November 14, 2025

Qingdao Future Medical Technology Co.,Ltd.
Xinxin Wang
RA Manager
South B1 Building E, No.621 Jiushui Rd, Laoshan District
Qingdao, Shandong 266000
China

Re: K251659
Trade/Device Name: Mesh Nebulizer (H6)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 30, 2025
Received: May 30, 2025

Dear Xinxin 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251659

Device Name

Mesh Nebulizer (H6)

Indications for Use *(Describe)*

The 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.

510(k) Summary

1. Contact Details

Applicant Name：Qingdao Future Medical Technology Co., Ltd.
Applicant Address: South B1 Building E, No.621 Jiushui Rd, Laoshan District ,Qingdao City, Shandong Province, China
Applicant Contact Telephone: +86-532-67785800
Applicant Contact Person: Xinxin Wang
Applicant Contact E-mail:wang.xinxin@yirdoc.com

2. Device Information

1） Type of 510(k) submission: Traditional
2） Common Name: Mesh Nebulizer
3） Trade Name: Yirdoc Mesh Nebulizer
4） Regulation Name: Nebulizer
5） Review Panel: Anesthesiology
6） Product Code: CAF
7） Regulation Number: 21 CFR 868.5630
8） Regulation Class: Class II
9） Model:H6

3. Predicate Device Information

Sponsor: Qingdao Future Medical Technology Co., Ltd.
Device: Intelligent Mesh Nebulizer
510(K) Number: K171549

4. Device Description

The Mesh Nebulizer H6 is a portable handheld device that uses micromesh vibration technology to generate aerosols for inhalation by patients. The H6 consists of a main unit, a nebulizer cup and optional accessories, including inhalation masks (available in child and adult sizes), a mouthpiece and a power cord. The main unit housing is made of ABS material, the nebulizer cup is made of PC material, the inhalation mask is made of PP&TPE&silicone material, and the mouthpiece is made of PP&silicone material. It can be powered by an internal lithium battery or by an adapter that complies with the IEC 60601-1 standard.

5. Indications for Use

The 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.

6. Comparison to predicate device (Indications for Use & Technological)

The subject device is substantially equivalent to predicate devices, K171549, Intelligent Mesh Nebulizer. The substantial equivalence chart is provided as follows:

Elements of Comparison	**Predicate Device (K171549)**	**Subject Device**	**Judgment**
Models	**NEB002**	**H6**	**--**
Company	Qingdao Future Medical Technology Co., Ltd.	Qingdao Future Medical Technology Co., Ltd.	--
Device Name	Intelligent Mesh Nebulizer	Mesh Nebulizer	--
Product code	CAF	CAF	SE
Regulation#	21CFR868.5630	21CFR868.5630	SE
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.	The 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.	SE
Principle of operation	Vibrating mesh	Vibrating mesh	SE
Ultrasonic Oscillation Frequency	Approx. 110KHz	110 KHz ± 10%KHz	SE
Aerosolization	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation	SE
Compressed gas source	None needed	None needed	SE
Medicine Capacity	8ml maximum,0.5ml minimum	8ml maximum,0.5ml minimum	SE

Nebulization rate	0.2ml/min	0.2ml/min	SE
Aerosol Performance	Table: Comparative particle test comparison	Table: Comparative particle test comparison	Similar, see Remark 1
Duration of Use	Single patient, multi-use	Single patient, multi-use	SE
Power supply	ZN-103450 Lithium battery: 3.7Vd.c. AC Adapter AC 100-240Va.c. 47-63Hz 0.4-0.2A	Lithium battery: 3.7Vd.c. Adapter AC 100-240Va.c.	SE
Waterproof	IP22	IP22	SE
Degree of protection against electric shock	Type BF applied part	Type BF applied part	SE
Type of protection Against electric shock	Internally power equipment	Internally power equipment	SE
Model of operation	Continuous operation	Continuous operation	SE
Power off	ON/OFF Button	ON/OFF Button	SE
Operation environment	5 to 40℃，15% to 90% RH	5 to 40℃，30% to 80% RH	Similar, see Remark 2
Storage environment	-25 to 70℃，90% RH	-25 to 60℃，15% to 90% RH	Similar, see Remark 2
Patient Connector	Mouthpiece or masks	Mouthpiece or masks	SE
Biocompatibility	All the patient contacting materials are compliance with ISO 10993	All the patient contacting materials are compliance with ISO 10993	SE
Electrical Safety	Compliance with IEC 60601-1 and IEC 60601-1-11	Compliance with IEC 60601-1 and IEC 60601-1-11	SE
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2 IEC 60601-4-2 FCC Part 15B	Similar, see Remark 3
Dimensions (mm)	74mm(L) 50mm(W) 111mm(H)	75mm(L)×50mm(W)×111mm(H)±2mm	Similar, see Remark 4
Weight (kg)	Approx.106g	95g±5g	Similar, see Remark 4
Shelf life	3 years	3 years	SE

Table: Comparative particle test comparison

Item	Predicate device(K171549)-Intelligent Mesh Nebulizer(Model: NEB002)			Subject device- Mesh Nebulizer (Model: H6)		
	Budesonide (2ml：1mg)	Salbutamol (2.5ml：5mg)	Acetylcysteine (3ml：0.3g)	Budesonide (2ml：1mg)	Salbutamol (2.5ml：5mg)	Acetylcysteine (3ml：0.3g)
MMAD(μm)	4.38~4.54	3.99~4.21	4.22~4.31	4.20~4.33	3.46~3.94	3.59~3.98
GSD	1.55~1.56	1.72~1.74	1.62~1.64	1.51~1.56	1.63~1.70	1.57~1.59
Respirable Fraction(%), <5μm	57.92~60.34	61.48~65.21	61.43~62.81	61.96~65.84	66.01~75.52	65.80~69.90
Respirable Fraction(%), <2μm	3.62~4.21	9.18~10.47	5.47~6.40	3.89~4.35	10.37~13.34	6.80~9.93
Respirable Fraction(%), >2μm <5μm	54.30~56.13	52.30~54.74	55.97~56.64	57.723~61.948	55.63~62.175	61.14 ~64.856
Fine Particle Dose (FPD), mg(<5μm)	0.105~0.111	0.867~0.943	39.716~46.113	0.204~0.219	1.289~1.485	65.799~69.900
Aerosol Output Rate,(ml/min) (Adult mouthpice)	0.03~0.04	0.12~0.13	0.09~0.10	0.07~0.09	0.12~0.18	0.08~0.13
Aerosol Output (mg) (Adult mouthpice)	0.197~0.223	2.12~2.17	85.90~89.34	0.268~0.293	2.151~2.204	115.033~116.47
Aerosol Output Rate,(ml/min) (Pediatric/ mouthpice)	0.03~0.07	0.05~0.11	0.05~0.09	0.04~0.07	0.08~0.11	0.06~0.09
Aerosol Output (mg) (Pediatric/mouthpice)	0.114~0.179	1.04~1.18	60.18~75.86	0.214~0.247	1.198~1.380	90.30~91.36
Aerosol Output Rate,(ml/min) (Pediatric/Mask)	0.02~0.06	0.05~0.07	0.05~0.08	0.03~0.06	0.05~0.07	0.02~0.08
Aerosol Output, (mg) (Pediatric/Mask)	0.100~0.148	1.00~1.10	57.46~73.73	0.147~0.222	1.05~1.170	69.67~85.40

Remark 1:
From the Table: Comparative particle test comparison, all of the parameters were similar withpredicate device, there were no statistically measurable differences between the subject device and predicate device, they are substantially equivalent, and the subject device didn't raise any problems of safety or effectiveness.

Remark2:
The operation and storage environment of subject devices is difference with predicate device, and they are both compliance with IEC60601-1-11, it will not raise any safety or effectiveness issue.

Remark 3:
The EMC (Electromagnetic Compatibility) assessment for the subject device has been expanded in scope, incorporating two additional test standards: IEC TR 60601-4-2 and FCC Part 15B. All test results demonstrate full compliance, thereby offering enhanced safety assurance for the device.

Remark 4:
The subject device has the similar specifications with the predicate device, such as dimensions, Weight, based on the nonclinical tests performed, those minor differences for specifications do not affects the safety and effective of the device.

Conclusion:
The subject devices have all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject devices.
Thus, the subject devices are substantially equivalent to the predicate device.

7. Summary of Non-clinical performance testing

7.1 Non-clinical testing

A Series of safety and performance tests were conducted on the subject device, Mesh Nebulizer H6.

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:
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:

- National Standard AAMI ES60601-1, ES60601-1:2005/AMD1:2012, ES60601-1:2005/AMD2:2021 (Consolidated Text) Medical electrical equipment - Part

1: General requirements for basic safety and essential performance (IEC 60601-1:2005/AMD2:2020)

- IEC 60601-1-11:2015/AMD1:2020 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.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC TR 60601-4-2:2016 Medical electrical equipment-Part 4-2: Guidance and interpretation-Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- 47 CFR Part 15, Subpart B(FCC Part15B)

Safety and performance:

Safety and performance testing of general purpose nebulizing systems intended for continuous or breath-actuated delivery of liquids, in aerosol form, to humans through the respiratory system were conducted on the device, and three kind of drugs used for testing, Salbutamol Sulfate Inhalation Solution, Budesonide Suspension Inhalation Solution and Acetylcysteine Inhalation Solution. Testing established that, with respect to safety and performance for nebulizing systems, the device meets the applicable requirements of:

- ISO 27427:2023 Anaesthetic and respiratory equipment-Nebulizing systems and components
- FDA Guidance: Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators

Biocompatibility testing

According to provision of ISO 10993-1:2018 annex A table A.1 and 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" evaluation testing, and consider the product character of Mesh Nebulizer, the following biological compatibility test need to be executed as follow:

- In Vitro Cytotoxicity Test -ISO10993-5
- Skin Sensitization Test -ISO10993-10
- Intracutaneous Reactivity Test-ISO10993-10
- Acute Systemic Toxicity Test -ISO10993-11
- Material-mediated pyrogens Test -ISO10993-11
- Subchronic systemic toxicity Test -ISO10993-11
- Subacute systemic Toxicity Test -ISO10993-11
- Chronic toxicity-ISO 10993-11
- Muscle implant Test -ISO10993-6
- Genetic toxicity-ISO 10993-3
- Carcinogenicity- ISO 10993-3
- Chemical characterization study- ISO10993-18

- Toxicological risk assessment study-ISO10993-17
- Biocompatibility evaluation- ISO 18562-1
- Test for emissions of particulate matter - ISO 18562-2
- Test for emissions of VOS -ISO 18562-3

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.

Software Verification and Validation Testing

The software verification and validation testing was conducted in accordance with, and documentation was provided as recommended by FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 1.2005 and IEC 62304:2006/AMD1:2015 Medical device software-software life-cycle processes.

Device Shelf-life, Lifetime in Use, Battery life and Packaging and Transport Testing

Device shelf life, lifetime in use, battery life packaging and transport were tested and the device meets the applicable requirements.

Reprocessing: Cleaning and Disinfection Validation

The cleaning and Disinfection Validation was conducted, the test result meets the applicable requirements. All the test results demonstrate Mesh Nebulizer H6 meets the requirements of its pre-defined acceptance criteria and intended uses.

7.2 Clinical Testing

No clinical test date was used to support the decision of substantial equivalence.

8. Conclusions

Mesh Nebulizer H6 has the same intended use and similar characteristics as the predicate device. From the above information we conclude the subject device, H6 is substantially equivalent to the predicate devices Intelligent Mesh Nebulizer.

9. Summary Prepared Date

Sep. 30, 2025