DEC 17 1998

K983403

9.2 Salter Labs Nebulizer Aerosol Expiration Filter 510(k) Summary

In accordance with 21 CFR section 807.92 Salter Labs is submitting the following safety and effectiveness summary.

1) Submitter Information

Salter Labs
100 W. Sycamore Road
Arvin, CA 93203
(805) 854-3166

2) Name of Device

Proprietary Name: Salter Labs Nebulizer Exhalation Aerosol Filter
Common Name is Exhalation Filter
Classification Name: Breathing Circuit Bacterial Filter

3) Substantially equivalent to Pari Exhalation Filter, K926455.

4) Device Description and System Overview:

The Salter Labs Aerosol Filter is designed to connect to the exhalation valve of the Salter Labs nebulizer mouthpiece. Since the exhalation valve of the Salter Labs Nebulizer product is designed with a non-standard diameter, the Salter Labs Nebulizer Exhalation Aerosol Filter is configured in such a way that it only fits the Salter Labs nebulizer product line: this device is not intended to be used with any other product. Product labeling clearly defines this product as an accessory to the Salter Labs nebulizer assembly.

The aerosol filter is a rectangular component that has been preformed to fit into an injection molded plastic housing. There are two design configurations: disposable and reusable. The reusable configuration allows the filter to be easily inserted and removed after each use. The filter is specified as a bacterial filter, although the intended use of the device is to remove aerosol particles, only. The surface area of the filter is ≥ 6.0 square inches, resulting in a specified resistance (exhalation force) of ≤ 2.0 cm H_20 from the patient. Product design performance has been validated using product design specifications according to Salter Labs procedures and validation requirements.

There are two defined product configurations for this device: disposable and reusable.

5) Statement of Intended Use:

The Salter Labs Nebulizer Exhalation Aerosol Filter is indicated for all circumstances where the reduction of medical aerosols during nebulizer use is required or recommended. The Salter Labs Nebulizer Exhalation Aerosol Filter comes in two configurations: a disposable device, which has a filter contained within a permanently sealed plastic case, and a reusable device designed to be used with Salter Labs nebulizer product. The Salter Labs Exhalation Aerosol Filter is intended to be used to reduce the amount of

unused medical aerosols exhaled by the patient using the Salter Labs nebulizer system. The product specification calls for at least a 95% effectiveness at aerosol removal. No claims of bacterial filtration effectiveness are made or intended.

6) Comparative data concerning the Salter Labs Nebulizer Aerosol Filter and competitive products follows:

   a) Technological Characteristics and Comparison:

	Salter Labs: Disposable Filter	Salter Labs: Reusable Filter	Pari	Marquest	King Systems
Brand Name:	Exhalation Aerosol Filter	Exhalation Aerosol Filter	Exhalation Filter	Respirguard II Filter	Virobac II Filter
Model #:	TBD	TBD	unknown	303	20800
Filter Type:	Hydrophobic Filter	Hydrophobic Filter	Hydrophobic Filter	Hydrophobic Filter	Hydrophobic Filter
Filter Manufacturer:	3M	3M	3M	3M	3M
Filter Material:	0.3 micron Filtrete Material	0.3 micron Filtrete Material	0.3 micron Filtrete Material	0.3 micron	0.3 micron
Total Filter Area:	≥ 6.0 sq. inches (rectangular)	≥ 6.0 sq. inches (rectangular)	approximately 4 sq. inches (circular)	approximately 4 sq. inches (circular)	approximately 4 sq. inches (circular)
Single-Use/ Reusable:	Disposable	Reusable (1 year)	Reusable (1 year)	Disposable	Disposable
Reuse Claims:	none	1 year	1 year	none	none
Sterile/Non-Sterile:	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Intended Use:	Nebulizer	Nebulizer	Nebulizer	Nebulizer, humidifier, O_2 Concentrator	Nebulizer, humidifier, O_2 Concentrator
Target Population:	Home Care & Hospital	Home Care & Hospital	Home Care & Hospital	Home Care & Hospital	Home Care & Hospital
Aerosol Filtration?	Yes	Yes	Yes	Yes	Yes
Bacterial Filtration?	No	No	Yes (but used primarily as aerosol filter)	Yes	Yes
Exhalation Resistance Force:	0.8 cm/H_2O**	0.8 cm/H_2O**	0.8 cm/H_2O (no valve) 7.0 cm/H_2O (with valve)**	1.2 cm/H_2O	unknown
Connector Size:	.794" (non-standard Salter sized connector)	.794" (non-standard Salter sized connector)	22mm	22mm	22mm

b) Brief Description of Non-Clinical Tests Identified in the Premarket Notification:

- performance validation to design specification
- aerosol removal testing and validation

c) Clinical Tests submitted: None.

d) Conclusions of all Testing: The Salter Labs Nebulizer Expiratory Aerosol Filter (in both the disposable and reusable configurations) met all design requirements and passed all validation test requirements. It was shown to have a > 95% rate of aerosol removal efficiency, with aerosols in the 1 to 10 micron range, with an average efficiency rating exceeding 99%. Aerosol sizes monitored varied from .01 microns to 9.9 microns. Typical aerosol sizes generated during nebulization range from 1 micron to 5 microns.

Cleaning and Reuse:

Only the Reusable Aerosol Filter is intended for reuse. The Salter Labs Reusable Nebulizer Exhalation Aerosol Filter is designed to be cleaned prior to each use. Cleaning instructions are contained in product literature and include directions for washing, chemical cleaning and short term autoclaving. Since this device is incorporated in the exhalation path of the Salter Labs Nebulizer family, this device is provided and intended to be used in a non-sterile condition.

Product Warranty:

Standard product warranties apply to the disposable product. The reusable product is warranted for one year. All products are warranted to be free of defects at time of receipt.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1998

Mr. Duane Kazal
Salter Labs Inc.
100 W. Sycamore Road
Arvin, CA 93203

Re: K983403
Salter Labs Nebulizer Exhalation Aerosol Filter
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: September 15, 1998
Received: September 28, 1998

Dear Mr. Kazal:

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 (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). 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 (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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 our 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

510(k) Number: K983403 ~~Unknown~~

Device Name: Salter Labs Nebulizer Exhalation Aerosol Filter.

Indications For Use:

This product is indicated for use whenever the physician or healthcare professional administering or prescribing medical aerosol products to a patient with a Salter Labs nebulizer wishes to minimize the amount of medical aerosol exhaled into the air.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Mark Mendoo 12-16-98
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number