K020797

MAY 0 3 2002

H. 510(k) Summary

Submitter: Nidek Medical Products, Inc.
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Date Submitted: 31 December 2001

Trade Name of Device: Pulmo-Mist Compressor

Common Name: Nebulizer

Classification Name: Nebulizer (Direct Patient Interface)
21 CFR 868.5630

Equivalent Legally Marketed Device: Invacare Model IRC 1001 Envoy Jr.

Description: The Pulmo-Mist compressor is an electrically powered piston type compressor that provides approximately 6 l/min of air flow against a back pressure of 10 psig. It is designed to supply air to a small volume nebulizer. The package optionally contains a legally marketed small volume disposable nebulizer kit, specifically the Westmed "VIXONE®", manufactured by Westmed, Inc. and private labeled for distribution by Nidek Medical Products, in the original manufacturer's unopened package,
Each such package includes a mouthpiece, a nebulizer, a connector tube and flexible air tubing and labeling.
The nebulization particle size varies slightly depending on the nebulizer used and on the viscosity of the material being nebulized. When used with the VIXONE, the MMAD is approximately 1 µm with a saline solution. Other manufacturers of small volume nebulizers report similar values for similar flow rates.

The Pulmo-Mist compressor is a portable unit. It weighs approximately 3.2 pounds and has dimensions of 7.5 in w x 4.5 in h x 7.5 in d.

Intended Use:	The intended use of the Pulmo-Mist compressor is to supply compressed air to a nebulizer to produce aerosolized medications as prescribed by a physician. The Pulmo-Mist compressor is designed for use by adult or pediatric patients requiring aerosolized medications.
Technological Characteristics:	The Pulmo-Mist compressor is technically equivalent to the referenced legally marketed device. Both devices comprise three basic components: a) an a.c. motor driven compressor which is from the same component supplier and the same model compressor, b) an ABS thermoplastic enclosure, and c) wiring, switch and interconnecting tubing. Both devices supply air to small volume nebulizers. The device contains no microprocessors or other electronic components that emit or are susceptible to electromagnetic interference.
Performance Data:	The Pulmo-Mist compressor was tested in accordance with the electrical, mechanical and environmental performance requirements for home use respiratory devices described in the Anesthesiology and Respiratory Devices Branch's March 1992 document entitled "Reviewer Guidance for Home Use Respiratory Devices" and the November 1993 document entitled "Reviewer Guidance for Premarket Notification Submissions". The Pulmo-Mist compressor met all the required performance criteria and functioned as intended. Additionally, the Pulmo-Mist compressor was designed according to Underwriter's Laboratory (UL) UL544 Standard for Medical and Dental Equipment and UL 1431 Standard for Personal Hygiene and Healthcare Appliances. Summary results for the legally marketed device show equivalent performance.
Conclusion:	Based on information contained in this 510(k) submission, Nidek Medical Products, Inc. concludes that the Pulmo-Mist compressor is substantially equivalent to the referenced legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2002

Nidek Medical Products, Inc.
c/o Pamela K. Gwynn
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle, NC 27709

Re: K020797
Pulmo-Mist Compressor Model #4323
Regulation Number: 868.6250, and 868.5630
Regulation Name: Portable Air Compressor, and Nebulizer
Regulatory Class: II (two)
Product Code: 73 BTI, and 73 CAF
Dated: April 18, 2002
Received: April 22, 2002

Dear Ms. Gwynn:

This letter corrects our substantially equivalent letter of May 3, 2002 regarding the indications for use of your device. Our letter incorrectly limited your device to use in military environments.

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 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). 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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number K020797

Device Name: Pulmo-Mist Nebulizer Compressor

Indications for Use: The Pulmo-Mist Nebulizer Compressor is intended to be used to supply a continuous positive pressure to a nebulizer device for the purpose of generating an aerosol medicine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020797

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