July 25, 2025

GuangDong EDA Technology Co., Ltd
% Todd Courtney
Vice President, Regulatory Affairs
Mcra.llc
803 7th Street, NW, 3rd Floor
Washington, District of Columbia 20001

Re: K243244
Trade/Device Name: Heated Breathing Tube
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE,
Dated: May 23, 2024
Received: October 11, 2024

Dear Todd Courtney:

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,

John S. Bender -S
2025.07.25 11:32:24 -04'00'

for 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)*
K243244

Device Name
Heating Breathing Tube

Indications for Use *(Describe)*
The Heated Breathing Tube is intended to be used for non-invasive respiratory therapy, such as CPAP/BiPAP therapy. It provides air connection between positive pressure ventilation, respiratory humidification therapy instrument, and ventilation mask, nasal cannula, trachea cannula etc. With the function of heating inside breathing tube, it can prevent condensation of the therapy air in the tube.

This device is single patient use only for adults.

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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025/6/4

1. Submission sponsor

Name: JOYTECH Healthcare Co., Ltd.
Address: No. 365. Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, China.
Contact person: Cong Jing
Title: Regulatory manager
E-mail: jingc@sejoy.com
Tel: +86-571-81957767

2. Submission correspondent

Name: Chonconn Consulting Co., Ltd.
Address: No. Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P.R. China 518067
Contact person: Yang Jie
E-mail: yangjie@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Compressor Nebulizer
Model	NB-1100, NB-1101, NB-1102, NB-1103
Common Name	Nebulizer
Regulatory Class	Class II
Classification	21CFR §868.5630 / Nebulizer
Submission type	Traditional 510(K)

4. Predicate Device Information

K110860, NE-C801 Nebulizer Compressor System, Omron Healthcare, Incorporated

5. Device Description

The compressor Nebulizer is mainly composed of the compressor and nebulizer kit(Optional). The compressor is mainly composed of shell, compressed motor, pump, fuse wire, air filter, power cord and plug (NB-1100,NB-1101,NB-1102,NB-1103 applicable), PCB (only model NB-1102,NB-1103applicable). The device is equipped with a nebulizer kit including Nebulizer Cup, Air Tube, Mouthpiece(Optional), Adult Mask(Optional), Child Mask(Optional) to easily delivery the medical aerosol. The Nebulizer kit is available in three models/configurations as below.

NK-101: Nebulizer Cup, Air Tube, Adult Mask and/or Child Mask, Mouthpiece;
NK-301: Nebulizer Cup, Air Tube, Adult Mask and/or Child Mask;
NK-501:Nebulizer Cup, Air Tube, Mouthpiece

This device operates on the Venturi principle. According to the principle of Venturi, the compressed air of the motor is used to form a high-speed air flow through the small pipe mouth. The negative pressure generated drives the liquid or other fluid to spray together on the barrier, and under the high-speed impact makes the droplets turn into mist particles to spray from the outlet trachea.

6. Intended use & Indication for use

The Compressor Nebulizer system is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders. The nebulizer is driven by the integral air compressor.

The system is designed for use with pediatric (ages 2 years and above) and adult patients in the home, hospital, and sub-acute settings.

7. Comparison to the Predicate Device

ITEM	**Proposed Device** Compressor Nebulizer NB-1100, NB-1101, NB-1102, NB-1103 **K243468**	**Predicate Device** Omron Compressor Nebulizer Systems NE-C801 **K110860**	**Comparison Result**
Manufacture	JOYTECH Healthcare Co., Ltd.	Omron Healthcare, Incorporated	/
Product code	CAF	CAF	Same
Indications for Use	The Compressor Nebulizer system is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders. The nebulizer is driven by the integral air compressor. The system is designed for use with pediatric (ages 2 years and above) and adult patients in the home, hospital, and sub-acute settings.	The NE-C801 Nebulizer Compressor System is intended to provide air to the pneumatic nebulizer in order to aerosolize medications for inhalation by the patient for respiratory disorders. The system is designed for use with pediatric (defined by the prescribed medication) and adult patients in the home, hospital, and sub-acute settings.	Same

Principle of Operation	Yes Pneumatic (gas powered) jet nebulizer	Yes Pneumatic (gas powered) jet nebulizer	Same
Compressed gas source	Nebulizer compressor	Nebulizer compressor Wall air / oxygen with flow rate control	Equival ent
Aerosolizatio n	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation	Same
Typical flow rate	≥6.5L/min	8 lpm	Similar
Reservoir size	8 ml	7 ml	Similar
Power Source	AC	AC	Same
Components available in kit with nebulizer	Mouthpiece or mask	Mouthpiece or mask	Same
Component / Accessories intended use	All are single patient, multi-use	All are single patient, multi-use	Same
Nebulizer components cleanable	Yes	Yes	Same
Standards met	ANSI AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 6060 1-1 IEC 60601-1-2	Equival ent
Operating conditions	+5°C to +40°C (+41°F to +104°F)/15% to 90% RH/ 860 hPa to 1060 hPa	10℃ to 40℃ 30% to 85% RH	Similar
Storage conditions	–20°C to +55°C (–4°F to +131°F)/5% to 93% RH/ 700 hPa to 1060 hPa	-20℃ to 60℃ 10% to 95% RH	Similar
Dimensions (mm)	267.9 mm × 157.3 mm × 104.6 mm 170.2 mm × 144.4 mm × 117.9 mm 246.3 mm × 121.6 mm × 148.5 mm 286 mm × 154 mm × 134.5 mm	142(W) x 72(D) x 98(H)	Similar
Weight(kg)	1.554kg 1.238kg 1.413kg 1.57kg	0.270kg	Similar

Aerosol performance	Table: Comparative particle test comparison	Table: Comparative particle test comparison	Equivalent

As evidenced by the above table, both the subject and the predicate devices have same intended use, but the subject and predicate devices have different technological characteristics. However, performance testing was conducted on the subject device, and it was established that the differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

Table: Comparative particle test comparison
Adult condition

Test items	Drug	Subject Device (JOYTECH NB-1103) with adult mask	Predicate device (OMRON NE-C801) with adult mask	Subject Device (JOYTECH NB-1103) with Mouthpiece	Predicate device (OMRON NE-C801) with Mouthpiece
MMAD(μm)	Albuterol Sulfate (5 mg/2.5 ml)	3.466±0.173	4.173±0.126	3.761±0.06	3.7±0.248
	Ipratropiμm Bromide (0.5 mg/2 ml)	3.413±0.061	4.227±0.383	3.954±0.032	4.067±0.16
	Budesonide (0.5 mg/2 ml)	4.781±0.102	6.06±0.352	5.344±0.025	5.704±0.124
GSD	Albuterol Sulfate (5 mg/2.5 ml)	1.988±0.033	1.845±0.046	2.013±0.016	1.993±0.029
	Ipratropiμm Bromide (0.5 mg/2 ml)	1.979±0.029	1.843±0.077	1.979±0.02	1.898±0.055
	Budesonide (0.5 mg/2 ml)	1.764±0.01	1.605±0.105	1.81±0.018	1.72±0.087
Respirable Dose(μg)	Albuterol Sulfate (5 mg/2.5 ml)	1628.633±99.49	1239.14±150.674	1556.481±102.075	1138.953±108.149
	Ipratropiμm Bromide (0.5 mg/2 ml)	153.331±4.765	147.57±11.505	145.246±2.803	132.881±16.413
	Budesonide (0.5 mg/2 ml)	82.049±1.341	63.292±10.329	78.617±1.532	63.24±4.57
Respirable fraction	Albuterol Sulfate (5 mg/2.5 ml)	67.273±2.066	58.136±2.583	60.726±0.999	63.741±3.979
	Ipratropiμm Bromide (0.5 mg/2 ml)	67.958±0.561	56.616±5.676	58.302±0.731	60.095±2.068
	Budesonide (0.5 mg/2 ml)	49.433±1.385	31.781±4.934	40.028±0.211	36.912±1.149

Total delivered Dose（μg）	Albuterol Sulfate (5 mg/2.5 ml)	2418.382±90.219	2131.073±210.711	2562.202±150.856	1788.603±272.194
	Ipratropiμm Bromide (0.5 mg/2 ml)	225.607±6.35	260.75±14	249.133±3.845	221.123±26.449
	Budesonide (0.5 mg/2 ml)	166.098±3.573	199.13±5.564	196.392±3.13	171.383±17.566
Total delivered Dose fraction（%）	Albuterol Sulfate (5 mg/2.5 ml)	46.227±1.75	40.801±4.143	49.063±2.955	34.316±5.245
	Ipratropiμm Bromide (0.5 mg/2 ml)	41.066±1.176	48.1±3.044	45.427±0.695	40.534±4.349
	Budesonide (0.5 mg/2 ml)	31.225±0.606	37.472±1.072	37.024±0.537	32.058±3.425
Coarse Particle Fraction (%)(>4.7μm)	Albuterol Sulfate (5 mg/2.5 ml)	35.924±2.212	45.607±2.486	42.39±0.981	39.467±4.121
	Ipratropiμm Bromide (0.5 mg/2 ml)	35.232±0.613	47.06±5.886	44.926±0.698	43.487±2.044
	Budesonide (0.5 mg/2 ml)	54.669±1.372	72.054±5.274	63.702±0.144	67.192±0.865
Fine Particle Fraction (%) (<4.7μm)	Albuterol Sulfate (5 mg/2.5 ml)	64.076±2.212	54.393±2.486	57.61±0.981	60.533±4.121
	Ipratropiμm Bromide (0.5 mg/2 ml)	64.77±0.612	52.94±5.886	55.074±0.698	56.513±2.044
	Budesonide (0.5 mg/2 ml)	45.333±1.373	27.946±5.274	36.298±0.144	32.808±0.865
Ultra-Fine Particle Fraction (%) (<1.0μm)	Albuterol Sulfate (5 mg/2.5 ml)	5.891±0.795	3.207±0.351	4.806±0.133	4.26±0.435
	Ipratropiμm Bromide (0.5 mg/2 ml)	5.093±0.416	2.456±1.207	4.006±0.252	2.932±0.23
	Budesonide (0.5 mg/2 ml)	/	/	/	/

Pediatric condition

Test items	Drug	Subject Device (JOYTECH NB-1103) with child mask	Predicate device (OMRON NE-C801) with child mask	Subject Device (JOYTECH NB-1103) with Mouthpiece	Predicate device (OMRON NE-C801) with Mouthpiece
MMAD(μm)	Albuterol Sulfate (5 mg/2.5 ml)	3.651±0.126	4.313±0.355	3.707±0.113	4.475±0.275
	Ipratropiμm Bromide(0.5 mg/2 ml)	3.727±0.045	4.464±0.365	3.846±0.076	4.521±0.36
	Budsonide (0.5 mg/2 mel)	5.249±0.036	5.82±0.411	5.757±0.029	6.248±0.373
GSD	Albuterol Sulfate (5 mg/2.5 ml)	2.253±0.023	2.066±0.052	2.361±0.028	2.141±0.011
	Ipratropiμm Bromide(0.5 mg/2 ml)	2.257±0.037	2.093±0.045	2.381±0.021	2.129±0.027
	Budesonide (0.5 mg/2 ml)	2.082±0.032	1.946±0.039	2.139±0.02	1.999±0.023
Respirable Dose(μg)	Albuterol Sulfate (5 mg/2.5 ml)	999.897±53.773	981.97±130.406	1298.691±62.27	1008.827±116.221
	Ipratropiμm Bromide(0.5 mg/2 ml)	90.589±7.122	113.967±14.919	128.632±3.083	106.836±13.229
	Budesonide (0.5 mg/2 ml)	51.307±3.217	55.097±4.08	56.223±0.77	50.723±8.793
Respirable fraction	Albuterol Sulfate (5 mg/2.5 ml)	64.296±1.681	57.134±4.819	62.503±1.297	54.422±3.494
	Ipratropiμm Bromide(0.5 mg/2 ml)	63.278±0.395	55.054±4.774	60.641±1.078	54.084±4.865
	Budesonide (0.5 mg/2 ml)	45.429±0.443	37.724±4.958	39.103±0.225	33.385±3.354
Total delivered Dose（μg）	Albuterol Sulfate (5 mg/2.5 ml)	1554.763±66.546	1721.173±331.733	2081.438±132.873	1855.027±279.931
	Ipratropiμm Bromide (0.5 mg/2 ml)	143.129±10.902	207.123±28.684	212.202±5.762	197.53±16.536

	Budesonide (0.5 mg/2 ml)	112.976±7.384	146.303±20.144	143.774±1.357	151.83±13.266
Total delivered Dose fraction （%）	Albuterol Sulfate (5 mg/2.5 ml)	29.758±1.286	32.967±6.141	39.856±2.599	35.502±5.346
	Ipratropiμm Bromide(0.5 mg/2 ml)	26.156±1.969	37.898±5.327	38.586±1.084	35.898±3.328
	Budesonide (0.5 mg/2 ml)	21.305±1.372	27.55±3.912	27.236±0.343	28.845±2.019
Coarse Particle Fraction (%)(>4.7μm)	Albuterol Sulfate (5 mg/2.5 ml)	38.54±1.74	46.27±4.824	40.247±1.363	48.871±3.508
	Ipratropiμm Bromide(0.5 mg/2 ml)	39.612±0.434	48.266±4.606	42.12±0.969	49.191±4.684
	Budesonide (0.5 mg/2 ml)	58.453±0.481	66.472±4.87	64.547±0.227	70.463±3.126
Fine Particle Fraction (%) (<4.7μm)	Albuterol Sulfate (5 mg/2.5 ml)	61.461±1.741	53.73±4.824	59.753±1.363	51.129±3.508
	Ipratropiμm Bromide(0.5 mg/2 ml)	60.389±0.433	51.734±4.606	57.881±0.968	50.809±4.684
	Budesonide (0.5 mg/2 ml)	41.547±0.481	33.528±4.87	35.454±0.227	29.537±3.126
Ultra-Fine Particle Fraction (%) (<1.0μm)	Albuterol Sulfate (5 mg/2.5 ml)	/	/	/	/
	Ipratropiμm Bromide(0.5 mg/2 ml)	/	/	/	/
	Budesonide (0.5 mg/2 ml)	/	/	/	/

Note: "/" means that the raw data is below the detection limit LOD and cannot be calculated

8. Non-Clinical tests summary

The following performance data were provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC):

Electrical safety and EMC testing were conducted on the device. Testing established that, with respect to electrical safety, the device meets the applicable requirements of:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Particle Size characterization testing:

Particle characterization testing was performed on the subject device with both proposed patient interface and on the predicate per FDA guidance “Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators” (FDA/CDRH – 1993).

Biocompatibility testing

According to FDA s 2023 Guidance entitled, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the following biological compatibility test need to be executed as follow:

In Vitro Cytotoxicity Test -ISO10993-5
Skin Sensitization Test(polar and non polar) -ISO10993-10
Intracutaneous Reactivity Test-ISO10993-23
Acute Systemic Toxicity Test (polar and non polar) -ISO10993-11
Material-mediated pyrogens Test -ISO10993-11
Bacterial Reverse Mutation Assay --ISO10993-3
In Vitro Mammalian Chromosomal Aberration test --ISO10993-3
Subacute systemic Toxicity Test (polar and non polar) -ISO10993-11
Subcutaneous Implantation Test -ISO10993-6
Chemical characterization study- ISO10993-18
Toxicological risk assessment study-ISO10993-17

Biocompatibility evaluation- ISO 18562-1
Test for emissions of particulate matter - ISO 18562-2
Test for emissions of VOCs -ISO 18562-3

Device life testing
Device life were tested with simulation method, the device meets the applicable requirements.

9. Clinical Tests
Not applicable.

10. Conclusion
Substantial equivalence comparisons, performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.