventilator housing	Yes
Dead Space (ml)	Not applicable as it is not in the patient circuit
Resistance to flow	$\leq$ 0.9 cm H_2O @ 40 Lpm $\leq$ 1.25 cm H_2O @ 60 Lpm
HEPA – particulate filtration efficiency (retention)	$\geq$ 99.97%of 0.3 micron DOP particle at 60 Lpm $\geq$ 99.97%of 0.3 micron DOP particle at 100 Lpm
Materials	
Housing K-resin	Yes
Filter media - HEPA	Paper fiber
Performance Standards	
None under Section 514	Yes
DOE 3025- 99, DOE 3020-97 and ASTM D2986 - DOP	Yes $\geq$ 99.97% of 0.3 micron DOP particle at 60 Lpm and 100 Lpm

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed device when compared to the predicate device is safe and effective and is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2004

Air Safety Ltd.
C/O Mr. Paul Dryden
ProMedic Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055

Re: K040712
Trade/Device Name: Air Safety HEPA Model 3500
Regulation Number: 21 CFR 868.5895
Regulation Name: Accessory to Continuous Ventilator (Respirator)
Regulatory Class: Class II
Product Code: MOD
Dated: March 17, 2004
Received: March 18, 2004

Dear Mr. Dryden:

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.

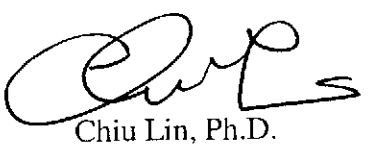
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Indications for Use

510(k) Number: K040712 (To be assigned)

Device Name: Air Safety HEPA filters - Model 3500/01

Intended Use:

Model 3500/01 is a replacement part for the ventilator. The Inlet Filter removes particles of 0.3 micron size (or larger) from entering the ventilator.

It is a HEPA grade particulate filter for use with the NPB Achieva or LP 10 ventilators. The filter is in the gas flow pathway.

Prescription Use XX **or** **Over-the-counter use __**
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K040712