Shenzhen Ivankaca Technology Co., Ltd
℅ Long Yang
Coo
Shenzhen Hlongmed Biotech Co., Ltd.
1201, Haosheng Business Center, 4096 Dongbin Road, Nanshan,
Shenzhen, P.R.C
Shenzhen, 518054 Cn

Re: K201397
Trade/Device Name: Ultrasonic Mesh Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: June 14, 2021
Received: June 14, 2021

Dear Long Yang:

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
Acting Assistant Director
DHT1C: Division of ENT, 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)*
K201397

Device Name
Ultrasonic Mesh Nebulizer

Indications for Use *(Describe)*
The Ultrasonic Mesh Nebulizer designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age), defined by the prescribed medication, 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 summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(K) number is:_____

Date of Summary: 2021.6.2_____

1. Submitter information

Manufacturer Name: Shenzhen Ivankaca Technology Co.,Ltd

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Fax: 0086- 755-28510161

Email: 798401644@qq.com

Date Prepared: June 2, 2021

2. Contact person

2.1 Primary Contact Person

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2.2 Secondary Contact Person

Sam WONG/General manager

Shenzhen Ivankaca Technology Co.,Ltd

Tel: 0086- 755-28510161

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3. Proposed device

Type of 510(k) submission	Traditional
Trade Name name	Ultrasonic Mesh Nebulizer
Common Name	Nebulizer
Model(s)	MY-123, MY-125, MY-126
Classification Name	Nebulizer (Direct Patient Interface)
Classification	II
Review Panel	Anesthesiology
Product Code	CAF
Regulation Class	II
Regulation Number	21 CFR 868.5630

4. Predicate device

510(k) Number：

K171549

Predicate Device Name：

Intelligent Mesh Nebulizer (model: NEB002)

Manufacturer：

Qingdao Future Medical Technology Co., Ltd

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

5. Description of Proposed Device

The proposed devices are vibrating mesh nebulizers that use low frequency vibration to create aerosol and deliver 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.

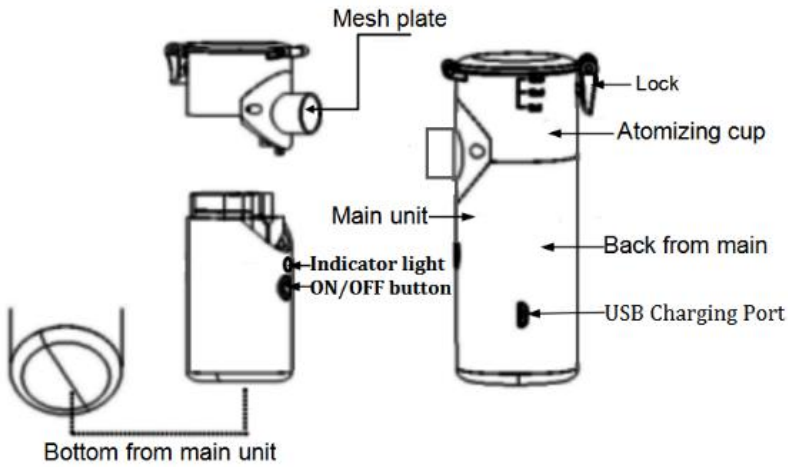
The proposed devices are portable size, curvaceous body design that is convenient to hold, Which are battery powered, 3.7V d.c. internally lithium battery. The medication

container capacity is 8ml maximum.

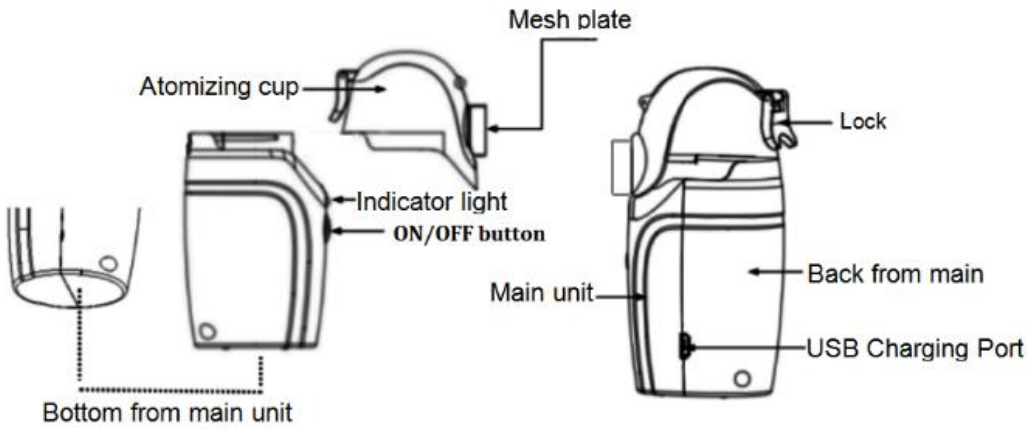
For devices, they are pushed by certain circuit frequency vibration to make piezoelectric ceramic vibrate harmony that caused high speed vibration of metal mesh. And the medicine liquid will be quickly popped through micro mesh hole of metal mesh plate to be countless micro atomizing particles. This will be further transferred by inhalation treatment using masks or mouthpieces to patients' respiratory system.

There are 3 models included, MY-123/MY-125/ MY-126, the three models have same intended use, mechanism of action, principle and specification. The difference between three models is appearance.

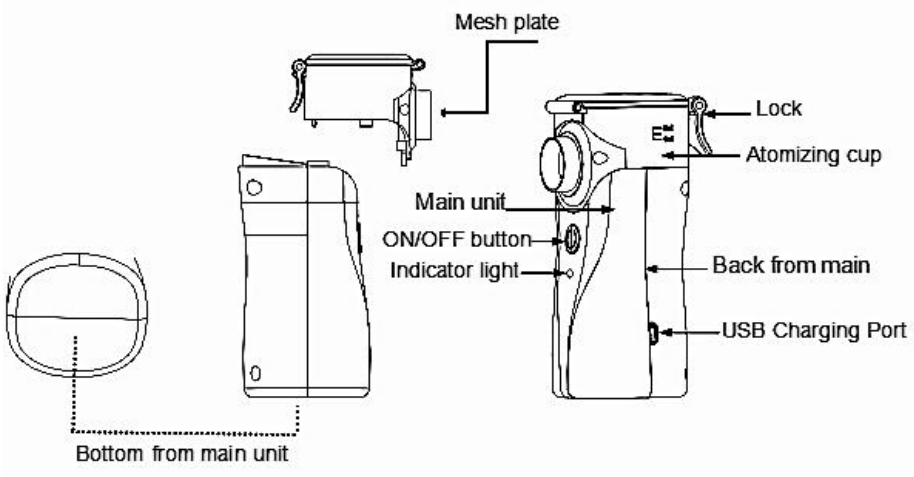
The proposed devices have the components shown as following illustration:



MY-123



MY-125



MY-126

Figure 1 Device Components illustration

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

Main Unit	Provide electricity
Atomizing Cup	filled with medicine liquid
Mesh Plate	Create low velocity aerosol
ON/OFF button	ON/OFF the nebulizer Press the ON/OFF button for 3s to turn on the power and press turn off again; The nebulizer will shut down automatically after 5min operation. Press on /off for 3S to start the machine when it is still in use
Indicator light	Blue light on when the nebulizer works regularly; Automatic turn off after blue light flashes when the battery is running out electricity; Blue lights flicker on when charging regularly; Green light on while finishing charging;
USB interface	Connect the nebulizer with the USB cable to 5Vd.c 1.0A min. power supply to recharge .

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Mask	Transport the aerosol to patient's respiratory system.
Mouthpiece	Transport the aerosol to patient's respiratory system.

Table 1 Main Components of Device introduction

The associated accessories include Mouthpiece, Adult Mask, Pediatric Mask, USB charging cable.

6. Intended Use/ Indications for Use

The Ultrasonic Mesh Nebulizer designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age), defined by the prescribed medication, and adult patients in the home, hospital and sub-acute care settings.

It is not intended for use with Pentamidine.

7. Technological Characteristics and Substantial Equivalence

Item	Subject Device	Predicate device	Remark
General Comparison			
K	/	K171549	/
Sponsor	Shenzhen Ivankaca Technology Co.,Ltd	Qingdao Future Medical Technology Co., Ltd	/
Trade/Device Name	Ultrasonic Mesh Nebulizer	Intelligent Mesh Nebulizer	/
Model(s)	MY-123 MY-125 MY-126	NEB002	/
Regulation Number	21 CFR 868.5630	21 CFR 868.5630	same
Regulation Name	Nebulizer	Nebulizer	same
Classification Name	Nebulizer (Direct Patient Interface)	Nebulizer (Direct Patient Interface)	same

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Regulatory Class	Class II	Class II	same
Product Code	CAF	CAF	same
Review Panel	Anesthesiology	Anesthesiology	same
Intended Use/ Indications for Use	The Ultrasonic Mesh Nebulizer designed to aerosolized liquid medications for inhalation by patient, the device may be used with pediatric (>4 years of age), defined by the prescribed medication, and adult patients in the home, hospital and sub-acute care settings. It is not intended for use with Pentamidine.	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.	same
Prescription/ OTC	Prescription	Prescription	same
Performance Comparison			
Lithium battery	3.7Vd.c.	3.7Vd.c.	Same
Nebulizing Method	Vibrating Mesh	Vibrating Mesh	same
Vibration Frequency	Approx. 110KHz	Approx. 110KHz	same
Nebulization Rate/Aerosol Flow rate	0.2ml/min minimum	0.2ml/min minimum	same
Medicine Capacity	8ml maximum,0.5ml minimum	8ml maximum,0.5ml minimum	same
Nebulizer Components Cleanable	Yes	Yes	same
Use	Single Patient	Single Patient	same
Patient Connector	Mouthpiece or mask	Mouthpiece or mask	same
Dimensions (mm)	Approx. 42(L)x55(W)x109(H)mm(MY-123) 49(L)x56(W)x120(H)mm(MY-125) 45(L)x47(W)x120(H)mm(MY-126)	50mm(L)×74mm(W)×111mm(H)	different
Weight (kg)	MY-123:113±5g MY-125:116±5g	Approx.106g	different

	MY-126: 110±5g		
Operating Conditions	5℃ to 40℃, 15% to 90% RH	5℃ to 40℃, 15% to 90% RH	same
Storage Conditions	-25℃ to 70℃, ≤90% RH	-25℃ to 70℃, ≤90% RH	same
Safety Comparison			
Patient Contact Materials	PVC	PVC	same
Cytotoxicity	Comply with 10993-1	Comply with 10993-1	same
Sensitization			
Irritation			
Electrical safety	Comply with 60601-1	Comply with 60601-1	same
EMC	Comply with 60601-1-2	Comply with 60601-1-2	same

Comparative particle test comparison can be refer to the following table:

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Item	Subject Device			Subject Device			Subject Device			Intelligent Mesh Nebulizer (model: NEB002) -K171549		
	Mouthpiece			Small mask			Big mask			Big mask		
	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide
MMAD(μm)	3.68±0.68	3.28±0.08	3.84 ± 0.66	3.75±0.63	3.25±0.11	3.85 ± 0.66	3.72±0.65	3.31±0.10	3.88 ± 0.68	3.70±0.66	3.29±0.12	3.87 ± 0.72
GSD	1.84±0.03	2.44±0.02	1.83 ± 0.035	1.86±0.05	2.46 ± 0.025	1.84 ± 0.035	1.82 ± 0.035	2.48 ± 0.031	1.84 ± 0.032	1.85±0.04	2.50 ± 0.033	1.81 ± 0.03
Respirable fraction 1 - 5 μm	63.5% ± 10.5	61.7% ± 10.5	62.4% ± 10.6	63.8% ± 11.8	60.8 % ± 11.6	63.4% ± 11.3	64.5% ± 10.2	58.8 % ± 10.2	64.5% ± 11.9	62.8% ± 11.3	57.6% ± 9.8	63.8% ± 11.6
Coarse particle fraction >5 μm	36.1% ± 11.3	29.1% ± 11.3	36.2% ± 12.1	33.4% ± 13.0	27.4% ± 13.0	35.4% ± 12.2	38% ± 10.8	30.5 % ± 12.3	33.8% ±12.4	37.2% ± 12.3	31.6% ± 11.9	34.4% ± 12.3
Fine particle fraction (FPF<5 μm)	65.4% ± 11.4	70.9% ± 11.3	63.8% ± 12.1	64.8% ± 12.6	69.6% ± 13.0	64.6% ±12.2	66.6% ± 13.0	69.5 % ± 10.3	66.2% ±12.4	67.7% ± 10.2	68.4% ± 10.8	65.6% ± 12.3
Ultra-fine particle fraction <1 μm	2.7% ± 0.9	9.2% ± 0.8	1.79% ± 0.6	2.2% ± 0.8	8.8% ± 1.2	1.77% ± 0.5	2.8% ± 1.2	7.2% ± 0.9	1.8% ± 0.6	3.2% ± 0.6	7.5% ± 1.1	1.78% ± 0.6

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Item	Subject Device			Subject Device			Subject Device			Intelligent Mesh Nebulizer (model: NEB002) -K171549		
	Mouthpiece			Small mask			Big mask			Big mask		
	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide
residual（%）	29.6% ± 5.2	26.9% ± 5.8	23.8% ± 3.53	28.6% ± 4.4	24.3% ± 5.4	23.6% ± 3.52	30.8% ± 5.8	24.17% ± 4.82	24.5% ± 3.58	31.5% ± 4.66	24.42% ± 4.96	26.3% ± 3.61
rate of recovery（%）	93.3% ± 3.66	96.4% ± 4.83	91.7% ± 4.52	91.7% ± 4.52	95.87% ± 3.85	92.6% ± 2.83	92.6% ± 2.83	95.07% ± 2.52	92.6% ± 2.83	91.2% ± 4.28	94.86% ± 2.65	93.3% ± 3.66
Aerosol output and aerosol output rate Aerosol output (ml)[a]	1.94 ± 0.02	1.86 ± 0.011	1.94 ± 0.02	1.93 ± 0.05	1.88 ± 0.01	1.94 ± 0.02	1.95 ± 0.01	1.87 ± 0.01	1.93 ± 0.03	1.96 ± 0.01	1.85 ± 0.012	1.92 ± 0.02
Aerosol output rate (ml/min)[b]	0.29 ± 0.02	0.27 ± 0.02	0.35 ± 0.02	0.30 ± 0.03	0.28 ± 0.02	0.34 ± 0.02	0.32 ± 0.03	0.28 ± 0.02	0.35 ± 0.02	0.32 ± 0.03	0.26 ± 0.02	0.33 ± 0.02
Dead volume (ml)	0.06 ± 0.02	0.14 ± 0.011	0.06 ± 0.02	0.07 ± 0.05	0.12 ± 0.01	0.06 ± 0.02	0.05 ± 0.01	0.13 ± 0.01	0.07 ± 0.03	0.04 ± 0.01	0.15 ± 0.012	0.08 ± 0.02
Respirable dose 1 - 5 μm	0.70ml ±	0.758ml	0.58ml	0.71ml ±	0.76ml ±	0.59ml	0.73ml ±	0.78ml ±	0.60ml	0.72ml ±	0.77ml ±	0.58ml

Item	Subject Device			Subject Device			Subject Device			Intelligent Mesh Nebulizer (model: NEB002) -K171549		
	Mouthpiece			Small mask			Big mask			Big mask		
	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide	Salbutamol (Ventolin)	Budesonide (Pulmicort)	Ipratropium bromide
	0.11	±0.15	±0.11	0.12	0.20	±0.11	0.12	0.20	±0.12	0.12	0.18	±0.12
Delivered dose	1.12ml ± 0.06	1.23ml ± 0.12	0.93ml ±0.02	1.12ml ± 0.08	1.26ml ± 0.1	0.93ml ±0.02	1.14ml ± 0.08	1.27ml ± 0.1	0.94ml ±0.02	1.13ml ± 0.08	1.24ml ± 0.12	0.92ml ±0.02

a：Continue the treatment until the medicine cup is empty or the mist stops.

b：The treatment time for aerosol output rate is 1 min.

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Analysis for difference:

The proposed devices have the same Intended Use, Classification, Nebulizing Method, Vibration Frequency, Aerosol Flow rate, Medicine Capacity, Operation and use with the predicate device.

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

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

8. Non-clinical Test conclusion

The following performance data were provided in support of the substantial equivalence determination.

a.Biocompatibility testing

The nebulizer's mouthpiece, Big mask, Small mask, Atomizing cup, Seal ring, Atomizing cup cover, nozzle,Mesh plate are patient-contacting device components.

No	patient-contacting device components	associated materials of construction for each component	If color additive contained	patient-contact classifications per ISO 10993-1
1	mouthpiece	PP1120	no	● Surface Contact ● Mucosal membrane ● Duration of Use(> 30 days)
2	Big mask	PP1120	no	
		TPE(TE-KJ3025TM)	no	
3	Small mask	PP1120	no	
		TPE(TE-KJ3025TM)	no	
4	Atomizing cup	PC2456	no	● External Communicating (Indirect gas pathway)
5	Seal ring	Silicone GA1053	no	
6	Atomizing cup cover	PC2456	no	
7	nozzle	PC2456	no	

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8	Mesh plate	Stainless304	no	● Tissue / Bone / Dentin communicating ● Duration of Use(> 30 days)

A biocompatibility evaluation for the proposed device was conducted in accordance with 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" . The evaluation included the following tests:

- 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
- Ames Test (polar and DMSO Extract)--ISO10993-3
- In Vitro Mammalian Chromosomal Aberration test --ISO10993-3
- Mammalian Erythrocyte Micronucleus Test(polar and non polar) --ISO10993-3
- Subcutaneous Implantation Test--ISO10993-6
- Test for emissions of VOCs and aldehydes-ISO 18562-3
- Test for emissions of particulate matter ozone CO2 and CO- ISO 18562-2
- Biocompatibility evaluation- ISO 18562-1

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.

b. 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,

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

c. Software Verification and Validation Testing

The software for this device is of a "moderate" level of concern,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".

d. Simulated shelf life testing, battery cycle life testing

e. Cleaning and Disinfection Validation

f. human factors validation testing

g. **Particle size distribution testing** per Section VII of the FDA Guidance: Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators，and three kind of drugs used for each testing, Salbutamol (Ventolin), Budesonide (Pulmicort) , Ipratropium bromide.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantial Equivalence Conclusion

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