K031908

JAN 1 4 2004

Attachment #2

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

Med2000 SpA
Via dell'Artigianato, 23/25
25080 Padenghe Sul Garda, (BS)
ITALY

Contact:

Mr. Sandro Rossi
CEO

Date Summary Prepared:

January 9, 2004

2. Name of the Device:

1. Med2000 Nebulizer Compressor, Model P1, with Nebulizer
2. Med2000 Nebulizer Compressor, Model P2, with Nebulizer
3. Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories

3. Predicate Device Information:

1. K#013027, Mister Neb ™ Nebulizer Compressor, with Nebulizer, Model HS123, Respironics Healthscan, Inc., Cedar Grove, NJ
2. K#961476, Salter Labs Ultramist Nebulizer, 8960 Series, Salter Labs, Arvin, CA
3. K#014056, Salter Labs Modified Ultramist Nebulizer, Salter Labs, Arvin, CA
4. K#021742, Galemed Neb-Easy Nebulizer, Galemed Corp., Temecula, CA

4. Device Description:

- **Med2000 SpA Nebulizer Compressors, Models P1 and P2:**

The two models (P1 and P2) differ only in minor cosmetic aspects of their shape that have no effect on performance or safety. These piston compressors are housed in a compact, irregularly-shaped white-plastic housing. Dimensions are: 60" x 4.7" x 2.4" for both compressors, and weigh 1.1 lbs. Neither models contain microprocessors. A "power cube" transformer (Med2000 Class 2 power unit) plugs into a wall outlet (2-blade plug) and provides 16 VAC to the motor via a thin 2-conductor cord that plugs into the compressor. The compressors are supplied with compatible patient tubing (2 meters), and will be marketed with a compatible medication nebulizer and respective instruction manuals.

- **Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories:**

The Nebulizer, Model A1/C (AndyFlow), is a device intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing.

This device operates on the Venturi principle and is refillable. It is manufactured using polypropylene plastics, injection molded and is intended for single patient use.

The Nebulizer, Model A1/C (AndyFlow), has several attachments that are used with the nebulizer during the nebulization process. The attachments include a mouthpiece, a 2 meter connecting tube (which connects to the lower part of the nebulizer opposite the mouthpiece), a pediatric breathing mask and an adult breathing mask. These are standard accessories for nebulizer devices.

The Nebulizer, Model A1/C (AndyFlow), is a hand-held pneumatically powered nebulizer that consists of a nebulizer top that is screwed into a nebulizer cup. The bottom of the cup has a fitting to accept a source of nebulizing gas. The device consists of a nebulizer portion (which forms and conveys an aerosol) and a reservoir portion (which contains non-aerosolized drug).

5. Intended Use:

The Med2000 SpA Nebulizer Compressors, Models P1 and P2, are AC-powered air compressors, with adapter, intended to provide a source of compressed air for medical purposes for use in home health care. These devices are provided with

the Model A1/C (AndyFlow) pneumatic nebulizer and should only be used with this nebulizer to produce a fine aerosol mist. of medication for respiratory therapy, for inhalation by a patient for treatment of respiratory disorders such as allergies, asthma, cystic fibrosis, COPD, etc. It can be used with adult or pediatric patients.

The Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories, is a pneumatic nebulizer which, when driven by a compatible air compressor, nebulizes specific inhalable drugs for inhalation by a patient. It can be used with adult or pediatric patients.

6. **Comparison to Predicate Devices:**

Nebulizer Compressors:

The Med2000 SpA Nebulizer Compressors, Models P1 and P2 (difference between models is body shape only) is substantially equivalent to the Mister Neb™ Nebulizer Compressor, with Nebulizer, Model HS123, K#013027, Respironics Healthscan, Inc., Cedar Grove, NJ. This predicate device was cleared with the same indications for use as our device.

Table 1, below, outlines similarities and differences between our nebulizer compressor and the predicate device, as follows:

TABLE 1: NEBULIZER COMPRESSOR COMPARISON CHART

CHARACTERISTICS	MED 2000 SpA NEBULIZER COMPRESSORS WITH NEBULIZER	MISTER NEB™ NEBULIZER COMPRESSOR WITH NEBULIZER
Model	P1 and P2	HS123
Dimensions	6.0" x 4.7" x 2.4" *	7.48" x 7.08" x 4.3"
Weight	2.3 lbs.	3.2.lbs
Electrical Requirements	115 VAC/16 VAC (with AC/AC adapter) 60 Hz	115 VAC/ 60 Hz
Power Consumption	23 watts	81 watts
Maximum Compressor Pressure	29 psig	29 psig
Maximum Flow	15 lpm	Not Available
Typical Performance with Nebulizer (Average Compressor Flow Rate)	9.0 lpm @ 6 psig	8.0 lpm @ 10 psig
Power Indicator	NO	NO
Intensity Control	NO	NO
Intensity Indicator	NO	NO

On/Off Switch	YES	YES
(*) Without AC/AC Adapter		

Nebulizer:

The Med200 SpA Nebulizer, and Accessories, Model A1/C (AndyFlow), is substantially equivalent to the Salter Labs Ultramist Nebulilzer, Model 9860 Series, K#961476 and K#014056, Salter Labs, Aruin, Ca, and, the Galemed Neb-Easy Nebulizer, K#021742, Galemed Corp, Temecula, CA. These predicate devices were cleared with the same indications for use as our device.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The following performance testing was conducted:

- EPA PM 10 Testing
- Nebulizer Particle Characterization Studies
- ISO 10993 Biocompatibility Testing
- Maximum pressure and flow under all combinations of the following:

  - Temperatures of +5º C and +20º C, and 40º C with 90% RH
  - Line voltage of 95, 115 and 132 V

  b. Storage at -20º C and at +60º C
  c. Fluid Spill Resistance
  d. Maximum Surface and Air Temperatures
  e. Sinusoidal Vibration
  f. Impact (drop) Resistance
  g. Leakage Current and Dielectric Withstand (Electrical Safety)

- EMC Testing

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. Conclusions:

The Med2000 SpA Nebulizer Compressors, Models P1 and P2, with Nebulizer, and, a separate Nebulizer, to be known as the Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories have the same intended use and similar characteristics as the predicate. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Med2000 SpA Nebulizer Compressors, Models P1 and P2, with Nebulizer, and, a separate Nebulizer, to be known as the Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 4 2004

Med2000 SpA
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants
55 Northern Blvd
Suite 200
Great Neck, New York 11021

Re: K031908
Trade Name: Med2000 Nebulizer Compressor, Model P1, with Nebulizer
Med2000 Nebulizer Compressor, Model P2, with Nebulizer
Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: II
Product Code: CAF, BTI
Dated: October 22, 2003
Received: October 23, 2003

Dear Ms. Goldstein-Falk:

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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031908

Device Name: Med2000 SpA Nebulizer Compressors, Models P1 and P2, with Nebulizer, and, Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories

Indications For Use:

The Med2000 SpA Nebulizer Compressors, Models P1 and P2, are AC-powered air compressors, with adapter, intended to provide a source of compressed air for medical purposes for use in home health care. These devices are provided with the Model A1/C (AndyFlow) pneumatic nebulizer and should only be used with this nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for inhalation by a patient for treatment of respiratory disorders such as allergies, asthma, cystic fibrosis, COPD, etc. It can be used with adult or pediatric patients.

The Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories, is a pneumatic nebulizer which, when driven by a compatible air compressor, nebulizes specific inhalable drugs for inhalation by a patient. It can be used with adult or pediatric patients.

Prescription Use ___√___ **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **OR** **(21 CFT 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031908