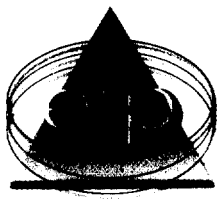
K012958

FEB 2 2 2002



510 (K) Summary

Emergency Filtration Products, Inc.
4335 S. Industrial Road
Suite 440
Las Vegas, NV 89103
702-798-4541 Telephone
702-798-4939 Fax
Douglas K. Beplate, President & Chief Technology Officer
8/27/01 Date Prepared

Trade Name:	Series 1 Breathing Circuit Filter
Common Name:	Breathing Circuit Filter
Classification Name:	Breathing circuit bacterial filter device CAH, Class II 21CFR868.5260

Emergency Filtration Products, Inc. wishes to introduce to the market the Series 1 Breathing Circuit Filter, a filter device intended to remove microbiological and particulate matter from the gases in a breathing circuit similar to the SIMS Portex, Inc. Breathing Filter and Filtered HME.

The Series 1 Breathing Circuit Filter features include the following:

- Hydrophobic filter media
- Hydrophilic filter media
- Sonic welded housing
- ISO compliant

Intended Use:	The Series 1 Breathing Circuit Filter is a filter device designed for use with all ISO compliant airway management systems including ventilators, respirators and anesthesia circuitry.
Technological Characteristics:	None
Substantial Equivalence:	Substantial equivalence is based on independent laboratory testing performed at Nelson Laboratories and the University of Cincinnati. The Series 1 Breathing Circuit Filter met all standards for filtration and humidity control consistent with industry standards.
Clinical Data:	Not available.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Mr. Douglas Beplate
Emergency Filtration Products, Inc.
4335 South Industrial Road, Suite 440
Las Vegas, NV 89103

Re: K012958
Series 1 Breathing Circuit Filter
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II (two)
Product Code: CAH
Dated: November 27, 2001
Received: January 10, 2002

Dear Mr. Beplate:

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.

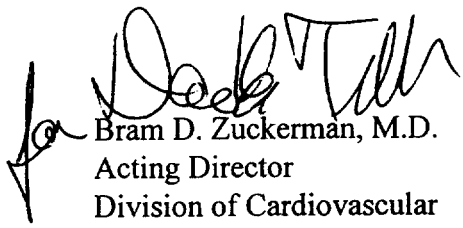
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K012958

Device Name: Breathing Circuit Filter

Indications For Use:

Heat and passive humidification with filtration between patient and circuit. Designed for use with ventilators, anesthesia machines, and open flow systems where filtration of inspired or expired gases is required such as in hospitals, surgical centers, long term health care facilities and institutions utilizing anesthesiology or respiratory equipment. Place at machine end on the inspiratory and/or expiratory side of the patient circuit. Single patient use. For prescription use only. For sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012958

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)