September 19, 2025

Shenzhen Jermei Medical Device Technology Co., Ltd.
% James Tsai
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K244035
Trade/Device Name: Portable mesh nebulizer (JM821)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: August 21, 2025
Received: August 21, 2025

Dear James Tsai:

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,
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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)*
K244035

Device Name
Portable mesh nebulizer

Indications for Use *(Describe)*
The portable mesh nebulizer is intended to aerosolize medicine liquid for inhalation by the patient. The device is used with adult and pediatric (≥3 years old) both in hospital, home, and sub-acute settings.
It is not intended for use with Pentamidine.

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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510(k) Summary

1. Administrative information

Date of Summary prepared:	September 17th, 2025
Manufacturer information:	Company: Shenzhen Jermei Medical Device Technology Co., Ltd. Address: Room 201, 202, 4th Bldg XianYuXing Company, 4th Bldg XianYuXing industrial Zone, Yuhe Road, Gonghe Community, Shajing Street, Baoan District, Shenzhen, P. R. China Contact person: Ms. Li Fang Phone: +86-755-27800690 Fax: +86-755-27800690 E-mail: lifang@szjermei.com
Submission Correspondent:	Company: Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen Contact person: James Tsai Phone: +86-755-86069197 E-Mail: james_tsai@cefda.com

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Portable mesh nebulizer
Classification name:	Nebulizer (Direct patient interface)
Review Panel:	Anesthesiology
Product Code:	CAF
Device Class:	II
Regulation Number:	868.5630

3. Predicate Device Information

510(K) Number:	K201397
Trade Device:	Ultrasonic mesh nebulizer
Classification name:	Nebulizer (Direct patient interface)
Product Code:	CAF
Device Class:	II
Regulation Number:	868.5630
Review Panel:	Anesthesiology

4. Device Descriptions

JM821 portable mesh nebulizer is a portable vibrating mesh nebulizer, which incorporates a piezoelectric transducer that vibrates at a nominal frequency when electrical current is applied. It is designed to nebulize liquid medications into fine particulates for inhalation by a patient, so as to therapy respiratory diseases.

The subject device is portable size, handheld design, it is powered by a 3.7V d.c. internally lithium battery, which is charged by an adapter.

The subject device does not contain any medicine. Only use physician-prescribed solutions that are approved for use with a general-purpose nebulizer. Consult drug manufacturer's instructions regarding suitability for nebulization.

The portable mesh nebulizer is single-patient, multiple-use. The mask can be can used for 30 sessions of aerosol treatment.

5. Intended Use/Indications for Use

The portable mesh nebulizer is intended to aerosolize medicine liquid for inhalation by the patient. The device is used with adult and pediatric (≥3 years old) both in hospital, home, and sub-acute settings.

It is not intended for use with Pentamidine.

6. Comparisons of technological characteristics with the predicate device

The subject nebulizer and Ivankaca nebulizer (K201397) are similar in intended purpose, structures, technical characteristics, and operation principle, the following table provides a comparison of the two devices.

Items	Subject Device (JM821, K244035)	Predicate Device (Ivankaca, K201397)	Comments
Regulation number	21 CFR 868.5630	21 CFR 868.5630	Substantial equivalence
Regulatory class	Class II	Class II	Substantial equivalence
Product code	CAF	CAF	Substantial equivalence
Intended Use/Indication for Use	The portable mesh nebulizer is intended to aerosolize medicine liquid for inhalation by the patient. The device is used with adult and pediatric (≥3 years old) both in hospital, home, and sub-acute settings. It is not intended for use with Pentamidine.	The Ultrasonic Mesh Nebulizer designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age), defined by the prescribed medication, and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with	Substantial equivalence (Note 1)

Items	Subject Device (JM821, K244035)	Predicate Device (Ivankaca, K201397)	Comments
		Pentamidine.	
Operation principle	Ultrasonic, vibrating mesh	Ultrasonic, vibrating mesh	Substantial equivalence
Environment of use	Clinic, home	Clinic, home	Substantial equivalence
OTC or Rx	Prescription	Prescription	Substantial equivalence
Lithium battery	d.c. 3.7 V	d.c. 3.7 V	Substantial equivalence
AC adapter/charger	Input: a.c. 100-240V, 50/60Hz, 0.16-0.07A; output: d.c. 5.0V, 1.0A Recharging cable/Type-C cable	Recharging cable/USB cable	Difference (Note 2)
Vibration frequency	Approx.114KHz	Approx.110KHz	Difference (Note 3)
Nebulization Rate/Aerosol Flowrate	≥0.25ml/min	≥0.2ml/min	Difference (Note 4)
Medicine Capacity	25ml maximum 0.5ml minimum	8ml maximum 0.5ml minimum	Difference (Note 5)
Hole size (nozzle)	18mm	16mm	Difference (Note 3)
Size of the nebulizer	62.5*52.5*156mm	42(L)x55(W)x109(H) mm (MY-123)	Difference (Note 6)
Weight of the nebulizer	176 g	Model MY-123: 113±5g	Difference (Note 6)
Duration of use	Single patient, multi-use	Single patient, multi-use	Substantial equivalence
Materials	Shell: ABS; Medication cup: PCTG; Mask: TPU	PVC Others: Not publicly available	Difference (Note 7)
Patient Connector	Mouthpiece or mask	Mask	Substantial equivalence (Note 8)
Operating conditions	5℃-40℃, ≤ 90%RH, 70kpa~106kpa	5℃ to 40℃, 15% to 90% RH	Substantial equivalence
Storage conditions	-25℃-70℃, ≤ 90%RH, 70kpa~106kpa	-25℃ to 70℃, ≤90% RH	Substantial equivalence
Electrical safety & EMC	IEC60601-1 IEC60601-1-2 IEC60601-1-11	IEC60601-1 IEC60601-1-2 IEC60601-1-11	Substantial equivalence

Note 1: Both the subject device and predicate device have the same indications for use, except the intended patient population, the subject device claims 3 years old

child, however, both 3-year-old and 4-year-old fall under the same category of children, which shall be used the subject device under the supervision of adults. In addition, other legally marketing devices also claims 3-year-olds or even younger patients, such as FOX MOBILE (K142059) claims patients of 3-year-old, InnoSpire Go (K170853) claims patients of 2-year-old. Therefore, the difference will not raise any new issues of safety and effectiveness for the subject device.

Note 2: The subject device provides the AC adapter and the charging port is type-C interface, which is different from the predicate device, the non-clinical tests show that the subject device conforms to the standards of IEC60601-1, IEC 60601-1-2, and IEC 60601-1-11. Therefore, the difference will not raise any new safe and effective issues for the subject device.

Note 3: The aerosol particles performance comparisons of the subject device and the predicate device are performed and analyzed due to the differences in the specifications of mesh sheet, hole size, and medication cup etc. Aerosol particulate performance comparisons are carried out in adult mode and child mode, the statistical analysis showed that differences in particulate characteristics are not statistically significant in the parameters of Total Mass, MMAD, GSD, Respirable fraction and Respirable mass between the subject device and the predicate device in a confidence level of 95%. Therefore, the difference will not raise any new issues of safety and effectiveness for the subject device.

Note 4: The nebulization rate claimed by the subject device are slightly larger than the predicate device, which means the subject device has a better nebulization efficiency, in the aerosol particle performance comparison testing, the “Durations from starting nebulization to ending nebulization” between the two devices are compared, and the results showed no statistical significance in a confidence level of 95%. Therefore, the difference will not raise any new safe and effective issues for the subject device.

Note 5: The medication volumes depend on the prescriptions by the doctors, the difference on the maximum fill volume will not influence the safety and performance of subject device, and will not raise any new issues of safety and effectiveness for the subject device.

Note 6: The differences of sizes and weights depend on designing variations among different manufacturers and differences in components. However, the subject device has undergone Electric safety and EMC tests, as well as performance tests and reliability tests. The difference will not raise any new issues of safety and effectiveness for the subject device.

Note 7: Materials of predicate device are not publicly available except for PVC, but the biocompatibility evaluations including the biocompatibility tests of the subject device are carried out according to FDA biological guidance, and the results of biocompatibility evaluation demonstrates a good biocompatibility performance of the subject device. Therefore, the differences will not raise any new safe and effective issues for the subject device.

Note 8: The accessories of predicate device include mask and mouthpiece, while the subject device contains only mask, the labeling of subject device is indicated

the accessory of mask clearly, and only mask is contained in the package. Therefore, the difference will not raise any new issues of safety and effectiveness for the subject device.

The subject device and the predicate device are similar in intended use/indication for use, structures, technical characteristics, and working principles, and there is no significant statistical difference in aerosol particle characteristics between subject device and predicate device. The minor differences will not raise any new issue on safety and effectiveness of the subject device. Therefore, the subject device is as safe and as effective to the legally marketed predicate device.

7. Brief discussions of the nonclinical tests

The following performance data were used in support of the substantial equivalence determination:

7.1 Electrical Safety and EMC of medical electrical device

- IEC 60601-1: 2005+A1:2012+ A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020 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: 2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 27427:2023 Respiratory therapy equipment - Part1: Nebulizing systems and their components Anaesthetic and respiratory equipment - Nebulizing systems and components

7.2 Biocompatibility evaluation

- ISO 10993-1: 2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-17: 2023 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
- ISO 10993-18: 2020 Biological evaluation of medical devices - part 18: Chemical characterization of medical device materials within a risk management process

- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Tests for emissions of volatile o Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)

7.3 Software verification and validation

- FDA guidance: Content of Premarket Submissions for Device Software Functions

7.4 Cleaning and disinfection validation

- FDA guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

7.5 Performance data

Aerosol characterization testing for the subject devices and predicate devices were conducted in accordance with the relevant sections of the CDRH Guidance Document “Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators” (FDA/CDRH - 1993). Tests were performed at both low and high supplied air flow rates for the subject devices. For each device, three drugs: Levosalbutamol hydrochloride, Ipratropium bromide, Budesonide were tested respectively. The comparison items include Mass Median Aerodynamic Diameter (MMAD), Geometric Standard Deviation (GSD), Respirable mass, Respirable Fraction and Total Mass. Also, the variability of intra-sample and inter-sample was tested for the subject devices.

a) Adult mode: aerosol particle characteristics (the sampling rate is 28 L/min, adult mask)

Parameters	Drugs	Subject nebulizer	Predicate nebulizer
Total Mass (μg)	Levosalbutamol hydrochloride	278.15 ± 4.82	271.93 ± 6.80
	Ipratropium bromide	248.67 ± 25.80	219.33 ± 24.25
	Budesonide	223.40 ± 13.80	226.01 ± 4.45
Particle Size-MMAD (μm)	Levosalbutamol hydrochloride	2.76 ± 0.10	2.93 ± 0.09
	Ipratropium bromide	2.65 ± 0.08	2.79 ± 0.13
	Budesonide	2.75 ± 0.14	2.88 ± 0.23
Geometric Standard Deviation	Albuterol sulfate	2.81 ± 0.31	2.52 ± 0.08
	Ipratropium bromide	2.45 ± 0.18	2.74 ± 0.19
	Budesonide	2.60 ± 0.28	2.38 ± 0.17

(GSD)			
Respirable fraction (%, 0.5-5μm)	Levosalbutamol hydrochloride	66.82% ± 2.50%	69.36% ±2.29%
	Ipratropium bromide	68.45% ± 2.97%	68.83% ± 0.56%
	Budesonide	67.99% ± 2.41%	70.36% ± 2.87%
Respirable Mass (μg, 0.5-5μm)	Levosalbutamol hydrochloride	185.85 ± 7.20	188.54 ± 4.22
	Ipratropium bromide	170.17 ± 18.56	150.87 ± 15.57
	Budesonide	151.71 ± 5.66	159.08 ± 9.08
Confidence level of testing	The test and number of samples tests provided a 95% confidence		

b) Pediatric mode: aerosol particle characteristics (the sampling rate is 12 L/min, child mask)

Parameters	Drugs	Subject nebulizer	Predicate nebulizer
Total Mass (μg)	Levosalbutamol hydrochloride	265.16 ± 12.09	264.15 ± 5.44
	Ipratropium bromide	227.43 ± 15.70	236.34 ± 19.76
	Budesonide	238.87 ± 22.57	227.13 ± 23.29
Particle Size-MMAD (μm)	Levosalbutamol hydrochloride	3.07 ± 0.05	3.15 ± 0.12
	Ipratropium bromide	3.17 ± 0.20	3.20 ± 0.16
	Budesonide	3.30 ± 0.08	3.31 ± 0.19
Geometric Standard Deviation (GSD)	Albuterol sulfate	2.31 ± 0.08	2.34 ± 0.03
	Ipratropium bromide	2.42 ± 0.11	2.38 ± 0.05
	Budesonide	2.47 ± 0.04	2.50 ± 0.12
Respirable fraction (%, 0.5-5μm)	Levosalbutamol hydrochloride	70.49% ± 0.01%	69.14% ± 0.02%
	Ipratropium bromide	67.97% ± 0.03%	68.12% ± 0.02%
	Budesonide	65.79% ± 0.01%	65.49% ± 0.03%
Respirable Mass (μg, 0.5-5μm)	Levosalbutamol hydrochloride	186.95 ± 10.21	182.65 ± 5.90
	Ipratropium bromide	154.28 ± 5.65	160.95 ± 14.02
	Budesonide	157.21 ± 15.78	148.24 ± 7.86
Confidence level of testing	The test and number of samples tests provided a 95% confidence		

8. Conclusions

The results of the substantial equivalence assessment, taken together with safety and performance testing data, demonstrate that JM821-Portable mesh nebulizer is

substantially equivalent to the predicate device.