K041418

JUN 1 0 2004

CardinalHealth

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McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Airlife™ Misty Finity™ Large Volume Continuous Nebulizer

Manufacturer:	Cardinal Health Corporation 1300 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact:	Lavenia Ford 1500 Waukegan Road MPWM McGaw Park, IL 60085
Telephone:	(847) 785-3323
Date Summary Prepared:	March, 2004
Trade Name:	Airlife™ Misty Finity™ Large Volume Continuous Nebulizer
Classification:	Class II per 21CFR § 868.5630
Classification Name:	Nebulizer
Predicate Device:	Westmed Heart Continuous Large Volume Nebulizer
Description:	The nebulizer is a single patient use device, which is filled with a fluid, typically respiratory medication and connected to an air source via flexible tubing. The nebulizer works by having the fluid come into contact with the steam of gas. The gas shatters the liquid into small particles. These particles then impact a baffle that further reduces the size of the particles. The majority of the larger particles settle inside the nebulizer as a result of gravity and inertia, returning the mist to liquid to repeat the nebulization process. The smaller particles are then administered as the patient inhales. The treatment is completed when the majority of fluid is nebulized.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Airlife™ Misty Finity™ Large Volume Continuous Nebulizer

Intended Use: This device is intended to be used to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. It's use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using the Airlife™ Misty Finity™ Large Volume Continuous Nebulizer. This product is a single patient use, non-sterile prescriptive device and is designed to be used in either a hospital, nursing homes, extended care facilities or outpatient clinics.

Substantial Equivalence: Airlife™ Misty Finity™ Large Volume Continuous Nebulizer is substantially equivalent to the Westmed Heart Continuous Large Volume Nebulizer

Summary of testing: All materials used in the fabrication of the Airlife™ Misty Finity™ Large Volume Continuous Nebulizer were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices"and were found similar to the predicate. These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use. Note Table below:

Characteristic	(Proposed Cardinal) Airlife Misty Finity Large Volume Continuous Nebulizer	(Predicate WestMed) Heart Large Volume Continuous Nebulizer K963910
Intended Use	This device is intended to be used to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing	Same
Type of Device	Disposable, Sold Non-Sterile, Single Patient Use	Same
Type of Air Source	Compatible with compressed air systems	Same
Nebulizer Flow Rates	10 lpm	10 or 15 lpm
Maximum Fill Capacity	240 ml	Same
Patient Population	Infant, Pediatric and Adult	Same
Accessories	Aerosol Masks, Tubing	Same
Materials	Thermo Plastics	Same
Manufacturing Process	Plastic Molding	Same

SMDA REQUIREMENTS (continued)

Summary of Testing:

"Performance evaluation of the proposed and predicated devices consisted of cascade impaction and output rate testing. Cascade impaction was conducted at a flow rate of 28.3 L/min, evaluating MMAD, GSD and deposited drug masses (total within impactor, at each stage and between 0.4 - 4.7 microns). Three different drug classes were tested; beta-agonist bronchodilator, anti-cholinergic bronchodilator and anti-inflammatory drugs. Test results found the performance of the Misty Finity substantially equivalent to the predicate device."

Test Description and Performance Summary - Particle Size

"%0.4 - 4.7 microns was calculated by summing the drug masses deposited onto stages 3-7 and dividing by the total mass collected in the impactor."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Cardinal Health
C/O Mr. Ned Devine
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K041418
Trade/Device Name: Airlife Misty Finity Large Volume Continuous Nebulizer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated on Submission: May 27, 2004
Date Received in ODE: May 27, 2004

Dear Mr. Devine:

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

Indications for Use

510(k) Number (if known): K041418

Device Name: Misty Finity™ Large Volume Continuous Nebulizer

Indications for Use:

This device is intended to be used to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Continuous Large Volume Nebulizer. This product is a single patient use, non-sterile prescriptive device and is designed to be used under medical supervision in hospitals, nursing homes, extended care facilities or outpatient clinics.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041418