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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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Attribute	Proposed The PFT Filter	Predicates
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. **EMS – PFT – K013123**
Environments of use	Hospital, Sub-acute Institutions, Doctor's offices, Laboratories	Hospital, Sub-acute Institutions, Doctor's offices, Laboratories **EMS – PFT – K013123**
Single patient use, single session, disposable	Yes	Yes **EMS – PFT – K013123**
May be used on different PFT testing machines	Yes	Yes – not specified **EMS – PFT – K013123**
Design and Performance Testing and Results		
Filter media type	Electrostatic	Electrostatic **EMS – K013123, PDS KoKo – K934475**
Internal volume	51 ml	50 ml **PDS KoKo – K934475**
Resistance to flow (Reported as an average)	0.5 cm H_2O @ 60 Lpm 0.7 cm H_2O @ 720 Lpm	0.5 cm H_2O @ 60 Lpm 0.7 cm H_2O @ 720 Lpm **EMS – K013123**
Bubble test per ASTM F316-03	1.0 cm H_2O @ .26 Lpm	1.2 cm H_2O @ 0.26 Lpm Reference only
Bacterial Filtration Efficiency Viral Filtration Efficiency Per Nelson Labs (MIL-M-36954 -1975)	99.9+% 99.9+%	99.99+% 99.99+% **PDS – KoKo-K934475**
Weight	46 gm	41 gm **PDS – KoKo – K934475**
Duration of use	< 24 hours	<24 hours or not specified **EMS PFT K013123**
Materials	Housing – polystyrene Media – spun polypropylene	Identical – **EMS – Filter– K013122** Identical – **AM Systems – K063526**
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.

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

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 **or** **Over-the-counter use __**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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