Shenzhen Homed Medical Device Co., Ltd.
Shi Shengming
Regulatory manager
3rd Floor, Block 1, Longquan Industrial Zone,
Huarong Road, Dalang Street
Shenzhen, Guangdong 518109
China

Re: K212395
Trade/Device Name: Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: January 25, 2022
Received: February 18, 2022

Dear Shi Shengming:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Brandon Blakely, PhD
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)*
K212395

Device Name
JLI nebulizer

Indications for Use *(Describe)*
The JLI nebulizer is used to administer various aerosol treatments to adult and pediatric patients in both the homecare and healthcare settings. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer. The JLI nebulizer is disposable, single-patient-use and intended for use with pediatric (5 years and older) and adult patient.

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

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92 on March 24, 2022

1. Submitter

Submitter's Name	Shenzhen Homed Medical Device Co., Ltd.
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2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	JLI Nebulizer
Classification name:	Nebulizer
Classification:	II
Review Panel:	Anesthesiology
Product Code:	CAF
Regulation Number:	868.5630

3. Predicate Device Information

Trade Name	BESMED Jet Nebulizer Bottle Set
510(k) Number	K091272
Classification name	Nebulizer
Classification:	II
Review Panel:	Anesthesiology
Product code	CAF
Regulation No.	868.5630

4. Device Descriptions

The JLI nebulizer is a small volume jet nebulizer designed to deliver aerosolized medications for inhalation to the respiratory system, the compressed air is forced into the nebulizer through a nozzle cover, where it accelerates and emerges at a high velocity, creating a vacuum (Venturi effect), in the process the liquid medicine is converted into small droplets called aerosol by impacting upon a rigid baffle, the aerosol may be used for inhalation treatment of a physician's prescription. The JLI nebulizer is disposable, single-patient-use.

The JLI nebulizer may replace the BESMED Jet Nebulizer Bottle (Besmed; Model PN-1128E; K091272), and connects to the accessories in K091272, which include Mouthpiece, T-piece, Corrugate tube and Air tube.

The JLI nebulizer is powered by air compressor, which is legally marketed on the USA (Manufacturer: HOMED; Model: JLN-2301AS, K161586).

5. Intended Use and Indications for Use

The JLI nebulizer is used to administer various aerosol treatments to adult and pediatric patients in both the homecare and healthcare settings. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer. The JLI nebulizer is disposable, single-patient-use and intended for use with pediatric (5 years and older) and adult patient.

6. Comparisons of technological characteristics with the predicate device

The JLI nebulizer and Besmed Nebulizer (K091272) are similar in purpose, composition, function, scientific technology and method of operation, the following table provides a comparison of the devices.

Items	Subject Device (JLI nebulizer, K212395)	Predicate Device (Besmed nebulizer, K091272)	Remark
Intended use/Indicati on for Use	The JLI nebulizer is used to administer various aerosol treatments to adult and pediatric patients in both the homecare and healthcare settings. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer. The JLI nebulizer is disposable, single- patient-use and intended for use with pediatric (5 years and older) and adult patient.	The BESMED Jet Nebulizer Bottle Set is used to administer various aerosol treatments to adult and pediatric patients in both the homecare and hospital settings. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer.	Same
Technology	Pneumatic Jet Nebulizer	Pneumatic Jet Nebulizer	Same
Operation principle	Venturi	Venturi	Same
Environment of use	Clinic, homecare	Clinic, homecare	Same
Patient Population	Intended for use with pediatric (5 years and older) and adult patient	Intended for use with pediatric and adult patient	Similar
Single patient use only	Yes	Yes	Same
OTC or Rx	Rx	Rx	Same
Anatomic Site	Mouth	Mouth	Same

Compositi o n	Nebulizer and accessories (mouthpiece, T-piece, corrugate	Nebulizer and accessories (mouthpiece, T-piece, corrugate	Same

Items	Subject Device (JLI nebulizer,K212395)	Predicate Device (Besmed nebulizer, K091272)	Remark
	tube, air tube)	tube, air tube)	
Dimensions	Height: 75.42mm	Height: about 75.9mm	Similar
	External diameter of aerosol outlet: 18.59mm	External diameter of aerosol outlet: about 18.0mm	
	Internal diameter of aerosol outlet: 17.79mm	Internal diameter of aerosol outlet: about 17.2mm	
	Diameter of air inlet: 5.73mm	Diameter of air inlet: about 5.8mm	
Aerosolization	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation	Same
Maximum Fill Volume	6 mL	6 mL	Same
Materials	Polypropylene (PP)	Not publicly available	Different
Type of gas source	Compressed air	Compressed air	Same
Biocompatibility	Conform to FDA guidance of biological evaluation of medical devices	Conform to FDA guidance of biological evaluation of medical devices	Same
Aerosol characterization	Aerosol particulate performance were tested in the modes of adult and pediatric, then parameters of Total Mass, MMAD, GSD, Respirable fraction and Respirable mass were substantially equivalent to the predicate device in a confidence level of 95%.		Similar

The subject device of JLI nebulizer and the predicated device of Besmed nebulizer are similar in purpose, composition, function, scientific technology and method of operation, both the subject device and predicated device have the similar patient population, type of gas source, biocompatibility performance, and there is not significant statistical difference in aerosol particles characteristics between subject device and predicate device. Only minor differences exist between the subject device and predicate device, which will not raise any new issue on safety and effectiveness of the subject device.

7. Brief discussions of the nonclinical tests

The subject device conforms to the following standards:

7.1 Biocompatibility evaluation

The biocompatibility evaluations of the subject device were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process” and FDA biocompatibility guidance, the subject devices will be classified as external communication devices-tissue contact, and considering the cumulative exposure, the contact time will be permanent, the biocompatibility tests should consider the Cytotoxicity test, Sensitization test, Irritation test, Pyrogen test, Systemic toxicity test, Implantation test, Genotoxicity test and Toxicological risk assessment. The testing standards include the following:

Standard	Descriptions

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 10993-10:2010	Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization
ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-3: 2014	Biological evaluation of medical devices-Part 3: tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-6: 2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ISO 10993-17-2002	Biological evaluation of medical devices-Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18: 2020	Biological evaluation of medical devices-Part 18: Chemical characterization of medical device materials within a risk management process

7.2 Dry Gas Pathway Testing

Testing pertaining to the dry gas pathway and associated risk assessments/conclusions were conducted by an independent source. Testing included the assessments of Emissions of volatile organic compounds (VOCs), Fine particles (particulate matter PM2.5&10). The testing standards include the following:

Standard	Descriptions
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 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 Performance data

Aerosol characterization tests 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), USP 40<601> Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers. For each device, three drugs: Albuterol sulfate (10mg/2ml), Ipratropium bromide (0.25mg/2ml), Budesonide (0.5mg/2ml) 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.

7.3.1 Aerosol particle characteristics (the sampling rate is 28 L/min)

Parameters	Drugs	JLI nebulizer	Besmed nebulizer
Total dose (mg)	Albuterol sulfate	7.4990±0.5384	7.5360±0.7936
	Ipratropium bromide	0.1863±0.0248	0.1963±0.0150
	Budesonide	0.3873±0.0285	0.3953±0.0252
MMAD (μm)	Albuterol sulfate	3.1233±0.2113	3.2233±0.1301

	Ipratropium bromide	2.7300±0.1389	2.6167±0.1604
	Budesonide	3.3333±0.1365	3.4733±0.1474
GSD	Albuterol sulfate	2.1100±0.0781	2.2267±0.0551
	Ipratropium bromide	2.7400±0.0173	2.7600±0.1179
	Budesonide	2.7733±0.0569	2.7867±0.0929
Respirable fraction (%)	Albuterol sulfate	72.84±2.30	69.83±1.46
	Ipratropium bromide	68.68±1.28	68.64±1.25
	Budesonide	62.25±0.65	60.92±1.15
Respirable mass (mg)	Albuterol sulfate	5.4701±0.5632	5.2694±0.6474
	Ipratropium bromide	0.1280±0.0175	0.1349±0.0126
	Budesonide	0.2411±0.0178	0.2408±0.0142

7.3.2 Aerosol particle characteristics (the sampling rate is 12 L/min)

Parameters	Drugs	JLI nebulizer	Besmed nebulizer
Total dose (mg)	Albuterol sulfate	6.9057±0.3856	6.5897±0.5465
	Ipratropium bromide	0.1513±0.0178	0.1527±0.0259
	Budesonide	0.3160±0.0288	0.3213±0.0326
MMAD (μm)	Albuterol sulfate	3.3033±0.1415	3.1933±0.1002
	Ipratropium bromide	2.8667±0. 2237	2.7100±0.1587
	Budesonide	3.3700±0.2193	3.5533±0.1858
GSD	Albuterol sulfate	2.1333±0.1060	2.2133±0.0702
	Ipratropium bromide	2.5600±0.0361	2.7567±0.2053
	Budesonide	2.6133±0.0058	2.6700±0.1136
Respirable fraction (%)	Albuterol sulfate	69.99±1.06	70.40±0.50
	Ipratropium bromide	69.22±1.99	67.92±2.26
	Budesonide	63.43±1.92	61.37±12.59
Respirable mass (mg)	Albuterol sulfate	4.8332±0.2848	4.6375±0.3511
	Ipratropium bromide	0.1045±0.0096	0.1035±0.0158
	Budesonide	0.2006±0.0218	0.1971±0.0212

8. Clinical Testing

Substantial equivalence does not depend on clinical test data.

9. Conclusions

Based on device comparison information and performance data, the differences in technological characteristics between the subject devise and predicate device do not raise any new safety and effectiveness issue. Therefore, the subject device is substantially equivalent to the predicate device.