K062014

MAR 2 2 2007

510(k) Summary
for the nebulizer compressors Master Neb, Primo Neb, SC03 , Neb Aid, 4.2.Neb, Q03, FJ03, and Walkie-Neb

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	FLAEM NUOVA Via Colli Storici 221, 223, 225 S. Martino della Battaglia Brescia 25010 Italy
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-207-1246
Summary Preparation Date:	January 30, 2007

2. **Names**

Device Name:	The families of Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, Q03, FJ03, and the Walkie-Neb.
Classification Name:	Portable air compressor Regulation number: 868.6250 Product Code: CAF

3. **Predicate Devices**

The nebulizer compressors Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, FJ03, Q03 and Walkie-Neb are substantially equivalent to a combination of the following devices:

- ✓ Respironics, nebulizer compressor MISTER NEB - K013027,
- ✓ Healthdyne Inc NEBULIZER SYSTEM - K922623,
- ✓ Invacare PRO, COMPACT e PORTABLE DESKTOP Nebulizer – K042483, and
- ✓ Salter Labs SALTER AIRE COMPRESSOR - K992285.

4. Device Description

The nebulizer compressors Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, FJ03, Q03 and Walkie-Neb are a family of nebulizer compressors intended to be used as compressed air generators for pneumatic nebulizers used by patients for aerosol therapy. There are 7 model families with an AC powered motor (Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, FJ03, and Q03) and one model with a DC low voltage motor (Walkie-Neb), with a rechargeable battery pack and an external charger/power supplier.

The 7 AC model families have different plastic housings, which define the model name of the product. Inside they have the same compressor but with different electrical motors, to provide different pneumatic performances.

5. Indications for Use

The nebulizer compressors Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, FJ03, and Q03 are intended to provide a source of compressed air for medical purposes, to be used in home health care and hospital use. The Walkie-Neb model is intended to be used only in home health care.

These devices are indicated to be used with all commercially available small volume pneumatic nebulizers, to produce a fine aerosol mist of medication for respiratory therapy, for both adult and pediatric patients who have been prescribed inhalation therapy or medication.

6. Performance Data

The performance tests performed by Flaem Nuova, as requested in "Reviewer guidance for nebulizers, metered dose inhalers, spacers and actuators" issued in October 1993, demonstrate that Flaem Nuova nebulizer compressors have the same effectiveness as their predicate devices because they have equivalent operating flow rate and pressure. Clinical data were not required.

7. Comparison to Predicate Devices

The Flaem Nuova compressors (Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, FJ03, Q03 and Walkie-Neb) and the predicate devices are indicated for the same intended use (Salter Labs, Salter Aire Compressor, K992285). They have the same AC and DC power supply and meet the same performance, safety and EMC requirements. The AC Flaem Nuova compressors, series F700, have the same compressor, electrical motor and thus the identical operating pressure and flow ranges as the Respironics Mister Neb compressor (K013027). The AC Flaem Nuova compressors series F1000 and F1500 have the same compressor, electrical motor and thus the identical operating pressure and flow ranges as the Healthdyne Inc. NEBULIZER SYSTEM compressor (K922623). The Walkie Neb Model has

mechanical configuration, batteries, charging system and accessories which are substantially equivalent to the configuration of the Invacare Portable Desktop (K042483). Concerning the operating pressure and flow ranges, the Walkie Neb has the equivalent performance to the Respironics Mister Neb compressor (K013027).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Flaem Nuova S.P.A.
C/O Ms. Maureen O' Connell
Regulatory Consultant
O' Connell Regulatory Consultants, Incorporated
5 Timber Lane
North Reading, Massachusetts 01864

MAR 2 2 2007

Re: K062014
Trade/Device Name: Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, FJ03, Q03 and WalkieNeb
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: March 5, 2007
Received: March 7, 2007

Dear Ms. O' Connell:

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.

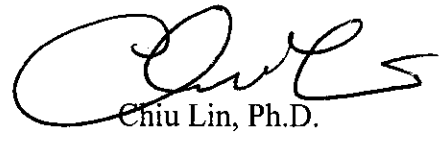
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.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

Indications for Use

510(k) Number (if known): ___________

Device Name: Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, FJ03, Q03 and Walkie-Neb

Indications for Use:

The nebulizer compressors Master Neb, Primo Neb, SC03, Neb Aid, 4.2.Neb, FJ03, and Q03 are intended to provide a source of compressed air for medical purposes, to be used in home health care and hospital use. The Walkie-Neb model is intended to be used only in home health care.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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