K123527

CareFusion

1500 Waukegan Road
McGaw Park, Illinois
60085-6787
847-473-7208 tel
847-473-7774 fax
carefusion.com

APR 25 2013

510(K) Summary of Safety and Effectiveness

Summary of 510(k) safety and effectiveness in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION

Name	CareFusion
Address	1500 Waukegan Road MPWM, McGaw Park, IL 60085 USA
Phone number	(847) 473-7208
Fax number	(847) 473-7774
Establishment Registration Number	8030673
Name of contact person	Erika Fernandez
Date prepared	November 14, 2012

NAME OF DEVICE

Trade or proprietary name	AirLife Small Volume Nebulizer
Common or usual name	Small Volume Nebulizer
Classification name	Nebulizer
Classification panel	73 Anesthesiology
Regulation	Class II per 21CFR §868.5630, Product code CAF
Legally marketed device(s) to which equivalence is claimed	K023602: AirLife Misty Max 10 Nebulizer K962879: NebuTech HDN
Device description	Pneumatic jet nebulizer that aerosolizes medication by driving a high pressure gas through the jet stem across the one piece jet immersed in the solution.
Intended use	This device is intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing. The patient population includes adults, pediatrics, and infants that are spontaneously breathing. The product is a prescriptive device intended to be used in a hospital setting.

CareFusion

1500 Waukegan Road
McGaw Park, Illinois
60085-6787
847-473-7208 tel
847-473-7774 fax
carefusion.com

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
	Proposed Device	Predicate Device
Intended Use	This device is intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing. The patient population includes adults, pediatrics, and infants that are spontaneously breathing.	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 Misty Max 10 nebulizer. This product is a single patient use, non-sterile prescriptive device and is designed to be used in either a hospital or homecare environment.
Indications for Use	This device is intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing. Its use is indicated when a licensed healthcare professional prescribes or administers medical aerosols to a patient using a small volume nebulizer. The patient population includes adults, pediatrics, and infants that are spontaneously breathing. The product is a single-patient; non-sterile, disposable, prescriptive device intended to be used in hospital setting.	The AirLife Misty Nebulizer is a pneumatic nebulizer which nebulizes specific drugs for inhalation by a patient. The patient population includes infant, pediatric and adult patients. Its use is indicated whenever a physician or healthcare professional administer or prescribes medical aerosol products to a patient using a small volume nebulizer. This product is a single patient use, non-sterile prescriptive device and is designed to be used in either a hospital or homecare environment.
Patient Population	adult, pediatric, infant	Same
Type of Device	Disposable Non-Sterile Single-Patient Use	Same
Core Technology	Pneumatic Jet	Same
Type of Gas Source	Compressed Air or Oxygen	Same
Nebulizer drive flow rates (LPM)	8 ± 1 LPM	6-10 LPM
Maximum Fill Capacity (mL)	10 mL	Same

CareFusion

1500 Waukegan Road
McGaw Park, Illinois
60085-6787
847-473-7208 tel
847-473-7774 fax
carefusion.com

Performance Data
Summary of non-clinical tests conducted for determination of substantial equivalence
Performance Test Summary
1. Biocompatibility Biocompatibility tests on the final finished product were performed according to ISO 10993-1. Cytotoxicity, Sensitization and Irritation studies were concluded with satisfactory results. **2. Simulated Life-Time** No performance degradation was observed for at least 50 treatments

CareFusion

1500 Waukegan Road
McGaw Park, Illinois
60085-6787
847-473-7208 tel
847-473-7774 fax
carefusion.com

3. Aerosol Characterization

		Recommended Nebulizer Set Flow Rate 8 ± 1 LPM					
Drug Description	**Aerosol Characteristic**	**7 LPM**		**8 LPM**		**9 LPM**	
Albuterol Sulfate (Adrenergic Bronchodilator, Beta-2 agonist). Typical dose 2.5 mg/3 ml (0.083% by volume) or 2500 µg of drug substance.	MMAD (µm)[2]	4.5 ± 0.1 µ		3.8 ± 0.1 µ		3.5 ± 0.1 µ	
	GSD[3]	2.1 ± 0.04		2.1 ± 0.02		2.1 ± 0.05	
	Extra-fine particles (< 1 µm)[4]	5.9 ± 0.3%	67 ± 5 µg	7.1 ± 0.3%	75 ± 2 µg	7.6 ± 0.4%	74 ± 4 µg
	Fine particles (< 5 µm)[4]	52 ± 2%	582 ± 27 µg	59 ± 1%	626 ± 12 µg	64 ± 2%	619 ± 24 µg
	Coarse particles (> 5 µm)[4]	48 ± 2%	547 ± 31 µg	41 ± 1%	438 ± 23 µg	36 ± 2%	354 ± 17 µg
	Respirable particles (1-5 µm)[4]	46 ± 2%	515 ± 24 µg	52 ± 1%	551 ± 12 µg	56 ± 2%	545 ± 23 µg
	Total mass of drug (in nebulizer)[5]	2500 µg		2500 µg		2500 µg	
	Total Delivered Mass of Aerosol[6]	45 ± 2%	1129 ± 38 µg	42 ± 1%	1064 ± 25 µg	39 ± 1%	973 ± 23 µg
	Average Treatment Time (minutes)[7]	3.4 ± 0.1		3.0 ± 0.1		2.7 ± 0.1	
Budesonide Suspension (Corticosteroid). Typical dose 0.50 mg/2 ml or 500 µg of drug substance.	MMAD (µm)[2]	5.6 ± 0.1 µ		5.1 ± 0.1 µ		4.7 ± 0.2 µ	
	GSD[3]	1.9 ± 0.03		1.9 ± 0.04		1.9 ± 0.1	
	Extra-fine particles (< 1 µm)[4]	4.8 ± 1.6%	11 ± 4 µg	4.7 ± 0.6%	9.4 ± 1.1 µg	7.0 ± 1.1%	13 ± 2 µg
	Fine particles (< 5 µm)[4]	39 ± 2%	87 ± 6 µg	45 ± 2%	92 ± 2 µg	50 ± 3%	93 ± 3 µg
	Coarse particles (> 5 µm)[4]	61 ± 2%	134 ± 10 µg	55 ± 2%	112 ± 8 µg	50 ± 3%	95 ± 8 µg
	Respirable particles (1-5 µm)[4]	35 ± 2%	78 ± 6 µg	41 ± 1%	83 ± 2 µg	43 ± 2%	80 ± 23 µg
	Total mass of drug (in nebulizer)[5]	500 µg		500 µg		500 µg	
	Total Delivered Mass of Aerosol[6]	44 ± 2%	222 ± 14 µg	41 ± 2%	205 ± 9 µg	38 ± 1%	188 ± 7 µg
	Average Treatment Time (minutes)[7]	1.9 ± 0.1		1.9 ± 0.1		1.7 ± 0.1	
Cromolyn Sodium (Nonsteroidal Anti-asthma Medication). Typical dose 20 mg/2 ml or 20000 µg of drug substance.	MMAD (µm)[2]	4.7 ± 0.2 µ		3.9 ± 0.1 µ		3.5 ± 0.1 µ	
	GSD[3]	2.0 ± 0.02		2.0 ± 0.02		2.0 ± 0.02	
	Extra-fine particles (< 1 µm)[4]	9.7 ± 1%	617 ± 57 µg	11 ± 1%	648 ± 31 µg	13 ± 1%	675 ± 49 µg
	Fine particles (< 5 µm)[4]	50 ± 2%	3170 ± 160 µg	58 ± 1%	3320 ± 150 µg	64 ± 3%	3310 ± 220 µg
	Coarse particles (> 5 µm)[4]	50 ± 2%	3220 ± 290 µg	42 ± 1%	2360 ± 140 µg	36 ± 3%	1900 ± 250 µg
	Respirable particles (1-5 µm)[4]	40 ± 1%	2550 ± 150 µg	47 ± 1%	2660 ± 120 µg	51 ± 2%	2640 ± 190 µg
	Total mass of drug (in nebulizer)[5]	20000 µg		20000 µg		20000 µg	
	Total Delivered Mass of Aerosol[6]	32 ± 2%	6380 ± 390 µg	28± 2%	5680 ± 240 µg	26 ± 2%	5220 ± 400 µg
	Average Treatment Time (minutes)[7]	2.1 ± 0.1		1.7 ± 0.1		1.6 ± 0.1	

[1] Performance data using Cascade Impactor (NGI) per USP 34 <1601> chilled to 5 °C with an extraction flow of 15 lpm for three common aerosolized medications. Treatment time was defined as onset of audible sputtering plus one minute. Values represent the Mean and 95% confidence interval of the mean.

[2] MMAD is Mass Median Aerodynamic Diameter.

[3] GSD is the Geometric Standard Deviation.

[4] Values are the mass of drug substance delivered in the specified size range of aerosol particles and the mass represented as a percentage of the Total Delivered Mass of Aerosol.

[5] Total mass of drug in nebulizer is the mass of drug substance placed in the nebulizer cup for typical dose listed.

[6] The total delivered mass of aerosol is the mass of drug substance recovered from the cascade impactor after treatment time. The mass is stated in micrograms of drug substance and as a percentage of the total mass of drug substance placed in the nebulizer.

[7] Treatment time, defined as onset of sputtering plus one minute, to deliver the aerosol masses starting with the initial mass of drug listed.

CareFusion

1500 Waukegan Road
McGaw Park, Illinois
60085-6787
847-473-7208 tel
847-473-7774 fax
carefusion.com

Results and Conclusion
Based upon the information provided the proposed device is substantially equivalent to the predicate devices, and raises no new issues of safety and effectiveness
Summary of clinical tests conducted for determination of substantial equivalence and/or of clinical information
N/A – No clinical tests were conducted for this submission
Conclusions drawn from non-clinical and clinical data
The results of the non-clinical tests show that the small volume nebulizer meets all performance requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2013

Ms. Erika Silva Fernandez
Manager, Regulatory Affairs
CareFusion
1500 Waukegan Road
WAUKEGAN IL 60060

Re: K123527
Trade/Device Name: Small Volume Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: March 21, 2013
Received: March 26, 2013

Dear Ms. Fernandez:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CareFusion

1500 Waukegan Road
McGaw Park, Illinois
60085-6787
847-473-7208 tel
847-473-7774 fax
carefusion.com

Indication for Use

510(k) Number (if known): K123527 ~~Unknown at this time~~

Device Name: Small Volume Nebulizer

Indications for Use: This device is intended to be used to aerosolize liquid medication into gases that are delivered directly to the patient for breathing. The patient population includes adults, pediatrics, and infants that are spontaneously breathing. The product is a prescriptive device intended to be used in hospital setting.

Prescription Use X or Over-The Counter Use _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chan O. Lee -S
2013.04.24
16:11:51 -04'00' For LS

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

510(k) Number: K123527