HCMed Innovations Co., Ltd.
Yiling Lee
Supervisor, Regulatory Affairs
Rm.B, 10F, No.319, Sec.2, Dunhua S. Rd., Da-an District,
Taipei City, 10669 Tw

Re: K202171
Trade/Device Name: Pulmogine® Vibrating Mesh Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: July 31, 2020
Received: August 3, 2020

Dear Yiling Lee:

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,

For Brandon Blakely
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)*
K202171

Device Name
Pulmogine® Vibrating Mesh Nebulizer

Indications for Use *(Describe)*
The Pulmogine® Vibrating Mesh Nebulizer is a system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients in hospital / institutional settings, home care use, schools, and long-term care facilities.

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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I. Submitter

Company:	HCMed Innovations Co., Ltd. Rm.B, 10F, No.319, Sec.2, Dunhua S. Rd., Da-an District, Taipei City 10669, Taiwan Tel: + 886-2-2732-6596
Official Contact:	Yiling Lee Supervisor, Regulatory Affairs yiling@hcmed-inno.com
Date of Submission:	July 1, 2021

II. Device

Name of Device:	Pulmogine® Vibrating Mesh Nebulizer
Common/Usual Name:	Vibrating Mesh Nebulizer
Model Number:	HCM-86C
Classification Regulation:	21 CFR 868.5630
Product Code:	CAF
Classification Name:	Nebulizer (Direct Patient Interface)
Regulatory Class:	II
Classification Panel:	Anesthesiology

III. Predicate Device

Product Code	**Manufacturer**	**510(k) Number**	**Device Name**
CAF	Omron Healthcare, Inc.	K062263	Omron Micro Air Vibrating Mesh Nebulizer, Model NE-U22

IV. Device Description

The Pulmogine® Vibrating Mesh Nebulizer, whose dimensions are 74 mm (L) x 46 mm (W) x 96 mm (H), is a small, dumbbell-shaped, handheld, and internally powered general-purpose nebulizer which utilizes vibrating mesh technology to generate aerosol. The Pulmogine® Vibrating Mesh Nebulizer is designed for a single patient, multiple uses, and mainly composed of a **Main Unit** and a **Medication Reservoir**.

The **Main Unit** contains the control circuitry and the firmware to control the vibrating mesh module in the Medication Reservoir and is powered by 2 AA alkaline batteries or an AC adaptor.

The **Medication Reservoir** contains the nebulizing module (mesh) where the liquid medication will be turned into aerosols. The prescribed medication is added into the reservoir with ten (10) ml of medication capacity, nebulized, and inhaled through the aerosol port.

The Pulmogine® Vibrating Mesh Nebulizer generates aerosol from liquid medication during turning on through pressing ON/OFF button and turning off when pressing ON/OFF button again, auto-turn off when no liquid detected, or 10-minute session completed. There are different LED lights to monitor the status and operating condition of the nebulizer: green indicates power on and normally working, yellow flash indicates low power caution, and constant yellow indicates shut-off due to too low power.

V. Indications for Use

The Pulmogine® Vibrating Mesh Nebulizer is a system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients in hospital / institutional settings, home care use, schools, and long-term care facilities.

VI. Non-clinical Testing

A series of including safety and performance tests were conducted on the proposed device, HCMed Pulmogine® Vibrating Mesh nebulizer, HCM-86C. These tests will be discussed in detail in the respective Volume of the submission.

✓ Biocompatibility

The materials in patient/drug contact are characterized as:

- External communicating device
- Tissue communicating
- Permanent duration (> 30days)

And

- Surface contact
- Mucosal membrane
- Permanent duration (>30days)

Therefore, we performed the following tests with guidance from ISO-10993-1 and the FDA biocompatibility guidance and the results were acceptable:

- Cytotoxicity – ISO10993-5: 2009
- Intracutaneous Irritation Study – ISO10993-10:2013

- Sensitization Study – ISO10993-10: 2013
- CO/CO_2/Ozone Analysis – ISO18562-3:2017
- EPA PM 2.5 & PM 10 Analysis – ISO18562-2:2017
- VOC Analysis – ISO18562-3:2017
- Acute Systemic Toxicity – ISO10993-11:2017
- Chemical characterization and risk assessment – ISO10993-18:2005, ISO18562-1:2017
- Genotoxicity – ISO10993-3:2014

✓ Electrical safety and electromagnetic compatibility (EMC)

The device complies with ANSI/AAMI ES60601-1:2005/(R)2012 and IEC 60601-1-2:2014 standards for safety and IEC 60601-1-11:2015 standard for EMC.

✓ Software validation test

The software for this device was considered as a "Moderate" level of concern since failure or latent flaw in the software could directly result in minor injury to the patient or operator.

✓ Performance test

To ensure proper performance in this application, the final products must demonstrate the following aerosol characterizations at adult and pediatric flow rate are comparable to the predicate device:

- Delivered dose (μg)
- Mass median aerodynamic diameter / MMAD (μm)
- Geometric standard deviation / GSD
- Total respirable dose (0.5 – 5μm)
- Coarse particle dose (> 4.7μm)
- Fine particle dose (< 4.7μm)
- Ultra-fine particle dose (< 1.0μm)

✓ Others

We also have performed tests as follows:

- Intra- and inter-sample variability
- Cleaning and disinfection validation
- Simulated lifetime testing

All test results were acceptable per the acceptance criteria detailed in the corresponding protocols and test reports.

VII. Clinical test

No clinical test data was performed to support the determination of substantial equivalence.

VIII. Comparison of Technological Characteristics with the Predicate Device

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

Table 1. Comparison of Predicate Device vs. Proposed Device

Product information	**Predicate Device**	**Proposed Device**	**Similar / Different**
Product name	Micro Air Vibrating Mesh Nebulizer	Pulmogine® Vibrating Mesh Nebulizer	N/A
Model number	NE-U22	HCM-86C	N/A
Manufacturer	Omron Healthcare, Inc.	HCMed Innovations Co., Ltd.	N/A
K number	K062263	Current submission	N/A
Product code	CAF	CAF	Similar
Regulation number	868.5630	868.5630	Similar
Classification	II	II	Similar
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 Pulmogine® Vibrating Mesh Nebulizer is a system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (5 years and older), defined by the prescribed medication, and adult patients in hospital / institutional settings, home care use, schools, and long-term care facilities.	Similar
OTC/Rx only	Prescription only	Prescription only	Similar
Patient Population	The device may be used with pediatric and adult patients	Pediatric (5 years and older), defined by the prescribed medication, and adult patients.	Similar

Environment of Use	in the home, hospital, and sub-acute care settings.	Hospital / institutional settings, home care use, schools, and long-term care facilities	Similar
Contraindications	It is not intended for use with Pentamidine.	It is not intended for use with Pentamidine.	Similar
Principle of Operation	Vibrating mesh	Vibrating mesh	Similar
Aerosolization	Continuous during inhalation and exhalation	Continuous during inhalation and exhalation	Similar
Compressed gas source	None needed	None needed	Similar
Reservoir volume	7 ml	10 ml	Different
Nebulization rate	0.25 ml/min to 0.9 ml/min	≥ 0.25 ml/min	Different
Duration of use	Single patient, multi-use	Single patient, multi-use	Similar
Nebulizer components cleanable	Yes	Yes	Similar
Software-driven	No	No	Similar
Power source	2x AA Batteries	2x 1.5V AA Alkaline Batteries	Similar
Power consumption	1.5 W	Approx. 1.2 W	Similar
Weight	97 gm w/o batteries	75 gm w/o batteries	Different
Dimensions (mm)	51 x 38 x 104	74 x 46 x 96	Different
Operating Conditions	0 to 45°C / 30-85% RH	5 to 40°C / 15-93% RH	Similar
Storage Conditions	-25 to + 70°C / 10-90% RH	-25 to + 70°C / < 93% RH	Similar
User Interface	On/Off switch LED indicators and tone sounds	On/Off switch LED indicators	Similar
Electrical Safety & electromagnetic compatibility	IEC 60601-1:2005 IEC 60601-1-2:2001 UL 60601-1	ANSI/AAMI ES60601-1:2005/(R)2012 IEC 60601-1-2:2014	Similar

	FCC Part 15 Subpart B Class B			IEC 60601-1-11:2015			
Materials in patient contact	Poly (bisphenol-A sulfone) (PSF) Silicone Polycarbonate (PC) Titanium NiPd			Polypropylene (PP) Silicone Polytetrafluoroethylene (PTFE) Acrylonitrile Butadiene Styrene (ABS) NiPd			Different
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)			Similar
@ Pediatric Flow Rate	**Albuterol Sulfate**	**Ipratropium Bromide**	**Cromolyn Sodium**	**Albuterol Sulfate**	**Ipratropium Bromide**	**Cromolyn Sodium**	MMAD, GSD, Total Dose Delivered, and Total Respirable Dose were substantially equivalent to the predicate device.
MMAD (µm)	3.77 ± 0.31	3.33 ± 0.21	3.17 ± 0.06	3.37 ± 0.23	3.20 ± 0.10	3.00 ± 0.20	
GSD	2.45 ± 0.11	2.75 ± 0.22	3.17 ± 0.17	3.02 ± 0.37	2.92 ± 0.11	3.11 ± 0.15	
Total Dose Delivered (µg)	1093 ± 229	369 ± 13	11796 ± 354	1528 ±139	299 ± 22	11088 ± 463	
Total Respirable Dose (µg)	1109 ± 128	187 ± 15	6259 ± 172	925 ± 152	173 ± 18	6167 ± 408	
@ Adult Flow Rate	**Albuterol Sulfate**	**Ipratropium Bromide**	**Cromolyn Sodium**	**Albuterol Sulfate**	**Ipratropium Bromide**	**Cromolyn Sodium**	
MMAD (µm)	3.13 ± 0.31	3.20 ± 0.35	3.03 ± 0.15	2.94 ± 0.25	2.76 ± 0.37	2.39 ± 0.24	
GSD	3.40 ± 0.17	2.74 ± 0.08	2.98 ± 0.24	3.01 ± 0.31	3.39 ± 0.51	2.70 ± 0.30	
Total Dose Delivered (µg)	2215 ± 84	377 ± 28	13208 ± 447	1596 ± 102	320 ± 15	11559 ± 440	
Total Respirable Dose (µg)	1093 ± 72	222 ± 28	7778 ± 457	950 ± 105	191 ± 20	7975 ± 764	

Software Level of Concern	Moderate	Moderate	Similar
Is the software dependent on external devices?	No	No	Similar

Substantial Equivalence Conclusion

As detailed above, the indication for use, patient population, the environment of use, technology characteristics, and the principle of operation are substantially equivalent. The materials in patient contact of the two devices are not identical, but the results of the biocompatibility assay for HCMed Pulmogine® Vibrating Mesh Nebulizer determined with the same criteria verified that the proposed device meets the biocompatibility requirements. Therefore, it can be concluded that the proposed device, HCMed Pulmogine® Vibrating Mesh Nebulizer, HCM-86C, has a substantially equivalence safety and effectiveness profile as compared to the legally marketed predicate device, Omron Micro Air Vibrating Mesh Nebulizer, NE-U22.