JAN - 7 2000

K992285

## 13. Salter Aire Compressor 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 Salter Aire Compressor
Common Name is Portable Air Compressor
Classification Name: Portable Air Compressor

**3) Substantially equivalent to: Medical Industry America Sport-Neb Compressor.**

**4) Device Description and System Overview:**

The Salter Labs Salter Aire Compressor is an AC powered, piston-type compressor that generates pressurized air for a nebulizer. It is designed to be small, light weight and portable. The device is manufactured by Salter Labs to Salter Labs design specifications.

The Salter Aire Compressor will be available in both 115 and 220 VAC models. The units have been designed and built according to applicable requirements of UL 1431 for USA models and IEC 601-1 for European models. All USA versions of the device will be 115VAC.

The Salter Aire Compressor is a prescription device and is designed to be a durable, reusable device that is intended to be used by hospital, clinic and home care markets. It has a 5 year warranty.

**System Similarities and Differences to Currently Marketed Devices**

The Salter Aire Compressor and the predicate devices upon which equivalence is sought share the same purpose: to provide the source of compressed air used to provide pressurized airflow in a nebulizer for the production of aerosol. Like the predicate devices reviewed, the Salter Aire Compressor is intended for the home care market and the hospital market.

All comparative products are essentially equivalent, and many share similar components and have similar output specifications.

Performance characteristics, as tested, are essentially equivalent to predicate devices, and all products share the same basic size and weight. The Salter Aire Compressor has been designed and tested to comply with all appropriate sections of the UL 1431 Standard for Personal Hygiene and Health Care Appliances, and complies with IEC 601-1 for European 220 volt versions.

Other than basic configuration and dimensional differences between the Salter Aire and predicate devices, there are no appreciable differences between units in terms of function, performance or utility.

**5) Statement of Intended Use:**

The Salter Aire Compressor is an AC-powered, piston type air compressor that generates pressurized air for use with a small volume nebulizer to produce an aerosol. This product is intended to be used primarily by patients in the home care market, although it may also be used by trained hospital personnel.

The Salter Aire Compressor is a prescription use, non-sterile, durable device.

**6) Comparative data concerning the Salter Aire Compressor and the defined benchmark predicate device:**

| Test Reading: | Salter Aire Compressor | MIA Sport-Neb |
|---|---|---|
| Internal Temp. | 92.3 to 128.5° F | 80.5 to 134.8° F |
| Dead Head Pressure in p.s.i. | 32 to 38.5 psi | 28 to 40 psi |
| Flow with Nebulizer | 6.7 to 7.5 LPM | 6.2 to 7.1 LPM |
| Free Flow Rate in SLPM | 11.3 to 12.8 LPM | 7.3 to 12.1 LPM |
| Time to Nebulize 3 cc $H_2O$: | 8 minutes | 8.5 minutes |

## b. Predicate Devices:

| Product: | Manufacturer: | 510(k) Number: |
|---|---|---|
| Sport-Neb | Medical Industry America | K964078 |
| Aeromax | Medical Industry America | K942444 |

Table 3.1 Predicate Devices

## c. Comparative Product Matrix

The chart below compares Salter Aire Compressor with predicate devices:

| item: | Characteristic: | Salter Labs Compressor | Medical Industries America Sport-Neb Compressor | Medical Industries America AeroMax Compressor |
|---|---|---|---|---|
| 1 | Type of compressor: | piston | piston | piston |
| 2 | Input power: | 110V 60Hz, 2.5 amps | 110V 60Hz, 1.8 amps | 110V 60Hz, 2.5 amps |
| 3 | Maximum output pressure at nebulizer: | 6.5 lpm | 6 lpm | approx. 6 lpm |
| 4 | Maximum flow: | 11 lpm | 11 lpm | 13 lpm |
| 5 | Operating Environment: | home care and hospital | home care | home care |
| 6 | Maximum operating temperature: | 128.5° F | 134.8° F | 130 ° F |
| 7 | Designed to conform to UL 1431 | Yes | unknown | unknown |
| 8 | Operating Life: | 5 years | 5 years | 5 years |
| 9 | Over-temperature Protection? | Yes | Yes | Yes |
| 10 | Portable? | Yes | Yes | Yes |
| 11 | Case material: | Plastic | Plastic | Plastic |
| 12 | Warranty: | 1 year | 1 year | 1 year |
| 13 | Electromagnetic Compatibility: | conforms to UL 1431, and IEC 601-1 | conforms to UL 1431 (personal hygiene products) | conforms to UL 1431 (personal hygiene products) |

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

- Verification and Validation testing to design specifications.
- Back pressure, flow rate and temperature testing and comparative product testing.
- Shipping test, including multiple container drops from a height of 4 feet onto a concrete floor.
- UL testing to UL 1431 Standard.

**e. Clinical Tests submitted: None.**

**f. <u>Conclusions of all Testing</u>:**

The Salter Labs Salter Aire Compressor met all design requirements and passed all validation test requirements. The device functioned properly and exhibited a predictable flow rate and pressure at an acceptable internal case temperature. The device was demonstrated to possess equivalent performance to predicate devices tested.

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

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

**i. Biocompatibility:** There are no biocompatible issues. No direct patient contact. All air lines are clean and oil-free. A replaceable foam filter maintains air cleanliness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2000

Mr. Gus Bock
Salter Labs
100 W. Sycamore Road
Arvin, CA 93203-2300

Re: K992285
Salter Aire Compressor
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: November 9, 1999
Received: November 12, 1999

Dear Mr. Bock:

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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SALTER LABS

## 3. Intended Use

The Salter Aire Compressor is an AC-powered, piston type air compressor that generates pressurized air for use with a small volume nebulizer to produce an aerosol. This product is intended to be used primarily by patients in the home care market, although it may also be used by trained hospital staff personnel as well.

The Salter Aire Compressor is a prescription use, non-sterile, durable device.

Please refer to section 7 of this submission for product use, testing and results.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992285

prescription use ✓



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