November 27, 2023

Dongguan SIMZO Electronic Technology Co.Ltd.
℅ Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting., Ltd
Room 1407, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong 518000
China

Re: K230379
Trade/Device Name: Portable (Ultrasonic) Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 9, 2023
Received: October 27, 2023

Dear Reanny Wang:

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.

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

Digitally signed by John S. Bender -S
Date: 2023.11.27 13:38:14 -05'00'

for Ethan Nyberg
Assistant Director
DHT1C: Division of Sleep Disordered

Breathing, Respiratory and
Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230379

Device Name
Portable (Ultrasonic) Nebulizer

Indications for Use *(Describe)*
The portable (Ultrasonic) nebulizer is an ultrasonic vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients in hospital/ institutional settings, home, schools, and long-term care facilities. 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.

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510(k) Summary

The assigned 510(k) number is: K230379

1.0 Information of Submitter and Correspondent

Submitter's information:

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Contact Person: Reanny Wang E-mail: reanny@reanny.com

2.0 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Portable (Ultrasonic) Nebulizer
Model:	NBM-1
Classification name:	Nebulizer (Direct Patient Interface)
Review Panel:	Anesthesiology
Product Code:	CAF
Device Class:	II
Regulation Number:	868.5630

3.0 Predicate Device Information

Sponsor: Qingdao Future Medical Technology Co., Ltd.
Device: Intelligent Mesh Nebulizer
510(K) Number: K171549

4.0 Device Description

The Portable (Ultrasonic) nebulizer NBM-1 is small, handheld, internally powered general purpose nebulizer which utilizes ultrasound vibrating mesh technology to generate aerosol. The Portable (Ultrasonic) nebulizer provides a vapor mist of medicine that has much smaller particles and can travel much deeper into the patient's lungs, resulting in much faster relief. The ultrasonic nebulizer is made up of main unit, medicine cup, adult mask, kid mask and mouth piece. The shell of nebulizer, battery cover and spray nozzle are made of ABS, the button decoration ring is silica gel, the medicine cup and button are made by PC, the mask is made of PVC, the mouth piece is made of PP and the nebulizer piece is stainless steel.

The Portable (Ultrasonic) nebulizer NBM-1 has the same working principle, specification, structure, intended use and software, the only differences is appearance.

5.0 Indications for Use

The portable (Ultrasonic) nebulizer is an ultrasonic vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients in hospital/ institutional settings, home, schools, and long-term care facilities.
It is not intended for use with Pentamidine.

6.0 Comparison to predicate device and conclusion

The subject device is substantially equivalent to predicate devices, K171549, Intelligent Mesh Nebulizer. The substantial equivalence chart is provided as follows:

Elements of Comparison	Predicate Device (K171549)	Subject Device	Judgment
Models	**NEB001**	**NBM-1**	**--**
Company	Qingdao Future Medical Technology Co., Ltd.	Dongguan SIMZO Electronic Technology Co. Ltd.	--

Elements of Comparison	Predicate Device (K171549)	Subject Device	Judgment
Models	**NEB001**	**NBM-1**	**--**
Device Name	Intelligent Mesh Nebulizer	Portable (Ultrasonic) Nebulizer	--
Product code	CAF	CAF	SE
Regulation #	21CFR868.5630	21CFR868.5630	SE
Intended use	The Intelligent Mesh Nebulizer designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age) and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.	The ultrasonic nebulizer is an ultrasonic vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients in hospital/institutional settings, home care use, schools, and long term care facilities. It is not intended for use with Pentamidine.	SE, see Remark 1
Principle of operation	Vibrating mesh	Vibrating mesh	SE
Ultrasonic Oscillation Frequency	Approx. 110KHz	110 KHz ± 10KHz	SE
Aerosolization	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation	SE
Compressed gas source	None needed	None needed	SE
Medicine Capacity	8ml maximum,0.5ml minimum	6 ml	Similar see Remark 2
Nebulization rate	≥ 0.2 ml/min	>0.2mL/min.	SE
Aerosol Performance	Table: Comparative particle test comparison	Table: Comparative particle test comparison	Similar, see Remark 3
Duration of Use	Single patient, multi-use	Single patient, multi-use	SE

Elements of Comparison	Predicate Device (K171549)	Subject Device	Judgment
Models	**NEB001**	**NBM-1**	**--**
Power supply	ZN-103450 Lithium battery: 3.7Vd.c. AC Adapter AC 100-240Va.c. 47-63Hz 0.4-0.2A	DC3.0V, 2×AA batteries	Difference, see Remark 4
Waterproof	IP22	IP22	SE
Degree of protection against electric shock	Type BF applied part	Type BF applied part	SE
Type of protection against electric shock	Internally power equipment	Internally power equipment	SE
Model of operation	Continuous operation	Continuous operation	SE
Power off	ON / OFF Button	On/Off button	SE
Operation environment	5℃ to 40℃, 15% to 90% RH	10 -40℃, 10%-95%RH	Similar, see Remark 5
Storage environment	-25℃ to 70℃, ≤90% RH	-20°C to 70°C, 10%-95% RH	Similar, see Remark 5
Patient Connector	Mouthpiece or masks	Mouthpiece or masks	SE
Biocompatibility	All the patient contacting materials are compliance with ISO 10993	All the patient contacting materials are compliance with ISO 10993	SE
Electrical Safety	Compliance with IEC 60601-1 and IEC 60601-1-11	Compliance with IEC 60601-1 and IEC 60601-1-11	SE
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	SE
Dimensions (mm)	50mm(L)×74mm(W)×111mm(H)	60mm×55mm×130mm	Similar, see Remark 6
Weight (kg)	Approx.106g	Approx.110g	Similar, see Remark 6

Table: Comparative particle test comparison

Item	Adult						Pediatric					
	Subject device- Portable (Ultrasonic) Nebulizer (Model: NBM-1)			Predicate device (K171549)- Intelligent Mesh Nebulizer (model: NEB001) -			Subject device- Portable (Ultrasonic) Nebulizer (Model: NBM-1)			Predicate device (K171549)- Intelligent Mesh Nebulizer (model: NEB001) -		
	albuterol sulfate	ipratropium bromide	cromolyn sodium	albuterol sulfate	ipratropium bromide	cromolyn sodium	albuterol sulfate	ipratropium bromide	cromolyn sodium	albuterol sulfate	ipratropium bromide	cromolyn sodium
Particle Size (MMAD)	2.09±0.19	2.10±0.14	2.07±0.19	2.27±0.21	2.37±0.35	2.27±0.25	3.66±0.22	3.48±0.30	3.64±0.21	3.73±0.35	3.60±0.17	3.73±0.21
Geometric Standard Deviation	1.94±0.21	1.91±0.15	1.78±0.13	1.80±0.20	1.73±0.12	1.67±0.06	2.01±0.23	1.98±0.18	1.97±0.17	2.10±0.17	2.10±0.17	1.90±0.10
Total Dose Delivered by device	1,529±65	235±20	7,236±753	1,541±65	242±4	6,983±852	1593.1±113.3	250.2±10.4	7394.3±445.5	1624.2±81.2	247.4±5.2	7279.3±545.9
Total Respirable Dose (0.5-5um)	1,048±106	156±13	5,341±589	1,133±109	164±7	5,157±629	961.6±129.3	150.8±7.1	4581.7±571.2	932.3±115.2	145.4±6.2	4369.4±201.8
Coarse Particle Dose (>4.7um)	397±57	66±9	1,626±224	333±52	66±11	1,507±198	618.3±62.3	95.5±7.8	2715.4±198.6	665.9±48.7	98.1±4.7	2790.8±338.0
Fine Particle Dose (<4.7um)	1,132±106	169±14	5,610±647	1,208±115	175±11	5,477±745	974.7±126.2	154.8±6.1	4679.0±597.7	958.3±114.8	149.3±7.4	4488.5±226.0
Ultra-fine Particle Dose (<1,0um)	258±47	41±4	1,222±128	243±28	36±8	1,091±139	81.0±21.0	12.0±2.8	384.4±88.8	98.0±6.9	13.4±1.5	353.0±26.9

Remark 1:

The indications for use of subject device and predicate device are similar, the intended patient population of subject device is same as predicate device, they are pediatric (>4 years of age=5 years and older) and adult patients.

The handheld nebulizers are common and usual used for Hospital/institutional settings, home care use, schools and long-term care facilities. They are both compliance with IEC 60601-1, IEC 60601-1-2 and IEC60601-1-11 standards. The propose environments of subject device is identical for the predicate device, it will not raise any problems of safety or effectiveness.

Remark 2:

The “Medicine Capacity” of subject is within the predicate device. The subject device has tested on safety and performance tests and the test results were complied with the test requests. Therefore, the subject device didn't raise any problems of safety or effectiveness.

Remark 3:

From the Table: Comparative particle test comparison, all of the parameters were similar with predicate device, there were no statistically measurable differences between the subject device and predicate device, they are substantially equivalent, and the subject device didn't raise any problems of safety or effectiveness.

Remark 4:

The “power supply” of subject device is difference with predicate device, the subject device use AA battery to supply power, the risk of AA battery is lower than Lithium battery. Otherwise, the subject device has been passed the test according to IEC 60601-1 standard, it will not raise any safety or effectiveness issue.

Remark 5:

The operation and storage environment of subject devices is difference with predicate device, and they are both compliance with IEC60601-1-11 standard, it will not raise any safety or effectiveness issue.

Remark 6:

The subject device has the similar specifications with the predicate device, such as dimensions, Weight, based on the nonclinical tests performed, those minor differences for specifications do not affects the safety and effective of the device.

Conclusion:

The subject devices have all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject devices are substantially equivalent to the predicate device.

7.0 Summary of Non-clinical performance testing

7.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device, Portable (Ultrasonic) Nebulizer NBM-1.

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:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD)
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11:2015 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.

Safety and performance:

Safety and performance testing of general purpose nebulizing systems intended for continuous or breath-actuated delivery of liquids, in aerosol form, to humans through the respiratory system were conducted on the device, and three kind of drugs used for testing, albuterol sulfate, ipratropium bromide, cromolyn sodium. Testing established that, with respect to safety and performance for nebulizing systems, the device meets the applicable requirements of:

- ISO 27427:2013 Anaesthetic and respiratory equipment-Nebulizing systems and components
- FDA Guidance: Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators

Biocompatibility testing

The nebulizer's mouthpiece, adult mask, kid mask, medicine cup and cover, button decoration ring, nebulizer piece are patient-contacting device components.

According to provision of ISO 10993-1:2018 annex A table A.1 and FDA's 2020 Guidance entitled, " Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" evaluation testing, and consider the product character of Portable (Ultrasonic) Nebulizer, 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-ISO10993-10
- Acute Systemic Toxicity Test (polar and non polar) -ISO10993-11
- Material-mediated pyrogens Test -ISO10993-11
- Ames Test (polar and DMSO Extract)--ISO10993-3
- In Vitro Mammalian Chromosomal Aberration test --ISO10993-3
- Subchronic systemic toxicity Test (polar and non polar) -ISO10993-11
- Subacute systemic Toxicity Test (polar and non polar) -ISO10993-11
- Muscle implant 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

Under the parameters of the tests, it is concluded that they are biocompatible, and that there are no new issues of safety regarding their use as intended.

Software Verification and Validation Testing

The software verification and validation testing was conducted in accordance with, and documentation was provided as recommended by FDA ' s Guidance , " Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 1, 2005" and IEC 62304:2015 Medical device software - Software life-cycle processes.

Device life testing, shelf-life testing, Battery life testing

Device life, shelf life and battery life were tested with simulation method, the device meets the applicable requirements.

Cleaning Validation

The cleaning was conducted, the test result meets the applicable requirements.

All the test results demonstrate Portable (Ultrasonic) Nebulizer NBM-1 meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate devices.

7.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

8.0 Conclusions

Portable (Ultrasonic) Nebulizer NBM-1 has the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates product safety by successful completion of testing to the IEC 60601-1, IEC60601-1-11 standards and electromagnetic standard IEC 60601-1-2. The performance test demonstrates the nebulizer meet the ISO 27427 standard and confirm the aerosol performance. These conclude that any differences in their characteristics do not raise any safety and effectiveness issues.

From the above information we conclude the subject device, NBM-1 is substantially equivalent to the predicate devices Intelligent Mesh Nebulizer.

9.0 Summary prepared date

October 27, 2023