Excellentcare Medical (Huizhou) Ltd.
℅ Elly Xu
Consultant Manager
Shenzhen Joyantech Consulting Co., Ltd.
NO. 55 Shizhou middle road, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K192971
Trade/Device Name: Nebulizer Kit
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 26, 2021
Received: June 10, 2021

Dear Elly Xu:

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 L. Blakely, Ph.D.
Assistant Director (Acting)
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)*
K192971

Device Name
Nebulizer Kit

Indications for Use *(Describe)*
The Nebulizer kit is used to aerosolize medication approved for nebulization and prescribed by a physician for delivery to the airways. The Nebulizer kit is intended for adult consistent with the indication for aerosol medication in hospitals and sub-acute institutions.

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

510k number: K192971

1. Administrative Information

Date of Summary prepared	May 26, 2021
Manufacturer information	Company name: Excellentcare Medical (Huizhou) Ltd. Company address: Shatou Industrial Zone. Yuanzhou Town. 516123 Huizhou Guangdong, China Contact person: Chunyu Zhao Phone: +86-752-6358312 Fax: +86-752-6358899 E-mail: bradleyzhao@aliyun.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen Contact person: James Tsai E-Mail: james_tsai@cefda.com; field@cefda.com
Establishment registration number	

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Nebulizer Kit
Classification name:	Nebulizer
Classification:	II
Review Panel:	Anesthesiology
Product Code:	CAF
Regulation Number:	868.5630

3. Predicate Device Information

Trade Name	Disposable hand held nebulizer (VixOne)
510(k) Number	K800562
Classification name	Nebulizer
Classification:	II
Review Panel:	Anesthesiology
Product code	CAF
Regulation No.	868.5630

4. Device Descriptions

The nebulizer kit is a small volume jet nebulizer designed to deliver aerosolized medications for inhalation to the respiratory system, the compressed air or oxygen is forced into the nebulizer through a converging nozzle, where it accelerates and emerges at a high velocity, creating a vacuum (Venturi effect), in the process the liquid medicine is converted into small droplets called aerosol by impacting upon a rigid baffle, the aerosol may be used for inhalation treatment of a physician's prescription. The nebulizer kit is single-patient, multi-use; it requires a cleaning and disinfection process before each use, and the service life is for 30 aerosol treatments.

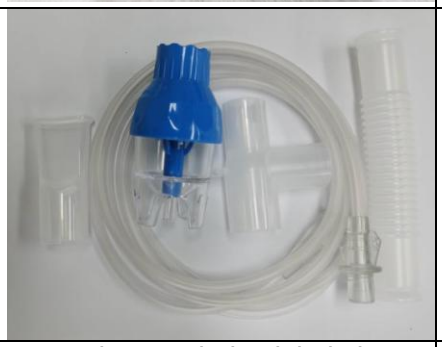
5. Intended Use/ Indications for Use

The Nebulizer kit is used to aerosolize medication approved for nebulization and prescribed by a physician for delivery to the airways. The Nebulizer kit is intended for adult patients consistent with the indication for aerosol medication in hospitals and sub-acute institutions.

6. Comparisons to predicate device

The subject Nebulizer kit and VixOne^{TM} Nebulizer (K800562) are similar in purpose, function, core technology and method of operation, the following table provides a comparison of the two devices.

Items	Proposed Device	Predicate Device (K800562)	Remark
Intended use/Indication for Use	The nebulizer kit is designed to aerosolize medication approved for nebulization and prescribed by a physician for delivery to the airways. The Nebulizer kit is intended for adult consistent with the indication for aerosol medication in hospitals and sub-acute institutions.	A handheld, pneumatic nebulizer designed to aerosolize prescription drugs for inhalation by a patient. Its use is indicated whenever a healthcare professional administers or prescribes medical aerosol products to a patient using a small volume nebulizer	Same
Technology	Pneumatic Jet Nebulizer	Pneumatic Jet Nebulizer	Same
Operation principle	Venturi	Venturi	Same
Environment of use	Hospital, clinic	Hospital, clinic	Same
Patient Population	Adult	Adult and pediatric	Similar
Single patient use only	Yes	Yes	Same
Anatomic Site	Mouth	Mouth	Same
Components	Nebulizer, A-type mouth piece, T-piece, Corrugated tube, and Air tube	Nebulizer, Mouth piece, T-piece, Corrugated tube, and Air tube	Same

Items		Proposed Device	Predicate Device (K800562)	Remark
Photos of components	Nebulizer (integral)			Same
	Nebulizer (component)			Same
	Nebulizer kit			Same
Aerosolization		Continuous during inhalation and exhalation	Continuous during inhalation and exhalation	Same
Type of device		Disposable, prescription only, non-sterile	Disposable, prescription only, non-sterile	Same
Flow rate		4-8L/min	4-10L/min	Different
Maximum Fill Volume		12 mL	10mL	Different
Materials		Polypropylene (PP), Polystyrene (PS), Polyethylene (PE), Ethylene-vinyl acetate copolymer (EVA), Polyvinyl chloride (PVC)	Not publicly available	Different
Type of gas source		Compressed air or oxygen	Compressed air or oxygen	Same
Biocompatibility		Conform to FDA guidance of Biological evaluation of medical devices	Conform to FDA guidance of Biological evaluation of medical devices	Same
Aerosol particle characteristics		The aerosol particle characteristics tests are carried out for the proposed device and predicate device, the parameters of total mass, MMAD, GSD, respirable fraction and respirable Mass are analyzed and compared at a 95% confidence level, there is not significant statistical difference between the two devices.		Different

The proposed device of Nebulizer kit and the predicated device of VixOne^{TM} Nebulizer are similar in purpose, function, core technology and method of operation, both the proposed device and predicated device have the similar patient population, type of gas source, biocompatibility performance, and there is not significant statistical difference in aerosol particles characteristics between nebulizer kit and VixOne. Only minor differences exist between the proposed device and predicate device.

7. Brief discussions of the nonclinical tests

The proposed device conforms to the following standards:

7.1 Biocompatibility evaluation

The biocompatibility evaluations of the proposed device were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process” and FDA biocompatibility guidance, the proposed devices will be classified as external communication devices-tissue contact, and considering the cumulative exposure, the contact time will be permanent. The testing standards include the following:

-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 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

-ISO 10993-3: 2014 Biological evaluation of medical devices-Part 3: tests for genotoxicity, carcinogenicity and reproductive toxicity

-ISO 10993-6: 2016 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

-ISO 10993-17: 2002 Biological evaluation of medical devices-Part 17: Establishment of allowable limits for leachable substances

-ISO 10993-18: 2020 Biological evaluation of medical devices-Part 18: Chemical characterization of medical device materials within a risk management process

7.2 Dry Gas Pathway Testing

Testing pertaining to the dry gas pathway and associated risk assessments/conclusions were conducted by an independent source. Testing included the assessments of Emissions of volatile organic compounds (VOCs), Fine particles (particulate matter PM2.5). The testing standards include the following:

-ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process

-ISO 18562-2: 2017 Tests for emissions of volatile Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter

-ISO 18562-3: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)

7.3 Performance data

Aerosol characterization tests for the proposed devices and predicate devices were conducted in accordance with the relevant sections of the CDRH Guidance Document “Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators” (FDA/CDRH-1993), USP 40<601> Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry

Powder Inhalers, and ISO 27427:2013 Anaesthetic and respiratory equipment-Nebulizing systems and components. For each device, four drugs: Albuterol sulfate (2.5mg/3.0ml), Ipratropium bromide (0.5mg/2.5ml), Cromolyn sodium (20mg/2ml) and Budesonide suspension (1mg/2ml) were tested respectively. The comparison items include Mass Median Aerodynamic Diameter (MMAD), Geometric Standard Deviation (GSD), Respirable mass, Respirable Fraction and Total Mass. Also the variability of intra-sample and inter-sample was tested for the proposed devices.

7.3.1 Aerosol particle characteristics (supplied air flow rate for nebulizer: 8L/min)

Aerosol characteristics	Aerosol particle characteristics	
	Proposed Device (K192971)	Predicate Device (K800562)
Total Mass (µg)	1146.80± 142.12 (Albuterol sulfate) 228.18±12.40 (Ipratropium bromide) 6307.49±802.07 (Cromolyn sodium) 467.07±34.11 (Budesonide Suspension)	1309.33± 137.13 (Albuterol sulfate) 213.81±15.03 (Ipratropium bromide) 7172.85±626.18 (Cromolyn sodium) 501.02±23.65 (Budesonide Suspension)
Particle Size-MMAD (µm)	2.80± 0.23 (Albuterol sulfate) 2.14±0.22 (Ipratropium bromide) 2.66±0.20 (Cromolyn sodium) 3.32±0.18 (Budesonide Suspension)	2.55± 0.15 (Albuterol sulfate) 2.07±0.20 (Ipratropium bromide) 2.41±0.15 (Cromolyn sodium) 3.11±0.18 (Budesonide Suspension)
Geometric Standard Deviation (GSD)	2.49± 0.16 (Albuterol sulfate) 2.81±0.06 (Ipratropium bromide) 2.48±0.09 (Cromolyn sodium) 2.27±0.08 (Budesonide Suspension)	2.51± 0.05 (Albuterol sulfate) 3.01±0.16 (Ipratropium bromide) 2.56±0.09 (Cromolyn sodium) 2.20±0.12 (Budesonide Suspension)
Respirable fraction (% 0.5-5µm)	70.76± 1 (Albuterol sulfate) 71.32±3 (Ipratropium bromide) 72.33±3 (Cromolyn sodium) 68.09±2 (Budesonide Suspension)	73.02± 2 (Albuterol sulfate) 68.86±1 (Ipratropium bromide) 73.52±3 (Cromolyn sodium) 71.82±4 (Budesonide Suspension)
Respirable Mass (µg 0.5-5)	810.89± 94.73 (Albuterol sulfate) 162.63±10.34 (Ipratropium bromide) 4576.38±739.65 (Cromolyn sodium) 318.22±27.49 (Budesonide Suspension)	956.45± 107.82 (Albuterol sulfate) 147.16±11.58 (Ipratropium bromide) 5273.70±512.70 (Cromolyn sodium) 359.25±7.21 (Budesonide Suspension)

7.3.2 Aerosol particle characteristics (supplied air flow rate for nebulizer: 4L/min)

Aerosol characteristics	Aerosol particle characteristics	
	Proposed Device (K192971)	Predicate Device (K800562)
Total Mass (µg)	1031.51± 113.44 (Albuterol sulfate) 199.78±15.60 (Ipratropium bromide) 5466.01±567.02 (Cromolyn sodium) 430.79±18.55 (Budesonide Suspension)	1104.12± 72.02 (Albuterol sulfate) 216.84±10.63 (Ipratropium bromide) 5987.10±715.04 (Cromolyn sodium) 452.60±22.52 (Budesonide Suspension)
Particle Size-MMAD (µm)	4.71± 0.11 (Albuterol sulfate) 3.21±0.17 (Ipratropium bromide)	4.52± 0.13 (Albuterol sulfate) 3.19±0.24 (Ipratropium bromide)

	4.25±0.18 (Cromolyn sodium) 4.97±0.14 (Budesonide Suspension)	4.09±0.10 (Cromolyn sodium) 4.84±0.15 (Budesonide Suspension)
Geometric Standard Deviation (GSD)	2.42± 0.05 (Albuterol sulfate) 2.76±0.16 (Ipratropium bromide) 2.52±0.01 (Cromolyn sodium) 2.53±0.13 (Budesonide Suspension)	2.40± 0.07 (Albuterol sulfate) 2.71±0.11 (Ipratropium bromide) 2.48±0.05 (Cromolyn sodium) 2.59±0.15 (Budesonide Suspension)
Respirable fraction (% 0.5-5μm)	52.17± 1 (Albuterol sulfate) 63.63±3 (Ipratropium bromide) 55.96±2 (Cromolyn sodium) 49.57±1 (Budesonide Suspension)	54.06±1 (Albuterol sulfate) 64.3±3 (Ipratropium bromide) 57.79±1 (Cromolyn sodium) 50.55±0.1 (Budesonide Suspension)
Respirable Mass (μg 0.5-5)	538.94± 70.97 (Albuterol sulfate) 126.97±10.16 (Ipratropium bromide) 3056.41±297.19 (Cromolyn sodium) 213.50±8.65 (Budesonide Suspension)	596.14± 35.20(Albuterol sulfate) 139.41±11.84 (Ipratropium bromide) 3460.11±416.01 (Cromolyn sodium) 228.69±9.93 (Budesonide Suspension)

7.4 Cleaning and Disinfection Validation

Microbiological efficiency control tests were conducted in order to validate the nebulizer cleaning and disinfection methods in the IFU. Testing involved validation of a manually cleaning method and a chemical disinfection method. All testing concluded that the nebulizer could be cleaned and disinfected effectively by use of the methods stated in the IFU. The references include the following:

-FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

-ASTM E1837-96 (Reapproved 2014): Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices.

8. Conclusions

Based on comparison information and testing data, including biocompatibility tests and aerosol particle performance tests, the nebulizer kit meets the requirements of its pre-defined acceptance criteria and intended use. Therefore, the proposed device is substantially equivalent to the predicate devices.