JUN - 8 2007

CONFIDENTIAL

K062484

510(k) Summary of Safety and Effectiveness for the Flaem Nuova RF6 Basic and RF6 Plus Nebulizers

This 510(k) Summary of Safety and Effectiveness 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
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Summary Preparation Date: August 23, 2006

2. Names

Device Name: RF6 Basic
RF6 Plus

Classification Name: Nebulizer
Regulation number: 868.5630
Product Code: CAF

3. Predicate Devices

The Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** are substantially equivalent to a combination of the following devices:

- ✓ Salter Labs, **8660 Series**– K962879
- ✓ Pari **LC STAR Reusable Nebulizer 22F50** - K963924
- ✓ Medic-Aid - **Sidestream Nebulizer** - K991725

4. Device Description

The Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** are hand-held, reusable, single patient use and pneumatically powered nebulizers. Both devices are made using similar materials and are used by patients with the same accessories set (mouthpiece, masks etc...). The primary difference

between the two devices is that the RF6 Plus is equipped with inspiration and expiration valves while the RF6 Basic is not.

5. **Indications for Use**
The Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** are reusable single patient use nebulizers which are used where a fine aerosol mist of medication must be delivered to a patient for the treatment of respiratory disorders. The Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** are intended to be used for both adult and pediatric patients who have been prescribed inhalation therapy or medication in both home health care and hospital use. The Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** may be used with compressed air or an air gas source providing air flow between 4 to 10 lmin.

6. **Performance Data**
The performance tests performed by Flaem Nuova, as required by the "Reviewer guidance for nebulizers, metered dose inhalers, spacers and actuators" issued on October 1993, demonstrate that the Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** have the same effectiveness as the identified predicate devices because they have equivalent performance parameters as the predicate devices including: MMAD, FPF, DD and DDR. MMAD, FPF, DD and DDR are the parameters used to evaluate the performance of nebulizers. Clinical data are not submitted because they are not required.

7. **Comparison to Predicate Devices**
The Flaem Nuova RF6 nebulizers and their predicate devices are indicated for the same intended use and have equivalent design solutions as the predicate devices. They have the same atomization principle used by all the nebulizers. The RF6 Plus has the same the valve system as that used in the Pari LC STAR (K963924). The RF6 Basic is similar to the Medic-Aid SIDESTREAM Nebulizer (K991725). In addition, the Flaem Nuova RF6 Nebulizers performance is equivalent to the predicate devices as shown in the bench tests presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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FLAEM NUOVA S.p.A.
C/O Maureen O'Connell
Regulatory Consultant
O'Connell Regulatory Consultants, Incorporated
5 Timber Lane
North Reading, Massachusetts 01864

Re: K062484
Trade/Device Name: Flaem Nuova RF6 Basic and RF6 Plus Nebulizers
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 05, 2007
Received: June 06, 2007

Dear Mr. 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.

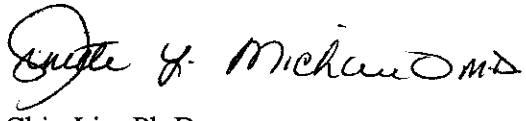
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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: Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers**

Indications for Use:

The Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** are reusable single patient use nebulizers which are used where a fine aerosol mist of medication must be delivered to a patient for the treatment of respiratory disorders. The Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** are intended to be used for both adult and pediatric patients who have been prescribed inhalation therapy or medication in both home health care and hospital use. The Flaem Nuova **RF6 Basic and RF6 Plus Nebulizers** may be used with compressed air or an air gas source providing air flow between 4 and 10 lmin.

NOTE

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)

[illegible] Sign-Off)
[illegible]ision of Anesthesiology, General Hospital,
[illegible]ection Control, Dental Devices

510(k) Number: K062484