4.1 Summary of Safety and Effectiveness

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

Non-Confidential Summary of Safety and Effectiveness

23-June-05

Official Contact: Steve Brown – Quality Manager

Proprietary or Trade Name: Air Safety Model 2800 PFT Filters

Common/Usual Name: PFT Filter

Classification Name: Diagnostic Spirometer Accessory, BZG

Predicate Devices: Engineered medical Systems – K013123

Device Description

The EMS PFT Filter is acompact, electrostatic filter with various end-fitting adaptable to various pulmonary function testing circuits. It has 75 ml deadspace and resistance of 0.7 cm H_2O at 720 lpm per ATS spirometry guidelines or 0.5 cm H_2O @ 60 lpm. There are various connectors to allow connection to various PFT equipment. Single patient use.

BFE and VFE testing has been performed by Nelson Laboratories to demonstrate substantial equivalence to the predicate device.

Intended Use and Environments

Indications for Use -- Model 2800 is indicated for use with pulmonary function testing equipment, to filter air between the patient's exhaled air and the testing equipment.

Environment of Use -- Hospital, Sub-acute Institutions, Physician Offices

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General Technical Characteristics

Attribute	Proposed device Filter – Model 2800	Predicate EMS K013123
Intended use	For use with pulmonary function testing equipment, to filter air between the patient's exhaled air and the testing equipment	For use with pulmonary function testing equipment, to filter air between the patient's exhaled air and the testing equipment
Intended for single patient	Yes	Yes
Prescription	Yes	Yes
Intended population	Any patient	Same
Intended Environment of Use	Hospital, sub-acute, physican office	Hospital, sub-acute
Can be used with several different PFT machines	Yes	Yes
Design Features		
Compact housing	Yes	Yes
Various end-fittings	Yes	Yes
Dead Space (ml)	75 ml	75 ml
Resistance to flow at 720 lpm per ATS standard for spirometry	0.7 cm H_2O	0.7 cm H_2O
Resistance to flow at 60 lpm	0.5 cm H_2O	0.5 cm H_2O
Bacterial filtration	99.9999%	99.9999%
Viral filtration	99.999+%	99.999+%
Weight	40 gm	40 gm
Materials		
Housing polystyrene	Yes	Yes
Filter media	Electrostatic polypropylene	Electrostatic polypropylene
Performance		
None under Section 514	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

The proposed device, Model 2800, is identical to the predicate. Air Safety manufactures the predicate for EMS, therefore there are no significant differences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2005

Air Safety Limited
C/O Mr. Paul Dryden
Regulatory Consultant
Promedic, Incorporated
6329 W. Waterview Ct.
McCordsville, Indiana 46055-9501

Re: K051712
Trade/Device Name: Model 2800 PFT Filter
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: II
Product Code: BZG
Dated: June 23, 2005
Received: June 27, 2005

Dear Mr. Dryden:

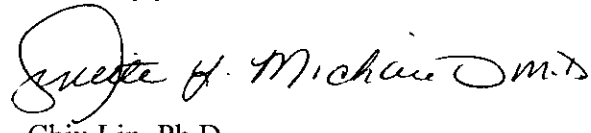
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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 (301) 443-6597 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

4.3 Indications for Use

510(k) Number: K051712

Device Name: Air Safety Model 2800 PFT filter

Intended Use: Model 2800 is indicated for use with pulmonary function testing equipment, to filter air between the patient's exhaled air and the testing equipment.

Single patient use

Environment of Use: Hospital, Sub-acute Institutions, Physician offices

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: K051712