AUG - 6 1999

K991788

13. Salter Labs PEP Device 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 PEP Device
Common Name is PEP Device
Classification Name: Nebulizer Accessory

3) Substantially equivalent to: Pari PEP Device

4) Device Description and System Overview:

The Salter Labs PEP Device (PEP Device) is a non-sterile, injection molded plastic device that will attach to the exhalation valve of the Salter Labs NebuTech™ Model 8960 & 8660 Nebulizer mouthpiece assembly or to the NebuTech™ mouthpiece placed in line in a 25 to 50 cm flex tube with a one-way valve at the distal opening. In either of these assemblies, the PEP Device will regulate the force and flow of exhalation to provide a specific therapeutic effect. The device is intended to be single patient use and is prescribed by a physician or licensed clinician.

The purpose of the Salter Labs PEP Device is to allow for a variable regulation of exhalation resistance through a selectable set of orifices in order to obtain a resistance at a given flow rate. The restriction of exhalation serves to open closed airways, enhancing aerosol deposition, increasing oxygenation and improving bronchial hygiene.

The Salter Labs PEP Device has a variable exhalation resistance capability. Effective exhalation resistance is determined by rotation of a "handle," located at the top of the device. The handle is connected to a disk that contains a set of predetermined exit ports. The diameter of these ports establishes the resistance to exhalation.

A manometer may be placed on the device port in order for the clinician to determine the correct resistance for each patient. This will also help the patient determine what

a proper exhalation force feels like. The patient will be instructed by the clinician on proper breathing techniques and the manometer will be used to assure that exhalation pressure ranges do not exceed 20cm of water pressure, which is considered to be the maximum average therapeutic target value. The prescribing doctor or licensed clinician will determine all appropriate settings and device use and application to meet the particular requirements of his/her patient.

Pressure Relief Valve:

The Salter Labs PEP Device is unique to current predicate devices in that it incorporates a pressure relief valve. This spring-activated valve is designed to open whenever exhalation pressures exceed 20cm water pressure, thereby helping to assure consistent product performance with minimum discomfort to the patient. Instructions are included with each device, and are intended for use by the clinician in his/her instructions of device use by the patient. As with all PEP devices, this device is intended to be used by each patient according to the specific directions of his/her clinician.

System Similarities and Differences to Currently Marketed Devices

The Salter Labs PEP Device and the predicate devices upon which equivalence is sought share the same purpose: to serve as a means of producing a controllable exhalation flow resistance in order to provide a small positive pressure in the lungs for lung exercise or during nebulizer aerosol treatment. This positive pressure allows for enhanced aerosol deposition within the lungs.

Additional Remarks: Similarities and Differences to Predicate Devices:

1. The Salter Labs PEP Device has an overpressure relief valve. The intent of this device is to provide device flow resistance to 20 cm H_20, which is considered to be an appropriate therapeutic value.

2. The Salter Labs PEP Device has been designed and is intended for use only with the Salter Labs Nebutech Nebulizer Mouthpiece. Product labeling clearly states that the PEP Device is intended for use only with the Salter Labs Nebutech Nebulizer.

5) Statement of Intended Use:

The purpose of the Salter Labs PEP Device is to allow for a variable regulation of exhalation resistance through a selectable set of orifices in order to obtain a specific resistance at a given flow rate. The restriction of exhalation serves to open closed airways, enhancing aerosol deposition, increasing oxygenation and improving bronchial hygiene.

6) Comparative data concerning the Salter Labs PEP Device and competitive products follows:

a) Technological Characteristics and Comparison of Salter Labs Prototype and Predicate devices at 30 Liters/minute flow rate:

Setting:	Salter Labs PEP back pressure cm H_2O	Pari PEP back pressure cm H_2O	Breather PEP back pressure cm H_2O	Little Puffer PEP: back pressure cm H_2O
1	6.0	5.0	7.5	0.3
2	7.0	7.8	8.5	6.1
3	8.0	12.4	10.0	12.5
4	9.0	19.4	19.0	off-scale
5	9.0	29.6		
6	12.0	60.6		
7	15.0	off-scale		
8	17.0	off-scale		
9	18.0			
10	21.0			

Comparative Test Results at 30 L/min

Where setting #1 represents the largest orifice, with gradually decreasing orifice size corresponding to the increase in setting number.

b. Predicate Devices:

Product:	**Manufacturer:**	**510(k) Number:**
Pari #783 PEP Device	Pari	K972042
Breather PEP Device	Instrumentation Industries, Inc.	K980725
Expiratory Resistance Exerciser	Mercury Medical	K954492

Table 3.1 Predicate Devices

c. Comparative Product Matrix

The chart below compares Salter Labs PEP Device with predicate devices:

	Salter Labs: PEP Device	Pari	III Breather PEP
Brand Name:	PEP Device	PEP Device	Breather
Model #:	TBD	783	Breather
Disposable?	Yes	Yes	Yes
To be used with a specific nebulizer product?	Yes	Yes	No
To be used as a lung exerciser?	Yes	Yes	Yes
Product made from:	polypropylene, ABS or K-Resin		
Prescribed Device?	Yes	Yes	Yes
Used in conjunction with a manometer?	Yes: initially	Yes	Yes
Advertised flow resistance values:	5 to 20 cm H_2O	10 to 20 cm H_2O	unknown
Reuse Claims:	Single Patient	Single Patient	unknown
Sterile/Non- Sterile:	Non-Sterile	Non-Sterile	Non-Sterile
Intended Use:	Flow restriction: use with nebulizer & as lung exerciser	Flow restriction: use with nebulizer & as lung exerciser	lung exerciser
Target Population:	home; hospital; clinic	home; hospital; clinic	home; hospital; clinic
Over pressure protection?	Yes	No	No
Location in the device:	expiratory flow pathway	inspiratory flow pathway	expiratory flow pathway

d. Brief Description of Non-Clinical Tests Identified in the Premarket Notification:

- Verification and Validation testing to design specifications.
- Back pressure testing and comparative product testing.

e. Clinical Tests submitted: None.

Conclusions of all Testing:The Salter Labs Nebulizer PEP Device met all design requirements and passed all validation test requirements. The device functioned properly and exhibited a controllable and predictable flow restriction below the design limit of 20 cm H_2O.

f. Software Validation: Not applicable: there is no software in this product.

g. Sterilization Validation: Not applicable: this product is sold and used as a non-sterile product.

h. Biocompatibility: All materials used in this device are incorporated in other Salter Labs devices, such as their nebulizer product lines and have shown themselves to be appropriate for the intended use described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 1999

Mr. Duane Kazal
Salter Labs
100 W. Sycamore Road
Arvin, CA 93203-2300

Re: K991788
Salter Labs PEP Device
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: May 20, 1999
Received: May 25, 1999

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

Salter Labs
100 W. Sycamore Road
Arvin, CA 93203
(805) 854-3166 (805) 854-3170 fax

FAX

Center for Devices and Radiological Health

510(k) Number (if known): K991788

Device Name: Salter Labs PEP Device

Indications for Use:

This product is indicated for use in patients where enhanced medicated aerosol deposition or lung exercise is recommended by a physician or licensed clinician. This device is intended to be used in the hospital, clinic and home care markets.

The Salter Labs PEP device is designed to be used with the Salter Labs Nebutech Nebulizer-series Mouthpiece as a stand-alone device, or the device may be used in conjunction with the Salter Labs Nebutech Nebulizer and the Salter Labs Aerosol Filter during the nebulization process.

This product is a nebulizer accessory that connects to the exhalation port of the Salter Labs Nebutech Nebulizer mouthpiece and serves to provide a controllable exhalation resistance of from 5 to 20 cm H_2O at flow rates ranging from 10 to 55 L/min.

8-3-99

X PRESCRIPTION USE ___ OVER-THE-COUNTER

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Pou

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991788