JUL 2 0 2004

**Exhibit #1**

## 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: K041327

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: May 17, 2004

2. **Name of the Device:**

MED2000 SpA Nebulizer, AndyFlow Model A1/C with accessories

3. **Predicate Device Information:**

K#031908, AndyFlow Nebulizer Model A1/C with accessories, MED2000 SpA, Italy

4. **Device Description:**

- **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.

5. **Intended Use:**

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.

The Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories, may be used with compatible compressors or an air source providing between 4 and 8 lpm.

6. **Comparison to Predicate Devices:**

The Med200 SpA Nebulizer, and Accessories, Model A1/C (AndyFlow), is substantially equivalent to the K#031908, AndyFlow Nebulizer Model A1/C with accessories, MED2000 SpA, Italy. The difference between the two devices is the labeling change made to the subject device: a flow range between 4 and 8 lpm has been added instead of one value and the pressure value has been deleted.

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

In accordance with the risk analysis testing, the following performance testing was performed:

- Nebulizer Particle Characterization Studies at 4 and 8 lpm ranges

Because the PCS testing revealed that no other parameters were affected, previously performed testing remained unchanged such as:

EPA PM 2.5 Testing
ISO 10993 Biocompatibility Testing

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

Not Applicable

## 9. Conclusions:

The Med2000 SpA Nebulizer AndyFlow Model A1/C with Accessories has 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, AndyFlow, Model A1/C with Accessories is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2004

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

Re: K041327
Trade/Device Name: Med2000 SpA Nebulizer Model A1/C (AndyFlow) with Accessories
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 2, 2004
Received: July 6, 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):** K041327

**Device Name:** The Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories

**Indications For Use:**

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.

The Med2000 SpA Nebulizer, Model A1/C (AndyFlow) with Accessories, may be used with compatible compressors or an air gas source providing between 4 and 8 lpm.

**Prescription Use** X
**(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: K041327