K013123

MAR 1 4 2002

Engineered Medical Systems, Inc.
2055 Executive Dr.
Indianapolis, IN 46241

Non-Confidential Summary of Safety and Effectiveness

March 7, 2002

EMS
2055 Executive Dr.
Indianapolis, IN 46241

Tel (317) 246-5500
Fax (317) 246-5501

Official Contact:	Bonnie Holly – Quality Manager
Proprietary or Trade Name:	EMS Pulmonary Function Testing Filter
Common/Usual Name:	PFT filter
Classification Name:	Filter, Bacterial, Breathing Circuit
Predicate Devices:	Pulmonary Data Services – KoKo – K934475

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 07. cm H_2O at 720 lpm per ATS spirometry or 0.5 cm H_2O @ 60 lpm. There are various connectors to allow connection to various PFT equipment. Single patient use.

Intended Use:

Indicated Use --	For use with pulmonary function testing. To filter air between the patient's exhaled air and the testing equipment. Single patient use.
Environment of Use --	Hospital, Sub-acute Institutions

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Comparison to Predicate Devices:

Attribute	EMS Proposed device Filter – Model # 5813	Predicate PDS KoKo K934475
Intended use	For use with pulmonary function testing. To filter air between the patient's exhaled air and the testing equipment	Same
Intended for single patient	Yes	Yes
Prescription	Yes	Yes
Intended population	Any patient	Same
Intended Environment of Use	Hospital, sub-acute	Same
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	60 ml
Resistance to flow at 720 lpm per ATS standard for spirometry	0.7 cm H_2O	<1.5 cm H_2O
Resistance to flow at 60 lpm	0.5 cm H_2O	<1.5 cm H_2O
Bacterial filtration	99.9999%	99.99+%
Viral filtration	99.999+%	99.99+%
Weight	40 gm	N/A
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

There are no significant differences between the intended device and the predicates – PDS – Koko K934475.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2002

Mr. Paul Dryden
Engineered Medical Systems
c/o ProMedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055-9501

Re: K013123
Pulmonary Function Testing Filter
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II (two)
Product Code: BZG
Dated: December 14, 2001
Received: December 17, 2001

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.

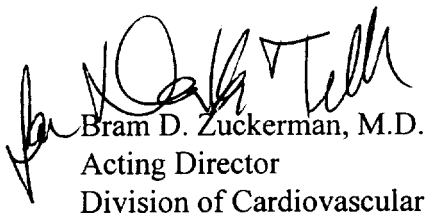
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K013123 (To be assigned)

Device Name: EMS Pulmonary Function Filter

Intended Use: For use with pulmonary function testing. To filter air between the patient's exhaled air and the testing equipment.

Single patient use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013123

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