

K043148

4.0 510(k) SUMMARY

DEC 13 2004

In accordance with 21 CFR section 807.92, Alliance Tech Medical, Inc. is submitting the following 510(k) summary:

4.1 Submitter Information:

Alliance Tech Medical, Inc.
Company Representative: John Silva, Exec. V.P.
5305 Mission Circle
Granbury, TX 76049
USA
FDA Registration No.: 3004476631
Owner / Operator No.: 9060999

4.2 Preparer of Submission and Contact for Information:

Solutions MDI, Inc.

Gus Bock, Managing Director
40310 Calle de Suenos
Murrieta, CA 92562
Telephone: (909) 698-1505 / Fax: (909) 677-3261

Keith Lowrey, Partner & Consultant (contact for correspondence and information)
611 South Schoolhouse Creek Rd.
Grants Pass, OR 97526
Telephone: (541) 476-1628 / Cell: (541-601-3695)

4.3 Name of Device:

Proprietary Name:	All Flow Pulmonary Function Filter.
Common Name:	Disposable bacterial/viral filter.
Classification Name:	Breathing circuit bacterial filter, [21 CFR 868.5260(a)].
Regulation Number:	21 CFR 868.5260(a) for Breathing circuit bacterial filters.
Product Code:	73 CAH
Class:	Class II (performance standards)

0011

4.4 Substantial Equivalence:

This submission establishes the substantial equivalence of the Alliance Tech Medical, Inc. All Flow Pulmonary Function Filter to five predicate devices:

- (1) The Main Flow Bacterial/Viral PF Filter, K961914, SE letter: 08/14/96.
- (2) The SpiroSafe Disposable PF Filter, K973314, SE letter: 11/21/97.
- (3) The KOKO Disposable PF Filter II, K934475, SE letter: 10/21/93.
- (4) The MicroGard Disposable PF Filter, K934272, SE letter: 11/24/93.
- (5) The MultiSPIRO Disposable PF Filter, K951410, SE letter: 04/24/95.

4.5 Description of the Device:

The All Flow Pulmonary Function Filter, manufactured by Alliance Tech Medical, Inc., is a disposable, single-use barrier type, bi-directional filter fabricated from a plastic resin that is supplied to the customer packaged and non-sterile. Fabricated with a filtering medium that is highly effective in reducing the numbers of both bacterial and viral contaminants that may be present in a patient's exhaled gas, the device's design also minimizes the resistance to air flow. The product is intended to protect both the patient and pulmonary function instruments from potential transmission of pathogens by droplets and aerosols.

The device consists of two molded plastic housings enclosing a disk of filter media. To avoid confusion, the patient housing side is made from a white opaque plastic and the machine housings are fabricated from the same plastic but with different colors. The colored end fits the machine and the white opaque end is for the patient side; therefore making clear definition as to which end is used for the patient and the machine.

Example of Filter Part No. 5551000 with patient and machine housing components separated:



Opaque white colored patient housing

White colored machine housing

Because spirometers can have different sensor diameters, the All Flow Pulmonary Function Filter is available in six different sizes and colors that correlate with their respective part numbers. The following chart lists the size and color of each model:

Filter Chart

ATM PF Filter Part No.	Color combination (patient housing / machine housing)	I.D / O.D (mm)
5551000	Opaque white / solid white	26.3 / 30.0
5552000	Opaque white / solid red	40.0 / 40.0
5553000	Opaque white / solid orange	45.0 / 48.5
5554000	Opaque white / solid blue	30 / 34
5555000	Opaque white / solid green	30 / 33.5
5556000	Opaque white / solid yellow	25.7 / 28.3

4.6 Intended Use of the Device:

The ATM All Flow Pulmonary Function Filter is designed as a disposable and single-use bi-directional filter for use in reducing possible bacterial and/or viral cross contamination of spirometers and pulmonary function testing instruments, associated valves and hoses, from aerosols and particulates, which may be present in a patient's exhaled gas. The device is indicated for diagnostic purposes.

4.7 Technological Characteristics in Comparison to the Predicates:

The All Flow Pulmonary Function Filter is substantial equivalent to the five predicate devices with respect to the following design characteristics and functions:

1. The devices are intended for use in reducing the possible cross contamination of spirometers and pulmonary function testing instruments from bacterial and/or viral pathogens by droplets, particulates, and/or aerosols.
2. The devices function as a barrier type, bi-directional filter, which is within a sealed double port assembly, with one port contacting the patient's mouth and the other port to be attached to the spirometers or pulmonary function-testing instrument.
3. The device housing components are fabricated from the same or similar plastic resin materials used in the predicate devices. The filter media is the same as or similar to that used in the predicate devices. These materials have long and extensive use in medical device applications.
4. The devices have been demonstrated to function effectively in reducing high challenge numbers of bacterial and viral contaminants.
5. The devices provide air filtration while minimizing airflow resistance through the filter assemblies to the pulmonary test equipment.
6. The devices meet the recommendations of the American Thoracic Society's Standardization of Spirometry.

4.8 Conclusions drawn from the Non-Clinical Tests:

Data provided in this submission indicate that the basic functional characteristics of the All Flow Pulmonary Function Filter are substantially equivalent to those of the predicate devices.

1. Bacterial Filtration Efficiency (BFE) testing demonstrated the All Flow Pulmonary Function Filter, at an increased challenge, to be %BFE = > 99.99%.

Viral Filtration Efficiency (VFE) testing demonstrated the All Flow Pulmonary Function Filter, at an increased challenge, to be %VFE = > 99.99%.

2. Airflow resistance testing demonstrated the device to an average of 2.625 cm H₂O/SLPM at 720 L. (Ref. 760 mm HGA 70 °F), which is approximately 0.23 cm H₂O/L/sec.
3. Filter dead space was demonstrated to be approximately 35 mL.
4. The device meets the recommendations of the American Thoracic Society's Standardization of Spirometry.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alliance Tech Medical, Incorporated
C/O Mr. Keith Lowrey
Solutions MDI, Incorporated
611 South Schoolhouse Creek Road
Grants Pass, Oregon 97526

Re: K043148
Trade/Device Name: All Flow Pulmonary Function Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: November 11, 2004
Received: November 16, 2004

Dear Mr. Lowrey:

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/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 STATEMENT

510(k) Number (if known): _____

Device Name: All Flow Pulmonary Function Filter

Indications for Use:

The Alliance Tech Medical, Inc. All Flow Pulmonary Function Filter is designed as a disposable and single-use, bi-directional filter for use in reducing possible bacterial and/or viral cross contamination of spirometers and pulmonary function testing instruments, associated valves and hoses, from aerosols and particulates, which may be present in a patient's exhaled gas. The device is indicated for diagnostic applications.

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

Concurrence of CRDH, Office of Device Evaluation (ODE)



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

510(k) Number: K0A3140

Prescription Use _____
(per 21 CFR 801.109)

OR Over-the-Counter Use _____
(Optional Format 1-2-96)