DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 6, 2017

Shenzhen Homed Medical Device Co., Ltd
Shengming Shi
Manager Of Technical Regulation Department
No.2 Building, Longgu Industrial Zone, Longhua Town
Shenzhen, 518109 CN

Re: K161586
Trade/Device Name: The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: August 4, 2017
Received: August 7, 2017

Dear Shengming Shi:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161586

Device Name
The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS)

Indications for Use *(Describe)*
The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) include an AC powered air compressor that provides a source of compressed air for home health care use. The compressor is used in conjunction with a jet (pneumatic) nebulizer to convert certain inhalable drugs into an aerosol form for inhalation by a patient. The device can be used with adult or pediatric patients (4 years and older).

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)

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K161586

510(K) SUMMARY

Submitter:

Shenzhen Homed Medical Device Co., Ltd.
No.2 Building, Longgu Industrial Zone, Longhua Town, Shenzhen, Guangdong, 518109, CHINA

- **Contact Person:**

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- **Date Prepared:**

Aug 30, 2017

Name of the Devices:

- **Device Common Name**: Nebulizer (direct patient interface)
- **Device Proprietary Name**: JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS)
- **Classification Name**：Nebulizer (Direct Patient Interface)
- **Regulation Number:** 21CFR 868.5630
- **Product Code**：CAF
- **Review Panel:** Anesthesiology

Legally Marketed Predicate Device(s):

K020932 Devilbiss Model 3655 Compressor/Nebulize

Indications for Use:

The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS,

JLN-2301AS, JLN-2317AS and JLN-2320AS) include an AC powered air compressor that provides a source of compressed air for home health care use. The compressor is used in conjunction with a jet (pneumatic) nebulizer to convert certain inhalable drugs into an aerosol form for inhalation by a patient. The device can be used with adult or pediatric patients (4 years and older).

Reference Guidance:

- Guidance for Industry and FDA Staff - Format for Traditional and Abbreviated 510(k)s
- Guidance for Industry and FDA Staff - The 510(k) Program Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
- Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators

Recognized Consensus Standard used

ISO 10993-1 : 2009

Biological evaluation of medical devices

IEC 60601-1: 2005 + A1: 2012

Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

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: 2010 + CORR.1: 2011

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

Device Description:

The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) is designed and manufactured by Shenzhen Homed Medical Device Co., Ltd.

The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) is a small, piston-type air compressor, sized to provide the proper flow and pressure sufficient to power jet (pneumatic)

nebulizers. The unit is designed and manufactured to comply with electrical and mechanical safety standards applicable to this type of device.

When the compressor is used in conjunction with a therapeutic nebulizer set, the system converts liquid medication into an aerosol form that can be inhaled by the patient for the treatment of a variety of respiratory disorders. The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) produces an aerosol output with the majority of the aerosol by mass contained in particles less than 5 microns in diameter.

The Besmed Nebulizer Set (Model No. PN-1128E) - (K091272) which has been under FDA clearance will be used with JLN-23XX Series Piston Compress Nebulizer.

Comparison to Predicate Devices:

The Substantial Equivalence Comparison Chat is provided as follows:

Table1: Substantial Equivalence Comparison Chat

Descriptive Information	Proposed Device	Predicate Device
510(K) Number	None	K020932
Proprietary or Model Name	The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS)	Devilbiss Model 3655 Compressor/Nebulize
Indication for Use	The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) include an AC powered air compressor that provides a source of compressed air for home health care use. The compressor is used in conjunction with a jet (pneumatic) nebulizer to convert certain	The DeVilbiss compressor / nebulizer Model 3655 includes an AC powered air compressor that provides a source of compressed air for home health care use. The compressor is used in conjunction with a jet (pneumatic) nebulizer to convert certain inhalable drugs into an aerosol form for inhalation by a patient. The device can be used

	inhalable drugs into an aerosol form for inhalation by a patient. The device can be used with adult or pediatric patients (4 years and older).	with adult or pediatric patients.
Compressor Type	Piston	Piston
Electrical Requirements	120VAC, 60Hz	115 VAC (±10%) 60 Hz
Power Consumption	200VA	140 watts maximum
Storage/Transport Temperature Range	-25 to 70℃(-13 to 158℉)	-40° to +158°F (-40° to +70°C)
Storage/Transport Humidity	10 - 95%	up to 95% non-condensing
Operating Humidity	10 - 95% non-condensing	up to 95% non-condensing
Operating Temperature Range	10 to 40℃ (50 to 104℉)	+40° to +104°F (+5 to +40°C)
Compressor Flow (Free flow)	8LPM	8 lpm
Max Pressure	30 psig or greater / 206 Kpa	35 psig (241 kPa)
Operating Pressure Range	30 psig or greater	/
Noise Level	below 63dBA	58-62 dBA
Biocompatibility	Biocompatible	Biocompatible
Guidance	Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators

Discussion of Non-Clinical Tests Performed:

The performance requirements for the JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) were verified according to the following tests to make sure to be substantial Equivalent to the predicate device.

The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) met the requirements of IEC 60601-1 and IEC 60601-1-2. These testes demonstrate the electrical safety and EMC protection of proposed devices meet the same standard as predicate device.

Laboratory testing, include noise tests, pressure tests and flowrate tests, were conducted to validate and verify that the JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) met all design specifications in various environments and was substantially equivalent to the predicate device.

The biocompatibility test were conducted on the JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) along to make sure the proposed device substantially equivalent to the predicate device in biological aspect.

Regard to product performance, the particle size distribution test via Cascade Impactor (conducted according EN13544-1) of the JLN-23XX Series Piston Compress Nebulizer (with models JLN-2317AS) with the nebulizer set (K091272) was performed in comparison to the predicate device (K020932) with three drugs (Ipratropium bromide, Ventolin, and Pulmicort). The test has shown the proposed device consistent regard to repeatability tests for each three classes of drug, and also demonstrated equivalent performance ability as the predicate device (K020932) that no significant difference in the particle distributions. The Proposed devices have same performance characteristics as the predicate device (K020932) and also meet its product specification as well.

Discussion of Clinical Tests Performed:

Not Applicable.

Conclusions:

The JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) has the same intended use and similar characteristics as the predicate device. Moreover, bench testing contained in this submission demonstrates that the JLN-23XX Series Piston Compress Nebulizer (with models JLN-2300AS, JLN-2301AS, JLN-2317AS and JLN-2320AS) is substantially equivalent to the predicate devices.