August 31, 2018

Qingdao Future Medical Technology Co., Ltd.
% Ray Wang
Official Correspondent
Beijing Believe Technology Service Co., Ltd.
5-402, Bldg #27, YangGuangYiShang, No.56,
LiangXiang East Rd., FangShan
Beijing, 102401 CHINA

Re: K171549
Trade/Device Name: Intelligent Mesh Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: July 23, 2018
Received: July 30, 2018

Dear Ray 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

James J. Lee -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)*
K171549

Device Name
Intelligent Mesh Nebulizer

Indications for Use *(Describe)*
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.

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 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K171549

1. Date of Preparation

   08/30/2018

2. Sponsor

   Qingdao Future Medical Technology Co., Ltd.

   Room 401 Building F, No. 169 Zhuzhou Road, Laoshan District, QingDao City Shangdong Province, China
   Contact Person: Wang WeiLai
   Position: General Manager
   Tel: 86-18669802350
   Fax:86-532-55677725
   Email: wang.weilai@smartdean.com

3. Submission Correspondent

   Beijing Believe Technology Service Co., Ltd.
   5-402, Building #27, YangGuangYiShang, No. 56, LiangXiang East Rd., FangShan District, BeiJing, China 102401
   Contact Person: Ray Wang
   Position: General Manager
   Tel: 86-18910677558
   Fax:86-10-59120817
   Email: Ray.wang@believe-med.com

4. Identification of Proposed Device

   Trade Name: Intelligent Mesh Nebulizer
   Common Name: Nebulizer
   Model(s): NEB001/NEB002

   Regulatory Information:
   Classification Name: Nebulizer (Direct Patient Interface)

Classification: II;
Product Code: CAF;
Regulation Number: 21 CFR 868.5630；
Review Panel: Anesthesiology;

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.

5. Device Description

The proposed device is a vibrating mesh nebulizer that uses low frequency vibration to create aerosol and delivers aerosolized medication to the lower respiratory tract by using a vibrating mesh to create aerosol and provide fine particles to the patient's lungs. The mesh plate has holes to create low velocity aerosol.

The proposed device is a portable size, curvaceous body design that is convenient to hold, and ability to detect the amount of medications available. Which is battery powered, 3.7V d.c. internally lithium battery. The medication container capacity is 8ml maximum.

The proposed device consists of two parts: physical device and APP software.
For physical device, it is pushed by certain circuit frequency vibration to make piezoelectric ceramic vibrate harmony that caused high speed vibration of metal mesh. And the medicine liquid will be quickly popped through micro mesh hole of metal mesh plate to be countless micro atomizing particles. This will be further transferred by inhalation treatment using masks or mouthpieces to patients' respiratory system.

For APP software, it consists of interactive games, Aerosol Flow rate adjustment, power off and information display which could enhance entertainment and users' adherence to the nebulizer during treatment. It could be connected to the physical device by bluetooth.

Firstly, when users inhale and exhale, the flow pressure could trigger two single-way switches(inhalation switch and exhalation switch) seprately on atomizing cup, then it could transmit signal to CPU of the device by sensor and the signal will be transmitted to the APP further by bluetooth to control playing interactive games.
Secondly, the APP could calculate atomizing time and dosage according to the information transmitted from physical device, and display them in the games.

There are 2 models included, NEB001/NEB002, the two models have same intended use, mechanism of action, principle and specification.
The only difference between two models is that the model NEB001 has two parts, Physical Device

and App software, the NEB001 has the function of Bluetooth for connection between the physical device and App; the model NEB002 only has physical devcie. The detailed difference shown as following:

Table 1 The Difference of Models

Model	NEB001	NEB002
Main Parts	Physical Device & APP software	Physical Device
Nebulization Rate	Adjustable as 0.21 ml/min., 0.27ml/min.,/ 0.30ml/min., 0.32 ml/min., 0.35ml/min. Controlled by APP	0.2ml/min minimum
Data Transmission	Bluetooth	N/A
The OS of connected smart device	Andriod 5.0 or higher	N/A

The proposed device has the components shown as following illustration:

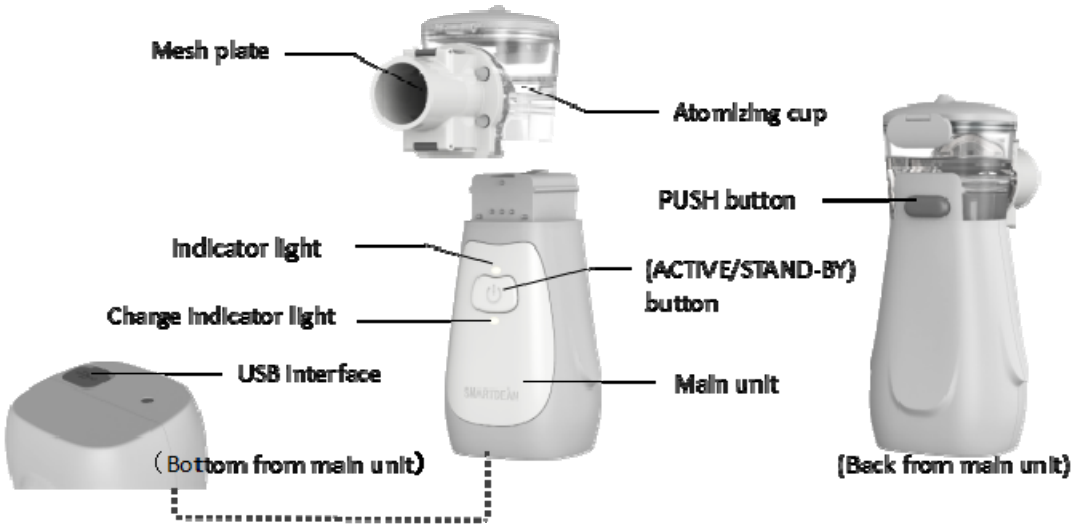

Figure 1 Physical Device Components illustration

The contents provided in the Table 2 are description about the components.

Table 2 Main Components of Physical Device introduction

Main Unit	Provide electricity.
Atomizing Cup	Filled with medicine liquid.
Mesh plate	Create low velocity aerosol
PUSH button	Disassemble the nebulizer.
(ACTIVE/STAND-BY)button	Active/stand-by the nebulizer.
Indicator light	flash blue light when the battery is running out electricity. Flash green light for 3s when there's no medicine liquid in the cup. Normally on green when the nebulizer working regularly.
Charge indicator light	Charge indicator .normally on orange when charging and tuns out to green while the charging finished.
USB interface	Connect wire and charging adaptor.
Mask	Transport the aerosol to patient's respiratory system.
Mouthpiece	Transport the aerosol to patient's respiratory system.
Adapter	Battery charging

6. Identification of Predicate Device

Predicate Device #1:
510(k) Number
K062263
Predicate Device Name
Micro Air Vibrating Mesh Nebulizer (NE-U22)
Manufacturer
Omron Healthcare, Inc.

Predicate Device #2：
510(k) Number
K132247
Predicate Device Name
Ultrasonic Mesh Nebulizer NE105

Manufacturer

Foshan Gaunying Electronics Co., Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2012 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 compatibility-Requirements and tests; which includes the tests as following:
  - IEC CISPR 11:2016 Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement;
  - IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test;
  - IEC 61000-4-3:2010 Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test;
  - IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test;
- IEC 60601-1-11:2015, Medical Electrical Equipment -- Part 1-11: General Requirements For The Basic Safety And Essential Performance - collateral standard: Requirements for medical electrical equipment and medical electrical system used in the home healthcare environment;
- 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 10993-3:2014 Biological Evaluation Of Medical Devices - Part 3: Tests For Genotoxicity, Carcinogenicity And Reproductive Toxicity;
- ISO 10993-6:2007 Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation;
- ISO 10993-11:2006 Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity;
- Software Validation Test;
- Particle Size Distribution testing with Cascade Impactor testing method ***AND*** Laser Light Scattering testing method, and three kind of drugs used for each testing, Pulmicort-contains Budesonide, BRICANYL-contains Terbutaline and Tobramycin in Physiological saline;
- Wireless Data Integrity Testing (only for NEB001);
- Wireless Coexistence Testing (only for NEB001);
- Breath Detection Testing (only for NEB001);

- Aerosol Flow rate testing (only for NEB001);
- Excessive Temperatures Test for battery, evaluate the device surface temperature when the inter battery under the "short" condition.
- Usability Study, performed for NEB001 and NEB002 respectively;
- Particle Size Distribution testing for pediatric patients (mouthpiece and face mask), simulation flow rate at 7L/min for pediatric population (>4 years of old). Cascade Impactor testing method ***AND*** Laser Light Scattering testing method, and three kind of drugs used for each testing, Pulmicort-contains Budesonide, BRICANYL-contains Terbutaline and Tobramycin in Physiological saline;

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 3 General Comparison

ITEM	**Proposed Device**	**Predicate Device #1** K062263	**Predicate Device #2** K032849	Remark
Product Code	CAF	CAF	CAF	Same
Regulation No.	21 CFR 868.5630	21 CFR 868.5630	21 CFR 868.5630	Same
Class	2	2	2	Same
Prescription/ OTC	Prescription	Prescription	Prescription	Same
Intended Use	The Intelligent Mesh Nebulizer designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.	The Omron NE-U22 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medications for inhalation by patient. The device may be used with pediatric and adult patients in the home, hospital, and sub-acute care settings. It is not intended for use with Pentamidine.	The Aeroneb Go Nebulizer, for use by pediatric and adult patients, is intended to aerosolize physician-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer	Same

Table 4 Performance Comparison

ITEM	**Proposed Device**	**Predicate Device #1** K062263	**Predicate Device #2** K032849	Remark
Power Source	ZN-103450 Lithium battery: 3.7Vd.c. AC Adapter AC 100-240Va.c.	Battery – 2 "AA" AC Adapter AC 120V (60Hz/DC 3V)	Battery—3 "AA" disposable or rechargeable batteries, 4.5 VDC, 350	Similar

	47-63Hz 0.4-0.2A		mA	
Nebulizing Method	Vibrating Mesh	Vibrating Mesh	Vibrating mesh	Same
Vibration Frequency	Approx. 110KHz	Approx. 180KHz	Approx. 100 KHz	Similar
Aerosol Flow rate	0.2ml/min minimum	0.25 ml/min to 0.9 ml/min	/	Similar
Particle Size	2.2μm±25%	Approx. 3 um	1.96-2.26 um	Similar
Medicine Capacity	8ml maximum,0.5ml minimum	7 ml	6 mL	Similar
Nebulizer Components Cleanable	Yes	Yes	Yes	Same
Use	Single Patient	Single Patient	Single Patient	Same
Patient Connector	Mouthpiece or mask	Mouthpiece	Mouthpiece or optional mask	Same
Wireless Connection	Bluetooth (Model NEB001)	NA	NA	Difference
Mobile Application	Yes (Model NEB001)	NA	NA	Difference
Dimensions (mm)	50mm(L)×74mm(W)×111mm(H)	38(W) x 51(D) x 104(H)	40 x 105 x 95 mm	Similar
Weight (kg)	Approx.106g	97 g	325 g	Similar
Operating Conditions	5℃ to 40℃, 15% to 90% RH	0℃ to 45℃, 30% to 85% RH	5°C to 45°C to 95% RH	Similar
Storage Conditions	-25℃ to 70℃, ≤90% RH	-25℃ to 70℃, 10% to 90% RH	-20°C to 60°C to 95% RH	Similar

Table 5 Safety Comparison

Item	**Proposed Device**	**Predicate Device #1** K062263	**Predicate Device #2** K032849	**Remark**
Patient Contact Materials	PVC	Polypropylene	PVC	Similar
Cytotoxicity	Comply with ISO 10993-1	Comply with ISO 10993-1	Comply with ISO 10993-1	Same
Sensitization				
Irritation				
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

Table 6 Comparative particle test Comparison

Item	NEB001						NEB002						Aeroneb Go (K032849)					
	mouthpiece			mask			mouthpiece			mask			mouthpiece			mask		
	Budesonide	Terbutaline	Tobramycin	Budesonide	Terbutaline	Tobramycin	Budesonide	Terbutaline	Tobramycin	Budesonide	Terbutaline	Tobramycin	Budesonide	Terbutaline	Tobramycin	Budesonide	Terbutaline	Tobramycin
MMAD(μm)	2.09-2.29	2.09-2.25	2.11-2.27	2.10-2.30	2.11-2.27	2.17-2.25	2.08-2.28	2.09-2.25	2.09-2.25	2.11-2.27	2.15-2.25	2.10-2.28	2.09-2.19	2.00-2.12	1.96-2.06	2.04-2.12	1.87-2.01	1.95-2.09
GSD（μm）	2.05-2.13	2.02-2.10	2.04-2.12	2.12-2.20	1.92-2.00	2.11-2.19	2.03-2.11	2.01-2.09	2.02-2.10	1.98-2.10	1.89-2.07	1.94-2.02	2.01-2.13	1.91-2.05	1.81-1.93	2.14-2.24	1.78-1.86	2.05-2.15
Particle mass collected by the cascade impactor	443.53-536.77	668.64-801.88	1293.08-1466.32	409.32-522.00	667.78-777.42	1198.98-1284.48	441.53-534.77	672.93-806.17	1286.83-1460.07	439.90-516.88	671.39-778.11	1209.44-1322.10	503.01-571.57	757.27-851.79	1414.18-1510.96	476.37-562.91	788.88-844.16	1394.47-1462.83
respirable particle fraction(%)（0.5-5μm）	83.24-88.84	84.11-91.23	80.99-88.11	83.91-90.03	84.09-91.21	84.12-91.24	83.39-88.99	83.56-90.68	79.89-87.01	81.70-88.54	82.63-88.33	82.42-87.90	85.21-88.89	84.26-88.64	82.56-88.26	83.80-88.94	81.07-85.87	81.92-86.60
coarse particle fraction(%)(>4.7μm)	12.89-18.97	14.14-14.44	14.14-14.42	15.58-15.86	15.14-15.42	13.07-13.35	13.88-19.96	13.05-13.33	15.2-15.48	13.74-17.82	14.01-14.23	16.21-16.35	13.69-14.03	14.69-14.86	17.21-17.47	16.50-16.84	18.17-18.29	16.91-17.19
ultra-fine particle fraction(%)(	11.37-15.47	9.99-14.89	7.67-12.57	10.67-15.57	7.78-12.68	7.80-11.90	11.09-15.19	9.99-14.89	8.67-13.57	9.27-11.43	8.20-12.36	9.33-10.45	13.57-18.31	14.60-17.08	14.38-16.86	10.12-14.22	11.32-15.50	9.89-15.83

<1µm)																	

Analysis for difference

The proposed device has the same Intended Use, Classification, Nebulizing Method, Operation and use with the predicate device.

The proposed device has the similar specifications with the predicate device, such as Power Source, Vibration Frequency, Aerosol Flow rate, Particle Size, Medicine Capacity, based on the nonclinical tests performed, those minor differences for similar specifications do not effects the safety and effective of the device.

The main differences are the functions of wireless connection and mobile application between the proposed device and predicate, the model NEB 001. For this difference, we have designed the proposed device as the FCC Part 15 rules and addressed the requirements of "Radio Frequency Wireless Technology in Medical Devices – Guidance for Industry and Food and Drug Administration" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". We have conducted the non-clinical test for such requirements or standards, such as software V&V testing, Testing of FCC Part 15 rules, IEC 60601-1-2 testing, Data Integrate Testing, Wireless Coexistence Testing, and we also conducted the risk management activities about the risks caused by wireless and mobile application as the guidance mentioned above.

The proposed device is substantially equivalent to the predicate device. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.