K971044

2. Premarket Notification [510(k)] Summary

Date of application : Feb-28-1997

NOV 13 1997

Applicant and manufacturer : **LA DIFFUSION TECHNIQUE FRANCAISE**
114/120 Rue Bergson, B.P. 132
42003 SAINT ETIENNE Cedex 1
FRANCE

Contact person : **Michel MASSARDIER, General Manager.**

Telephone : **(33) 4.77.74.51.11**
Fax : **(33) 4.77.79.67.72**

Device trade name : **ATOMISOR**

Reference : **AL with NL9 Nebulizer**

Device common or usual name or classification : **AEROSOL GENERATOR**

Intended use : **Delivery of aerosol to the airways**

Marketed device to which equivalence is claimed : **PRONEB (Pariboy)**

The ATOMISOR AL is a small and easy to use portable compressor for jet nebulizer aerosol generator. The pump inside is a diaphragm pump and the casing of the compressor is made of metal with a plastic carrying handle on top. In order to ease its' transportation, in case of rental for example, the ATOMISOR AL can be sold with a PVC carrying case in which both the compressor and the nebulizer can be placed. When used, the compressor is removed from the carrying-case.

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COMPRESSORS	PRONEB	ATOMISOR AL
Size	3 ¾" x 6 ½" x 8 ¼"	8.2" x 5.5" x 6.6"
Weight	4.2 pounds	9.7 pounds
Sound level	49 decibels	65 decibels
Electrical Requirements	120 V AC, 0.8 A, 60 Hz	110 V AC, 0.55 A, 60 Hz
Ambient Temperature Range	10 °C-40 °C -(50 ° F-104 °F)	10°C- 40° C (50° F - 104° F)
Power Wattage	45 W (96 VA)	60 VA
Safety systems	Thermal proctection against overheating	Not necessary
Replaceable, External Fuses	NO	YES
Compressor	Diaphragm type, oil free	Diaphragm type, oil free
Replaceable, External filter	Cellulose	N/A
NEBULIZERS	PARI LC	ATOMISOR NL9
Average Nebulization Time	5.5 - 7 minutes	10 minutes
Nebulizer Output Rate	0.32 ml/minute	0.2 ml/minute
M.M.A.D.	4.0 microns	1.8 microns
Particle Size Range	0.5 - 5 microns	80% between 0.5 and 5.5 microns
Nebulizer Type	Reusable	Reusable
Cleaning	Handwash, dishwasher	Handwash, boiling water, dishwasher
Autoclave	Autoclave at 277°F, 10 minutes	Autoclave at 277°F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1997

LA Diffusion Technique Francaise
c/o Ms. Cheryl Ward
Medical Consulting Service, Inc.
P.O. Box 162283
Altamonte Springs, Florida 32716-2283

Re: K970844
Atomisor
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: February 28, 1997
Received: March 7, 1997

Dear Ms. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K970840

Device Name : ATOMISOR AL + NL9 NEBULIZER

Indications For Use :

The ATOMISOR AL + NL9 NEBULIZER is an aerosol generator for the delivery of aerosol to the airways. Because they have been designed to be operated together, the ATOMISOR NL9 nebulizer and the ATOMISOR AL compressor should never be used separately.
Caution : Federal law restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

A. Gorbowski

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)