AUG - 5 1998

K980052

Emergency Filtration Products, Inc.

Manufacturers of the RespAide™ CPR Mask
321 North Mall Drive, Suite H-103, St. George, UT 84790
500 North Rainbow, Suite 300, Las Vegas, NV 89107
Tel: 435-656-3697; Fax: 435-656-5610
E-Mail: efpinc@infowest.com

510 (K) Summary

Emergency Filtration Products, Inc.
321 North Mall Dr., Suite H103
St. George, UT 84790
(435)656-3697, (435)656-5610 FAX

Michael J. Crnkovich, President
1/2/98 Date Prepared

Device Name:	RespAide™
Common Name:	Valve for CPR Assistance
Classification Name:	Non re-breathing valve 21 CFR 868.5870 73 CBP, Class II

Emergency Filtration Products, Inc. wishes to introduce to the market the RespAide™ air filtering CPR assistance mask, a device similar to the Laerdal pocket mask. Both products are one way valve, CPR assistance masks.

RespAide™ features include the following:

- One Way Valve with Hydrophobic and Hydrophilic Filters
- Pillow Mask
- ISO Fittings

- Nylon Stuff Sack
- Mouthpiece
- Latex Gloves
- Antiseptic Wipe
- Biohazard Bag for disposal after use

Intended Use

RespAide™ is designed to be used in an emergency situation where CPR assistance is required. RespAide™ offers to the administrator of CPR the comfort that the risk of transmission of various pathogens is greatly reduced and, therefore, the hesitancy factor for providing CPR is overcome. RespAide™ should be made available to all consumers for office, automobiles, boats, swimming pools, industry, airlines, and anywhere an incident of respiratory or cardiac arrest may occur.

Technological Characteristics

None.

Substantial Equivalence

Substantial equivalence is based on independent laboratory testing performed at Nelson Laboratories where RespAide™ met and exceeded all standards for filtration and differential air flow 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

AUG - 5 1998

Mr. Doug Beplate
Emergency Filtration Products, Inc.
321 North Mall Drive, Suite H-103
St. George, UT 84790

Re: K980052
RespAide
Regulatory Class: II (two)
Product Code: 73 CBP
Dated: July 20, 1998
Received: July 23, 1998

Dear Mr. Beplate:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices:

General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K980052/S2

510(k) Number (if known): K980052

Device Name: RespAide

Indications For Use: Non Re-Breathing Valve, 73 CBP, Class II under CFR 868.5870
Respiratory assisted device - used in cardiac or respiratory arrest to assist in cardiopulmonary resuscitation (CPR).

FDA/CDRH/ODE/DHC
23 Jun 03 05 14

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OK-1

Prescription Use_____ OR Over-The-Counter Use ✓

Mark Milner

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices