June 21, 2018

Shenzhen Homed Medical Device Co,.Ltd.
Shengming Shi
Manager of Technical Regulation Department
3rd Floor, Block 2, Longgu Industrial Zone, Huawang Road
Tongsheng Community, Dalang Street, Longhua New District
Shenzhen, 518109 Cn

Re: K170886
Trade/Device Name: HOMED Mesh Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 22, 2018
Received: May 23, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amy K. Levelle -S

for Tina Kiang, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K170886

Device Name

HOMED Mesh Nebulizer (Model JLN-MBXXX; XXX: 001~005)

Indications for Use *(Describe)*

The HOMED Mesh Nebulizer is an ultrasonic vibrating mesh nebulizer system designed to aerosolize physician-prescribed liquid medications for inhalation to a patient except for Pentamidine. The device may be used with patients 5 years and older in the home, hospital, and sub-acute care settings.

Type of Use *(Select one or both, as applicable)*

XX 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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K170886

Shenzhen Homed Medical Device Co., Ltd
3rd Floor, Block 2, Longgu Industrial Zone,
Huawang Road, Tongsheng Community
Dalang Street, Longhua New District
Shenzhen 518 10 9, PRC

Official Contact: Shengming Shi
Manager of Technical Regulation Department
Tel – 011 0755-29821675

Proprietary or Trade Name: HOMED Mesh Nebulizer

Common/Usual Name: Nebulizer (Direct Patient Interface)

Classification Name: Nebulizer (Direct Patient Interface)
Product Classification – CAF
21 CFR 868.5630
Class II

Predicate Devices: K062263 – Omron NE-U22

Device Description:
The HOMED Mesh Nebulizer is a small, handheld, internally powered general purpose nebulizer which utilizes vibrating mesh technology to generate aerosol.

Components
The **Medicine Cup** contains the nebulizing module where aerosol will be generated. Prescribed medication is placed in the Cup, nebulized and inhaled via the integral mouthpiece.

The Medicine Cup is single patient, multi-use. Cleaning is performed after each use by rinsing with distilled water and disinfected via immersion in boiled water for 10 minutes. The performance met its specification criteria of 90 days.

The cup medication capacity is 6 ml.

The **Main Unit** contains the 2 "AA" batteries or AC Adaptor and firmware to control the vibrating mesh module in the Medicine Cup.

The HOMED Mesh Nebulizer aerosolizes upon turning on by pressing the ON/OFF button and turns off by pressing again or automatically after treatment completion in 30 minutes. To monitor nebulization status and device operating condition, there are different LED colors shown. Normal working condition is indicated by a green while an orange color signifies a malfunction.

There is one model of the subject device, the housing may be offered in various colors, but the unit is fundamentally identical.

Indications for Use:
The HOMED Mesh Nebulizer is an ultrasonic vibrating mesh nebulizer system designed to aerosolize physician-prescribed liquid medications for inhalation to a patient except for

Pentamidine. The device may be used with patients 5 years and older in the home, hospital, and sub-acute care settings.

Principle of Operation / Technology

The HOMED Mesh Nebulizer operates by electrically activating piezoelectric ceramic actuator (PZT) which then transduces the vibration generated to the adjacent supporting plate and polymer mesh bearing numerous apertures. The vibration actively pushes out the liquid medication by physically breaking surface tension of the solution through mesh holes thereby achieving final nebulization. Aerosol generation can subsequently be modulated the vibration frequency that is controlled by the firmware stored within Main Unit to maintain a frequency of approximate 117 kHz, nebulization rate of $\geq$ 0.25 ml/min and a power consumption of <1.5 W.

Table 1 – Performance Specifications

Features	Mesh Nebulizer
Indications for use **Environment of Use** **Patient Population**	The HOMED Mesh Nebulizer is an ultrasonic vibrating mesh nebulizer system designed to aerosolize physician-prescribed liquid medications for inhalation to a patient except for Pentamidine. The device may be used with patients 5 years and older in the home, hospital, and sub-acute care settings
Vibrating mesh technology	Yes
Software driven	Yes - firmware
Patient Interface	Mouthpiece
Nebulizer components cleanable	Medicine Cup and Mouthpiece
Operating conditions	10ºC to 40ºC 30% to 75% RH
Storage conditions	-20ºC to 70ºC, 20% to 80% RH
Power Sources	2 – "AA" Alkaline batteries – 3 V
	AC Adapter – 100-240 V, 50/60Hz Output 1.5 V, 1 A
Dimensions	77 mm (L) x 74 mm (W) x 48 mm (H)
Weigh	80 gr without batteries
MMAD	< 5 microns
Nebulization rate	$\geq$ 0.25 ml / min
Medication capacity	6 ml

Comparison to Predicate

Tables 2 provides a comparison of the proposed device to the predicate.

Table 2 – Comparison of Proposed vs. Predicate Device

Features	Predicate Omron NE-U22 K062263	Proposed Portable Nebulizer
Indications for use	The Omron NE-U22 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medications for inhalation by the patient.	The HOMED Mesh Nebulizer is an ultrasonic vibrating mesh nebulizer system designed to aerosolize physician-prescribed liquid medications for inhalation to a patient except for Pentamidine. The device may be used with patients 5 years and older in the home, hospital, and sub-acute care settings.
Patient Population	The device may be used with pediatric and adult patients	
Environment of Use	home, hospital, and sub-acute care settings	
Contraindications	It is not intended for use with Pentamidine.	It is not intended for use with Pentamidine.
Principle of Operation	Vibrating mesh	Vibrating mesh
Aerosolization	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation
Compressed gas source	None needed	None needed
Reservoir volume	7 ml	6 ml
Nebulization rate	0.25 ml/min to 0.9 ml/min	$\geq$ 0.25 ml/min
Duration of Use	Single patient, multi-use	Single patient, multi-use
Nebulizer components cleanable	Yes	Yes
Software driven	No	Yes
Power source	2 – "AA" Battery	2 – "AA" battery AC Adaptor
Power consumption	1.5 W	< 1.5 W
Weight	97 gm w/o batteries	80 gm w/o batteries
Dimensions (mm)	51 x 38 x 104	77 x 74 x 48
Operating Conditions	0 to 45ºC / 30-85% RH	10 to 40ºC / 30-75% RH
Storage Conditions	-25 to + 70ºC / 10-90% RH	-20 to + 70ºC / 20-70% RH
User interface	On/Off switch LED indicators	On/Off switch LED indicators
Standards met	ES60601-1 IEC 60601-1-2	ES60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11
Performance		
Materials per ISO 10993-1	External Communicating (Indirect gas pathway) Tissue / Bone / Dentin communicating Duration of Use – permanent (> 30 days) And Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days)	External Communicating (Indirect gas pathway) Tissue / Bone / Dentin communicating Duration of Use – permanent (> 30 days) And Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days)
MMAD	MMAD, GSD, Total Respirable Dose, and Total Dose were substantially equivalent to the predicate.	
GSD		
Total Respirable Dose		
Total Dose		

Features	Predicate Omron NE-U22 K062263	Proposed Portable Nebulizer
Software		
Level of Concern	Moderate	Moderate
Device Specific	Yes	Yes
Dependent on external devices	No	No
Signals	LED and tone sounds	LED and tone sounds

Substantial Equivalence Discussion
The HOMED Mesh Nebulizer is viewed as substantially equivalent to the predicate device because:

Indications for Use – The proposed indications for use are to aerosolize commonly prescribed medications.
Discussion - The indications for use are identical for the proposed device and the predicate – K062263 – Omron NE-U22 nebulizer.

Patient Population – The patient population of adult and pediatric (defined by the prescribed medication) patients that is consistent with the indications for the aerosol medication. This is similar to the predicate – K062263 – Omron NE-U22 nebulizer.
Discussion - The patient population is similar for the proposed device and the predicate – K062263 – Omron NE-U22 nebulizer.

Environment of Use – The proposed environments of use are common and usual for handheld nebulizers, namely Hospital/institutional settings, home care use, schools and long term care facilities.
Discussion – The environment of use is similar for the proposed device and the predicate – K062263 – Omron NE-U22 nebulizer.

Technology – The design as a vibrating mesh nebulizer which is the similar principle of operation.
Discussion – The technology is similar for the proposed device as compared to the predicate – K062263 – Omron NE-U22 nebulizer.

Summary of Non-Clinical Performance Testing

We performed a number of non-clinical tests to demonstrate that the HOMED Mesh Nebulizer is equivalent to the predicate K062263 – Omron NE-U22 nebulizer.

- Shelf-life, Useful-life, Simulated Life Cycle testing
- Cleaning
- Electrical Safety, EMC, EMC
- Particle Characterization per Cascade Impactor

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: (1) IEC 60601-1:2012; (2) IEC 60601-1-2:2014; (3) IEC 60601-1-11:2012.

Software Verification and Validation Testing

Verification and validation testing was conducted in accordance with, and documentation was provided as recommended by FDA's Guidance 337, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*". The software for this device is of a "moderate" level of concern, since a failure or latent flaw in the software could lead to a delay in delivery of appropriate medical care.

Biocompatibility

The materials in patient / drug contact are characterized as:

- External Communicating (Indirect gas pathway)
- Tissue / Bone / Dentin communicating
- Duration of Use – permanent (> 30 days)

And

- Surface Contact
- Mucosal membrane
- Duration of Use – permanent (> 30 days)

Discussion - We performed ISO 10993-1 tests to support biocompatibility. They included:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Irritation
- Sub-chronic Systemic toxicity
- Acute Systemic Toxicity
- Pyrogen
- Genotoxicity
- Implantation
- Gas Emission VOC plus Inorganic compounds - CO, CO_2, and Ozone
- $PM_{2.5}$

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

Particle Characterization

Comparative aerosol characterization (particle size distribution) performed between the subject and predicate device. The following tables summarize the results, in all the results very similar compared to that of the predicate.

Table 3 – Comparative Aerosol Performance – Adult Flow Rate – 28 lpm

Features	Predicate Omron NE-22 K062263	Proposed Mesh Nebulizer
Particle Characterization per Cascade Impactor @ 28 lpm – Adult Flow		
Particle size (MMAD)		
Ventolin	2.850-3.148	2.792-2.922
Budesonide	2.686-2.761	2.532-2.577
Atrovent	2.761-3.103	2.412-2.552
Geometric Std. Dev. (GSD)		
Ventolin	2.814-3.011	2.818-2.866
Budesonide	3.112-3.221	3.115-3.165
Atrovent	2.824-3.070	2.746-2.845

Total Respirable Dose (0.5-5 µ) / %		
Ventolin	62.1-64.9%	64.8-67.2%
Budesonide	63.4-65.4%	64.0-65.7%
Atrovent	61.3-67.0%	67.3-69.1%
Coarse Particle Dose (>4.7 µ) / %		
Ventolin	33.1-37.2%	30.4-32.2%
Budesonide	28.2-31.0%	26.8-29.7%
Atrovent	12.6-38.6%	23.1-25.9%
Fine Particle Dose (<4.7 µ) / %		
Ventolin	62.6-66.4%	68.0-69.6%
Budesonide	69.0-87.5%	70.3-73.2%
Atrovent	61.6-76.3%	74.0-76.9%
Ultra-fine Particle Dose (< 1.0 µ) / %Ventolin	3.4-5.0%	5.0-5.4%
Budesonide	7.8%	8.9-9.2%
Atrovent	6.8-8.4%	9.2-10.6%
Total Delivered Dose (µg) / %		
Ventolin	21.3-23.6%	22.1-22.8%
Budesonide	17.5-19.6%	18.0-18.6%
Atrovent	17.6-19.1%	18.0-18.5%
95% confidence intervals		

Table 4 – Comparative Aerosol Performance – Pediatric Flow Rate – 12 lpm

Features	Predicate Omron NE-22 K062263	Proposed Mesh Nebulizer
Particle Characterization per Cascade Impactor @ 12 lpm – Pediatric Flow		
Particle size (MMAD)		
Ventolin	2.996-3.575	3.177-3.388
Budesonide	2.778-2.997	2.739-2.850
Atrovent	2.782-3.077	2.805-2.920
Geometric Std. Dev. (GSD)		
Ventolin	2.533-2.736	2.450-2.767
Budesonide	2.813-2.964	2.933-3.011
Atrovent	2.778-3.019	2.580-2.746
Total Respirable Dose (0.5-5 µ) / %		
Ventolin	55.7-64.5%	55.5-62.6%
Budesonide	60.1-63.3%	61.3-63.2%
Atrovent	54.1-73.6%	65.3-69.8%
Coarse Particle Dose (>4.7 µ) / %		
Ventolin	33.9-43.7%	37.2-39.3%
Budesonide	28.8-39.0%	30.7-32.1%
Atrovent	6.0-57.6%	26.6-30.5%
Fine Particle Dose (<4.7 µ) / %		
Ventolin	56.3-66.1%	60.6-62.8%
Budesonide	61.0-71.1%	67.9-69.3%
Atrovent	42.4-93.5%	69.5-73.4%
Ultra-fine Particle Dose (< 1.0 µ) / %Ventolin	2.1-3.0%	2.2-2.6%
Budesonide	6.7-7.4%	7.8-8.7%
Atrovent	4.0-6.5%	5.1-6.9%
Total Delivered Dose (µg) / %		
Ventolin	20.822.1%	21.1-21.9%
Budesonide	15.9-16.8%	16.1-16.8%
Atrovent	15.0-17.6%	16.0-16.7%
95% confidence intervals		

Particle size characterization (MMAD) was verified after two years of real-time aging using both cascade impactor technique.

Substantial Equivalence Conclusion

As detailed, the indications for use, patient population, environment of use, technology or principle of operation and performance are substantially equivalent.

The differences between the proposed HOMED Mesh Nebulizer and the predicate – K062263 – Omron Model NE-U22 based upon the comparative performance testing we can conclude that the proposed device can be determined to be substantially equivalent to the predicate.