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

K013089

Non-Confidential Summary of Safety and Effectiveness

March 13, 2002

Engineered Medical Systems
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 HEPA Filter and HEPA Filter / HME

Common/Usual Name: Bacterial / Viral Filter and Heat and Moisture Exchanger

Classification Name: Filter, Bacterial, Breathing Circuit, CAH

Predicate Devices:
Mallinckrodt Sterivent and Sterivent "S"– K941676
Mallinckrodt – Hygroster – K941585
Mallinckrodt Hygrobac "S" – K941381
ARC Medical Filter – K011212
Allegiance Two Way HEPA – K011132
SIMS Filter – K002201

Device Description

The EMS HEPA Filter and combined HEPA filter / HME are available in multiple sizes and shapes, rectangular and round, and incorporate standard 15 / 22 mm connectors with a gas sampling luer port. The depth filter uses a pleated paper fiber for filtration and a foam media for the HME media. Each filter is individually tested for rating performance according to BS 3928 Sodium Flame for Air filters. The "HEPA" performance was in accordance to DOE 3202-97 and ASTM D2986 – DOP.

Intended Use

Indicated Use -- For use with ventilators, anesthesia machines, and open flow systems where filtration of inspired and / or expired gases is desired and to add maintain and retain moisture for the exhaled breathe of the patient. For adults patients with Tidal Volumes > 150 ml. Intended for use up to 24 hours.

Environment of Use -- Home, Hospital, Sub-acute Institutions, Emergency services

General Technical Characteristics

Attribute	EMS – Proposed devices
Indications for use - To filter inspired and / or expired gases.	Same
Intended for single patient, up to 24 hours	Yes
Prescription	Yes
Intended population	Any patient
Intended Environment of Use	Home, Hospital, sub-acute, Emergency services
Placement in various locations in circuit	Yes
Design	
Gas sampling port	Yes
Standard 15/22 mm connectors	Yes
Dead Space (ml)	45 to 80 ml
Resistance to flow	$\leq$ 3.4 cm H_2O @ 60 lpm
Bacterial filtration – BFE – Nelson Lab.	99.9999%
Viral filtration – VFE – Nelson Lab.	99.9999%
Weight (gm)	27 to 35 gm
Humidification output (mg H_2O/l)	27 mg H_2O /L at TV of 500 cc, where applicable
Materials	
Housing polystyrene	Yes
Filter media	Paper fiber
Performance Standards	
None under Section 514	Yes
ISO 5356-1 Conical 15/22	Yes
ISO 594-2 Luer Fittings	Yes
ISO 9360 – HME moisture output	Yes
DOE 3202-97 and ASTM D2986 - DOP	99.97%

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and are substantially equivalent to the predicate devices.

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: K013089
EMS HEPA Filter and HME Combinations (model # 5804, 5805 and 5814)
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II (two)
Product Code: 73 CAH
Dated: December 13, 2001
Received: December 14, 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.

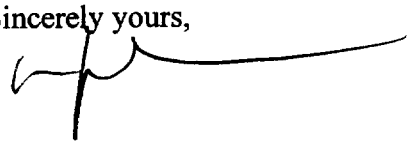
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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: K013089 (To be assigned)

Device Name: EMS HEPA and HEPA / HME

Intended Use: For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is desired and to add maintain and retain moisture for the exhaled breathe of the patient

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013089

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