

**510(k) Summary**

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28-Feb-09

**MAR - 2 2009**

Pulmonary Filtration Technologies, LLC  
755 A Buckley Rd. Tel – 800-837-6751  
San Luis Obispo, CA 93401 Fax – 805-763-1303

**Official Contact:** Richard J. White, President

**Proprietary or Trade Name:** The PFT Filter

**Common/Usual Name:** PFT filter

**Classification Name:** Diagnostic spirometer (accessory)

**Device:** The PFT Filter

**Predicate Devices:** Engineered Medical Systems – PFT – K013123  
PDS KoKo – K934475

**Device Description:**

The PFT Filter is filter for use with PFT equipment and testing. It is intended to interface between the equipment and the patient during the test. It has a lightweight, compact housing with electrostatic filter media.

**Indications for Use:**

Indications for Use -- For use with pulmonary function testing. To filter air between the patient's exhaled air and the testing equipment. Single patient use, single session, disposable.

Environment of Use -- Hospital, Sub-acute Institutions, Doctor's offices, Laboratories

Contraindications -- None

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<b>Attribute</b>	<b>Proposed The PFT Filter</b>	<b>Predicates</b>
Indications for Use	For use with pulmonary function testing. To filter air between the patients's exhaled air and the testing equipment.	For use with pulmonary function testing. To filter air between the patients's exhaled air and the testing equipment. <b>EMS – PFT – K013123</b>
Environments of use	Hospital, Sub-acute Institutions, Doctor's offices, Laboratories	Hospital, Sub-acute Institutions, Doctor's offices, Laboratories <b>EMS – PFT – K013123</b>
Single patient use, single session, disposable	Yes	Yes <b>EMS – PFT – K013123</b>
May be used on different PFT testing machines	Yes	Yes – not specified <b>EMS – PFT – K013123</b>
<b>Design and Performance Testing and Results</b>		
Filter media type	Electrostatic	Electrostatic <b>EMS – K013123,</b> <b>PDS KoKo – K934475</b>
Internal volume	51 ml	50 ml <b>PDS KoKo – K934475</b>
Resistance to flow (Reported as an average)	0.5 cm H <sub>2</sub> O @ 60 Lpm 0.7 cm H <sub>2</sub> O @ 720 Lpm	0.5 cm H <sub>2</sub> O @ 60 Lpm 0.7 cm H <sub>2</sub> O @ 720 Lpm <b>EMS – K013123</b>
Bubble test per ASTM F316-03	1.0 cm H <sub>2</sub> O @ .26 Lpm	1.2 cm H <sub>2</sub> O @ 0.26 Lpm Reference only
Bacterial Filtration Efficiency	99.9+%	99.99+%
Viral Filtration Efficiency	99.9+%	99.99+%
Per Nelson Labs (MIL-M-36954 -1975)		<b>PDS – KoKo-K934475</b>
Weight	46 gm	41 gm <b>PDS – KoKo – K934475</b>
Duration of use	< 24 hours	<24 hours or not specified <b>EMS PFT K013123</b>
Materials	Housing – polystyrene Media – spun polypropylene	Identical – <b>EMS – Filter– K013122</b> Identical – <b>AM Systems – K063526</b>
Performance under Section 514	None	None

**Differences Between Other Legally Marketed Predicate Devices**

The is viewed as substantially equivalent to the following predicate devices –  
K934475 – PDS – KoKo and K013123 – Engineered Medical Systems - PFT Filter

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Pulmonary Filtration Technologies, LLC  
C/o Mr. Paul Dryden  
President  
Promedic, Incorporated  
24301 Woodsage Drive  
Bonita Springs, Florida 34134

MAR - 2 2009

Re: K083233  
Trade/Device Name: The PFT Filter  
Regulation Number: 21 CFR 868.1840  
Regulation Name: Diagnostic Spirometer  
Regulatory Class: II  
Product Code: BZG  
Dated: February 16, 2009  
Received: February 18, 2009

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.

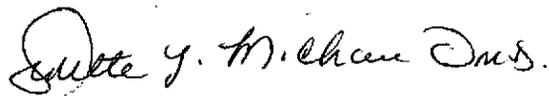
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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,



Ginette Y. Michaud, M.D.  
Acting 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**

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**510(k) Number:** K083233

**Device Name:** The PFT Filter

**Indications for Use:**

For use with pulmonary function testing. To filter air between the patients's exhaled air and the testing equipment. Single patient use, single session, disposable.

**Prescription Use XX**  
(Part 21 CFR 801 Subpart D)

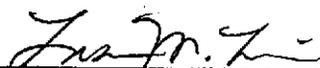
or

**Over-the-counter use \_\_\_**  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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