AUG 2 4 2004

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K041974

1. Submitter's Identification:

MED2000 SpA
Via Dell'Artigianato, 23/25
25080 Padenghe sul Garda – Brescia
Italy
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Date Summary Prepared: July 21, 2004

Contact: Mr. Sandro Rossi, CEO

2. Name of the Device:

1. MED2000 SpA Nebulizer Compressor, Model P3, with Nebulizer
2. MED2000 SpA Nebulizer Compressor, Model P4, with Nebulizer
3. MED2000 SpA Nebulizer Compressor, Model P5, with Nebulizer

3. Predicate Device Information:

K# 031908, Med2000 SpA Nebulizer Compressor, Models P1 and P2, with Nebulizer, Med2000 SpA, Italy

4. Device Description:

These line powered piston compressors are housed in a plastic cabinet (case). The plastic cabinet is the only distinctive component between the three devices, that are identical for all other components, material and characteristics. Dimensions are 4.7 in. x 9.1 x 7.5 in. and weight 3.3 lbs. P3, P4 and P5 units contain no microprocessors or other electronic components. They operate from 115 VAC, 60 Hz. Each unit is supplied with an instruction manual and an accessory kit containing a nebulizer –Andyflow- with tubing, an adult and a pediatric mask, a mouthpiece.

In use, the compressor is placed on a flat surface and the nebulizer tubing is connected to the hose barb. Inlet air to the compressor passes through a replaceable filter.

5. Intended Use:

The MED2000 SpA Nebulizer Compressors, Models P1, P2 and P3, are AC-powered air compressors 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.

6. Comparison to Predicate Devices:

The subject devices (P3, P4 and P5) and the predicate devices (P1 and P2) are indicated for the same intended use, meet electrical, mechanical, environmental safety and EMC requirements, and have similar compressor operating pressure and flow ranges. Performance characteristics are basically the same. The differences between the subject devices and predicates are in power consumption and electrical requirements.

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

Testing information demonstrating safety and effectiveness of the P3, P4 and P5 nebulizer compressors, with Nebulizer Andiflow in the intended environment of use is supported by testing that was conducted in accordance with FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

Testing included:

EPA PM 2.5 Testing
EMC testing
Dielectric Withstand
Current Dispersion Test or Leakage Current Test
Surface Temperature Test
Air Temperature Test
Storage conditions
Operating environment extremes
Sinusoidal Vibration Test

Impact Resistance –Drop Test
Fluid Spill Resistance Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the MED2000 SpA Nebulizer Compressors P3, P4 and P5, with Nebulizer device sample(s) tested met all relevant requirements of the aforementioned testing requirements.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The MED2000 SpA Nebulizer Compressors, Models P3, P4 and P5, with Nebulizer, have the same intended use and similar characteristics as the predicate devices. Moreover, bench testing contained in this submission demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the MED2000 SpA Nebulizer Compressors, Models P3, P4 and P5, with Nebulizer, 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

AUG 2 4 2004

MED2000 SpA
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard Suite 200
Great Neck, New York 11021

Re: K041974
Trade/Device Name: Med2000 SpA Nebulizer Compressors, Models P3, P4 and P5, With Nebulizer
Regulation Number: 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: II
Product Code: BTI
Dated: July 21, 2004
Received: July 26, 2004

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

Exhibit #B

510(k) Number (if known): K041974

Device Name: Med2000 SpA Nebulizer Compressors, Models P3, P4 and P5, with Nebulizer

Indications For Use:

The Med2000 SpA Nebulizer Compressors, Models P3, P4 and P5, with Nebulizer, are AC-powered air compressors 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.

Prescription Use ___√___ **(Per 21 CFR 801 Subpart D)** **OR** **Over-The Counter Use**_____ **(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: K041974