April 29, 2025

Enchant Tek Co. Ltd.
% Paul Dryden
President
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K242354
Trade/Device Name: AllNEB
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: April 1, 2025
Received: April 1, 2025

Dear Paul Dryden:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242354

Device Name
AllNEB Breath Actuated Nebulizer

Indications for Use *(Describe)*
AllNEB Breath Actuated Nebulizer is intended for adults and pediatric patients over 5 years old, who are under the care or treatment of a licensed healthcare provider or physician. AllNEB is intended for the administration of aerosolized medication prescribed by a physician or healthcare professional. AllNEB is to be used at home or in hospitals and clinics.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared:	29-Apr-25
Sponsor:	Enchant Tek Co. Ltd. No. 210 Xiangzhong Rd. Dongshan Township, Yilan County Taipei, TW 26950 Tel +886- 03-959-3500
Sponsor Contact:	Ling Leonard – QA/RA Supervisor
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	AllNEB
Common/Usual Name:	Nebulizer
Classification Name:	Nebulizer (direct patient interface) 21CFR 868.5630
Product Code:	CAF
Predicate Device:	AeroEclipse II Breath Actuated Nebulizer – K053605
Common/Usual Name:	Nebulizer
Classification Name:	Nebulizer (direct patient interface) 21CFR 868.5630
Product Code:	CAF

Device Description: AllNEB is a jet nebulizer intended to administer medication (prescribed by a physician or health care provider) in the form of an aerosol for patient inhalation. It operates in conjunction with a compressed air source and a liquid medication. The subject device is designed to produce and deliver aerosolized medication only during the patient inspiratory cycle, reducing fugitive emissions to the environment. It can be used in hospitals, clinics and in the home.

Principle of Operation: The gas orifice is located in the center of the nebulizer. The driving gas (air or oxygen) passes through the small orifice and is deflected by a baffle on the actuator. The high velocity jet of gas produces a negative pressure behind it, which draws liquid up to the nozzle area. The deflected gas flow shears off the liquid being drawn up which generates the aerosol

Indications for Use:
AllNEB Breath Actuated Nebulizer is intended for adults and pediatric patients over 5 years old, who are under the care or treatment of a licensed healthcare provider or physician. AllNEB is intended for the administration of aerosolized medication prescribed by a physician or healthcare professional. AllNEB is to be used at home or in hospitals and clinics.

Patient Population:
Pediatrics (5 years and older) to Adults.

Environments of use:
Home, hospitals, and clinics.

	Subject Device AllNEB – K242354	Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605	Comment
Manufacturer	Enchant	Trudell Medical International	
Prescriptive	Rx	Rx	Similar
Classification	21 CFR 868.5630 - CAF Nebulizer - Direct patient interface	21 CFR 868.5630 - CAF Nebulizer - Direct patient interface	Similar
Indications for use	AllNEB Breath Actuated Nebulizer is intended for adults and pediatric patients over 5 years old, who are under the care or treatment of a licensed healthcare provider or physician. AllNEB is intended for the administration of aerosolized medication prescribed by a physician or healthcare professional. AllNEB is to be used at home or in hospitals and clinics.	The AeroEclipse* II Breath Actuated Nebulizer is intended to be used by patients who are under the care or treatment of a licensed healthcare provider or physician. The device is intended to be used by these patients to administer aerosolized medication prescribed by a physician or health care professional. The intended environments for use include the home, hospitals and clinics.	The predicate device does not disclose the patient age range.
Intended Use Environment	Home or in hospitals and clinics	Home or in hospitals and clinics	Similar
Principle of Operation	Pneumatic Jet Nebulizer	Pneumatic Jet Nebulizer	Similar
Aerosolization Mode	Built-in mode selector for breath actuated or continuous mode	Built-in mode selector for breath actuated or continuous mode	Similar
Single Patient Use	Yes	Yes	Similar
Type of Device	Single patient use, multiple use, prescription only, non-sterile	Single patient use, multiple use, prescription only, non-sterile	Similar
Type of gas source	Compressed air or oxygen	Compressed air or oxygen	Similar
Flow Rate	5 – 8 lpm (liters per minute)	2.75 – 8 lpm (liters per minute)	Similar
Maximum Fill Volume	6ml	6ml	Similar
Basic Components	BAN with Mouthpiece, Oxygen Tubing	BAN with Mouthpiece, Oxygen Tubing	Similar Oxygen tubing is user supplied

	Subject Device AllNEB – K242354	Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605	Comment
Biocompatibility	Surface Contact, mucosal and Externally Communicating, Tissue contact, Permanent Duration ISO 10993-1 and ISO 18562-1	Surface Contact, mucosal and Externally Communicating, Tissue contact, Permanent Duration	Similar

	Subject Device AllNEB - 242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605			Comment
Comparative Performance							
Breath Actuated Mode – Adult settings							
MMAD	Albuterol Sulfate	5 lpm 1.51	8 lpm 2.03	Albuterol Sulfate	5 lpm 2.03	8 lpm 2.23	Similar
	Ipratropium Bromide	1.47	1.90	Ipratropium Bromide	1.93	2.23	Similar
	Cromolyn Sodium	1.50	1.87	Cromolyn Sodium	2.00	2.07	Similar
GSD	Albuterol Sulfate	5 lpm 2.43	8 lpm 1.67	Albuterol Sulfate	5 lpm 1.70	8 lpm 1.63	Similar
	Ipratropium Bromide	2.13	1.67	Ipratropium Bromide	1.67	1.70	Similar
	Cromolyn Sodium	2.29	1.70	Cromolyn Sodium	1.70	1.73	Similar
Total Dose Delivered	Albuterol Sulfate	5 lpm 1,228	8 lpm 1,293	Albuterol Sulfate	5 lpm 1,367	8 lpm 1,474	Similar
	Ipratropium Bromide	188	208	Ipratropium Bromide	203	242	Similar
	Cromolyn Sodium	5,255	5,781	Cromolyn Sodium	5,868	6,505	Similar

	Subject Device AllNEB - K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605			Comment
Total Respirable Dose (0.5-5 um)	Albuterol Sulfate	5 lpm 834	8 lpm 862	Albuterol Sulfate	5 lpm 847	8 lpm 899	Similar
	Ipratropium Bromide	129	136	Ipratropium Bromide	132	138	Similar
	Cromolyn Sodium	3,635	4,070	Cromolyn Sodium	3,681	4,030	Similar
Coarse Particle Dose (>4.7 um)	Albuterol Sulfate	5 lpm 218	8 lpm 258	Albuterol Sulfate	5 lpm 350	8 lpm 426	Similar
	Ipratropium Bromide	30	43	Ipratropium Bromide	48	76	Similar
	Cromolyn Sodium	868	904	Cromolyn Sodium	1,411	1,549	Similar
Fine Particle Dose (<4.7 um)	Albuterol Sulfate	5 lpm 1,010	8 lpm 1,035	Albuterol Sulfate	5 lpm 1,017	8 lpm 1,048	Similar
	Ipratropium Bromide	158	165	Ipratropium Bromide	155	167	Similar
	Cromolyn Sodium	4,388	4,877	Cromolyn Sodium	4,456	4,957	Similar
Ultra-Fine Particle Dose (<1.0 um)	Albuterol Sulfate	5 lpm 397	8 lpm 317	Albuterol Sulfate	5 lpm 307	8 lpm 275	Similar
	Ipratropium Bromide	62	52	Ipratropium Bromide	50	52	Similar
	Cromolyn Sodium	1,704	1,463	Cromolyn Sodium	1,369	1,501	Similar
Constant-Output Mode – Adult settings Adult settings							
MMAD	Albuterol Sulfate	5 lpm 1.46	8 lpm 2.06	Albuterol Sulfate	5 lpm 2.07	8 lpm 2.20	Similar
	Ipratropium Bromide	1.51	2.06	Ipratropium Bromide	1.93	2.10	Similar
	Cromolyn Sodium	1.52	2.03	Cromolyn Sodium	1.97	2.30	Similar
GSD	Albuterol Sulfate	5 lpm 2.04	8 lpm 1.62	Albuterol Sulfate	5 lpm 1.63	8 lpm 1.63	Similar
	Ipratropium Bromide	2.56	1.62	Ipratropium Bromide	1.67	1.67	Similar
	Cromolyn Sodium	2.24	1.67	Cromolyn Sodium	1.63	1.67	Similar
Total Dose	Albuterol Sulfate	5 lpm 1,232	8 lpm 1,367	Albuterol Sulfate	5 lpm 1,376	8 lpm 1,463	Similar

	Subject Device AllNEB - K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605			Comment
Delivered	Ipratropium Bromide	193	219	Ipratropium Bromide	200	248	Similar
	Cromolyn Sodium	5,246	5,674	Cromolyn Sodium	5,783	6,339	Similar
Total Respirable Dose (0.5-5 um)	Albuterol Sulfate	5 lpm 846	8 lpm 957	Albuterol Sulfate	5 lpm 880	8 lpm 871	Similar
	Ipratropium Bromide	132	152	Ipratropium Bromide	126	150	Similar
	Cromolyn Sodium	3,687	3,787	Cromolyn Sodium	3,672	3,845	Similar
Coarse Particle Dose (>4.7 um)	Albuterol Sulfate	5 lpm 208	8 lpm 256	Albuterol Sulfate	5 lpm 341	8 lpm 446	Similar
	Ipratropium Bromide	35	41	Ipratropium Bromide	48	68	Similar
	Cromolyn Sodium	832	1,127	Cromolyn Sodium	1,450	1,831	Similar
Fine Particle Dose (<4.7 um)	Albuterol Sulfate	5 lpm 1,025	8 lpm 1,111	Albuterol Sulfate	5 lpm 1,036	8 lpm 1,017	Similar
	Ipratropium Bromide	158	178	Ipratropium Bromide	152	180	Similar
	Cromolyn Sodium	4,415	4,547	Cromolyn Sodium	4,332	4,508	Similar
Ultra-Fine Particle Dose (<1.0 um)	Albuterol Sulfate	5 lpm 402	8 lpm 299	Albuterol Sulfate	5 lpm 303	8 lpm 284	Similar
	Ipratropium Bromide	62	49	Ipratropium Bromide	46	52	Similar
	Cromolyn Sodium	1,661	1,340	Cromolyn Sodium	1,399	1,247	Similar
Breath Actuated Mode – Pediatric settings							
MMAD	Albuterol Sulfate	5 lpm 1.37	8 lpm 2.19	Albuterol Sulfate	5 lpm 1.93	8 lpm 2.87	Similar
	Ipratropium Bromide	1.39	2.24	Ipratropium Bromide	1.67	2.93	Similar
	Cromolyn Sodium	1.32	2.12	Cromolyn Sodium	1.60	3.10	Similar
GSD	Albuterol Sulfate	5 lpm 1.54	8 lpm 1.94	Albuterol Sulfate	5 lpm 2.57	8 lpm 1.97	Similar
	Ipratropium Bromide	1.52	1.96	Ipratropium Bromide	2.93	2.00	Similar
	Cromolyn Sodium	1.40	1.94	Cromolyn Sodium	2.17	2.13	Similar

	Subject Device AllNEB K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer -K053605			Comment
Total Dose Delivered	Albuterol Sulfate	5 lpm 1347.3	8 lpm 1193	Albuterol Sulfate	5 lpm 1709.4	8 lpm 1515	Similar
	Ipratropium Bromide	210.9	196	Ipratropium Bromide	250.7	245	Similar
	Cromolyn Sodium	5436.7	5124	Cromolyn Sodium	6340.4	6474	Similar
Total Respirable Dose (0.5-5 um)	Albuterol Sulfate	5 lpm 892.2	8 lpm 805	Albuterol Sulfate	5 lpm 927.4	8 lpm 795	Similar
	Ipratropium Bromide	140.5	132	Ipratropium Bromide	137.4	128	Similar
	Cromolyn Sodium	3675.5	3595	Cromolyn Sodium	3657.4	3468	Similar
Coarse Particle Dose (>4.7 um)	Albuterol Sulfate	5 lpm 266.1	8 lpm 234	Albuterol Sulfate	5 lpm 595.5	8 lpm 570	Similar
	Ipratropium Bromide	41.6	38	Ipratropium Bromide	84.2	95	Similar
	Cromolyn Sodium	916.3	833	Cromolyn Sodium	1907.3	2326	Similar
Fine Particle Dose (<4.7 um)	Albuterol Sulfate	5 lpm 1081.2	8 lpm 959	Albuterol Sulfate	5 lpm 1114.0	8 lpm 945	Similar
	Ipratropium Bromide	169.3	157	Ipratropium Bromide	166.5	150	Similar
	Cromolyn Sodium	4520.4	4291	Cromolyn Sodium	4432.7	4148	Similar
Ultra-Fine Particle Dose (<1.0 um)	Albuterol Sulfate	5 lpm 334.5	8 lpm 217	Albuterol Sulfate	5 lpm 348.0	8 lpm 205	Similar
	Ipratropium Bromide	47.7	37	Ipratropium Bromide	50.4	35	Similar
	Cromolyn Sodium	1457.3	996	Cromolyn Sodium	1292.0	962	Similar
Constant-Output Mode – Pediatric settings							
MMAD	Albuterol Sulfate	5 lpm 1.39	8 lpm 2.20	Albuterol Sulfate	5 lpm 1.70	8 lpm 2.77	Similar
	Ipratropium Bromide	1.37	2.24	Ipratropium Bromide	1.97	2.77	Similar
	Cromolyn Sodium	1.38	2.33	Cromolyn Sodium	1.77	2.73	Similar

	Subject Device AllNEB K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer -K053605			Comment
GSD	Albuterol Sulfate	5 lpm 1.91	8 lpm 1.97	Albuterol Sulfate	5 lpm 3.17	8 lpm 2.10	Similar
	Ipratropium Bromide	1.72	1.96	Ipratropium Bromide	2.70	2.10	Similar
	Cromolyn Sodium	1.50	1.96	Cromolyn Sodium	2.67	2.03	Similar
Total Dose Delivered	Albuterol Sulfate	5 lpm 1316	8 lpm 1171	Albuterol Sulfate	5 lpm 1651	8 lpm 1441	Similar
	Ipratropium Bromide	200	183	Ipratropium Bromide	256	233	Similar
	Cromolyn Sodium	5734	5255	Cromolyn Sodium	6654	6789	Similar
Total Respirable	Albuterol Sulfate	5 lpm 886	8 lpm 807	Albuterol Sulfate	5 lpm 897	8 lpm 731	Similar
Dose (0.5-5 um)	Ipratropium Bromide	136	125	Ipratropium Bromide	133	126	Similar
	Cromolyn Sodium	3862	3670	Cromolyn Sodium	3698	3624	Similar
Coarse Particle Dose (>4.7 um)	Albuterol Sulfate	5 lpm 250	8 lpm 220	Albuterol Sulfate	5 lpm 577	8 lpm 556	Similar
	Ipratropium Bromide	36	36	Ipratropium Bromide	94	81	Similar
	Cromolyn Sodium	1021	921	Cromolyn Sodium	2180	2450	Similar
Fine Particle Dose (<4.7 um)	Albuterol Sulfate	5 lpm 1067	8 lpm 952	Albuterol Sulfate	5 lpm 1074	8 lpm 885	Similar
	Ipratropium Bromide	164	146	Ipratropium Bromide	161	152	Similar
	Cromolyn Sodium	4713	4334	Cromolyn Sodium	4475	4339	Similar
Ultra-Fine Particle Dose (<1.0 um)	Albuterol Sulfate	5 lpm 313	8 lpm 216	Albuterol Sulfate	5 lpm 313	8 lpm 232	Similar
	Ipratropium Bromide	48	31	Ipratropium Bromide	48	38	Similar
	Cromolyn Sodium	1393	926	Cromolyn Sodium	1229	1044	Similar

	Subject Device AllNEB K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605			Comment
Simulated Breathing Comparison							
Breath Actuated Mode Simulated Breathing – Adult settings							
MMAD	Albuterol Sulfate	5 lpm 1.51	8 lpm 2.03	Albuterol Sulfate	5 lpm 2.03	8 lpm 2.23	Similar
	Ipratropium Bromide	1.47	1.90	Ipratropium Bromide	1.93	2.23	Similar
	Cromolyn Sodium	1.50	1.87	Cromolyn Sodium	2.00	2.07	Similar
GSD	Albuterol Sulfate	5 lpm 2.43	8 lpm 1.67	Albuterol Sulfate	5 lpm 1.70	8 lpm 1.63	Similar
	Ipratropium Bromide	2.13	1.67	Ipratropium Bromide	1.67	1.70	Similar
	Cromolyn Sodium	2.29	1.70	Cromolyn Sodium	1.70	1.73	Similar
Total Dose Delivered	Albuterol Sulfate	5 lpm 982	8 lpm 946	Albuterol Sulfate	5 lpm 1,074	8 lpm 1,092	Similar
	Ipratropium Bromide	149	159	Ipratropium Bromide	155	181	Similar
	Cromolyn Sodium	4,130	4,488		4,668	4,959	Similar
Total Respirable	Albuterol Sulfate	5 lpm 668	8 lpm 632	Albuterol Sulfate	5 lpm 665	8 lpm 666	Similar
Dose (0.5-5 um)	Ipratropium Bromide	103	104	Ipratropium Bromide	101	103	Similar
	Cromolyn Sodium	2,860	3,159	Cromolyn Sodium	2,922	3,076	Similar
Coarse Particle Dose (>4.7 um)	Albuterol Sulfate	5 lpm 173	8 lpm 189	Albuterol Sulfate	5 lpm 275	8 lpm 315	Similar
	Ipratropium Bromide	24	33	Ipratropium Bromide	36	56	Similar
	Cromolyn Sodium	678	701	Cromolyn Sodium	1,130	1,179	Similar
Fine Particle Dose (<4.7 um)	Albuterol Sulfate	5 lpm 809	8 lpm 757	Albuterol Sulfate	5 lpm 799	8 lpm 777	Similar
	Ipratropium Bromide	125	126	Ipratropium Bromide	119	124	Similar
	Cromolyn Sodium	3,451	3,787	Cromolyn Sodium	3,538	3,781	Similar

	Subject Device AllNEB K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605			Comment
Ultra-Fine Particle Dose (<1.0 um)	Albuterol Sulfate	5 lpm 319	8 lpm 231	Albuterol Sulfate	5 lpm 242	8 lpm 204	Similar
	Ipratropium Bromide	49	40	Ipratropium Bromide	38	39	Similar
	Cromolyn Sodium	1,337	1,138	Cromolyn Sodium	1,085	1,150	Similar
Constant-Output Mode Simulated Breathing – Adult settings							
MMAD	Albuterol Sulfate	5 lpm 1.46	8 lpm 2.06	Albuterol Sulfate	5 lpm 2.07	8 lpm 2.20	Similar
	Ipratropium Bromide	1.51	2.06	Ipratropium Bromide	1.93	2.10	Similar
	Cromolyn Sodium	1.52	2.03	Cromolyn Sodium	1.97	2.30	Similar
GSD	Albuterol Sulfate	5 lpm 2.04	8 lpm 1.62	Albuterol Sulfate	5 lpm 1.63	8 lpm 1.63	Similar
	Ipratropium Bromide	2.56	1.62	Ipratropium Bromide	1.67	1.67	Similar
	Cromolyn Sodium	2.24	1.67	Cromolyn Sodium	1.63	1.67	Similar
Total Dose Delivered	Albuterol Sulfate	5 lpm 517	8 lpm 570	Albuterol Sulfate	5 lpm 560	8 lpm 601	Similar
	Ipratropium Bromide	83	89	Ipratropium Bromide	85	106	Similar
	Cromolyn Sodium	2,297	2,346		2,439	2,619	Similar
Total Respirable	Albuterol Sulfate	5 lpm 355	8 lpm 399	Albuterol Sulfate	5 lpm 357	8 lpm 357	Similar
Dose (0.5-5 um)	Ipratropium Bromide	57	61	Ipratropium Bromide	54	64	Similar
	Cromolyn Sodium	1,616	1,567	Cromolyn Sodium	1,550	1,589	Similar
Coarse Particle Dose (>4.7 um)	Albuterol Sulfate	5 lpm 87	8 lpm 106	Albuterol Sulfate	5 lpm 139	8 lpm 184	Similar
	Ipratropium Bromide	15	17	Ipratropium Bromide	21	29	Similar
	Cromolyn Sodium	362	465	Cromolyn Sodium	612	758	Similar

	Subject Device AllNEB K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605			Comment
Fine Particle Dose (<4.7 um)	Albuterol Sulfate	5 lpm 430	8 lpm 463	Albuterol Sulfate	5 lpm 421	8 lpm 417	Similar
	Ipratropium Bromide	68	72	Ipratropium Bromide	65	77	Similar
	Cromolyn Sodium	1,935	1,881	Cromolyn Sodium	1,827	1,861	Similar
Ultra-Fine Particle Dose (<1.0 um)	Albuterol Sulfate	5 lpm 169	8 lpm 125	Albuterol Sulfate	5 lpm 124	8 lpm 117	Similar
	Ipratropium Bromide	26	20	Ipratropium Bromide	20	22	Similar
	Cromolyn Sodium	729	555	Cromolyn Sodium	589	513	Similar
Breath Actuated Mode Simulated Breathing – Pediatric settings							
MMAD	Albuterol Sulfate	5 lpm 1.37	8 lpm 2.19	Albuterol Sulfate	5 lpm 1.93	8 lpm 2.87	Similar
	Ipratropium Bromide	1.39	2.24	Ipratropium Bromide	1.67	2.93	Similar
	Cromolyn Sodium	1.32	2.12	Cromolyn Sodium	1.60	3.10	Similar
GSD	Albuterol Sulfate	5 lpm 1.54	8 lpm 1.94	Albuterol Sulfate	5 lpm 2.57	8 lpm 1.97	Similar
	Ipratropium Bromide	1.52	1.96	Ipratropium Bromide	2.93	2.00	Similar
	Cromolyn Sodium	1.40	1.94	Cromolyn Sodium	2.17	2.13	Similar
Total Dose Delivered	Albuterol Sulfate	5 lpm 1059.0	8 lpm 937	Albuterol Sulfate	5 lpm 1190.1	8 lpm 1,040	Similar
	Ipratropium Bromide	166.7	153	Ipratropium Bromide	184.9	186	Similar
	Cromolyn Sodium	4288.9	4,171	Cromolyn Sodium	5152.0	4,954	Similar
Total Respirable Dose (0.5-5 um)	Albuterol Sulfate	5 lpm 703.2	8 lpm 632	Albuterol Sulfate	5 lpm 645.8	8 lpm 548	Similar

	Subject Device AllNEB - K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605			Comment
	Ipratropium Bromide	111.1	103	Ipratropium Bromide	101.1	97	Similar
	Cromolyn Sodium	2898.6	2,931	Cromolyn Sodium	2969.6	2,649	Similar
Coarse Particle Dose (>4.7 um)	Albuterol Sulfate	5 lpm 207.5	8 lpm 183	Albuterol Sulfate	5 lpm 414.9	8 lpm 389	Similar
	Ipratropium Bromide	32.7	30	Ipratropium Bromide	62.4	72	Similar
	Cromolyn Sodium	723.1	673	Cromolyn Sodium	1551.7	1786	Similar
Fine Particle Dose (<4.7 um)	Albuterol Sulfate	5 lpm 851.5	8 lpm 754	Albuterol Sulfate	5 lpm 775.3	8 lpm 651	Similar
	Ipratropium Bromide	134.0	123	Ipratropium Bromide	122.5	114	Similar
	Cromolyn Sodium	3565.8	3,498	Cromolyn Sodium	3600.3	3,168	Similar
Ultra-Fine Particle Dose (<1.0 um)	Albuterol Sulfate	5 lpm 262.8	8 lpm 171	Albuterol Sulfate	5 lpm 241.8	8 lpm 141	Similar
	Ipratropium Bromide	37.7	29	Ipratropium Bromide	37.0	26	Similar
	Cromolyn Sodium	1151.2	810	Cromolyn Sodium	1051.7	735	Similar
Constant-Output Mode Simulated Breathing – Pediatric settings							
MMAD	Albuterol Sulfate	5 lpm 1.39	8 lpm 2.20	Albuterol Sulfate	5 lpm 1.70	8 lpm 2.77	Similar
	Ipratropium Bromide	1.37	2.24	Ipratropium Bromide	1.97	2.77	Similar
	Cromolyn Sodium	1.38	2.33	Cromolyn Sodium	1.77	2.73	Similar
GSD	Albuterol Sulfate	5 lpm 1.91	8 lpm 1.97	Albuterol Sulfate	5 lpm 3.17	8 lpm 2.10	Similar
	Ipratropium Bromide	1.72	1.96	Ipratropium Bromide	2.70	2.10	Similar
	Cromolyn Sodium	1.50	1.96	Cromolyn Sodium	2.67	2.03	Similar

	Subject Device AllNEB - K242354			Predicate Device AeroEclipse II Breath Actuated Nebulizer - K053605			Comment
Total Dose Delivered	Albuterol Sulfate	5 lpm 526	8 lpm 463	Albuterol Sulfate	5 lpm 592	8 lpm 534	Similar
	Ipratropium Bromide	80	72	Ipratropium Bromide	96	79	Similar
	Cromolyn Sodium	2351	1970		2561	2348	Similar
Total Respirable	Albuterol Sulfate	5 lpm 355	8 lpm 319	Albuterol Sulfate	5 lpm 321	8 lpm 271	Similar
Dose (0.5-5 um)	Ipratropium Bromide	54	50	Similar	50	43	Similar
	Cromolyn Sodium	1583	1376	Similar	1426	1254	Similar
Coarse Particle Dose (>4.7 um)	Albuterol Sulfate	5 lpm 99	8 lpm 87	Similar	5 lpm 207	8 lpm 206	Similar
	Ipratropium Bromide	15	14	Ipratropium Bromide	36	27	Similar
	Cromolyn Sodium	418	346	Cromolyn Sodium	838	846	Similar
Fine Particle Dose (<4.7 um)	Albuterol Sulfate	5 lpm 427	8 lpm 377	Albuterol Sulfate	5 lpm 385	8 lpm 328	Similar
	Ipratropium Bromide	66	58	Ipratropium Bromide	61	52	Similar
	Cromolyn Sodium	1933	1625	Cromolyn Sodium	1723	1502	Similar
Ultra-Fine Particle Dose (<1.0 um)	Albuterol Sulfate	5 lpm 125	8 lpm 85	Albuterol Sulfate	5 lpm 112	8 lpm 86	Similar
	Ipratropium Bromide	19	12	Ipratropium Bromide	18	13	Similar
	Cromolyn Sodium	572	348	Cromolyn Sodium	471	361	Similar

Discussion of Differences

The subject device differs in the following ways from the predicate:
The predicate device does not specify an age range.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and non-clinical testing that the subject device and predicate have been found to be substantially equivalent.