June 20, 2025

HCmed Innovations Co., Ltd.
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Drive NE
Saint Petersburg, Florida 33704

Re: K250583
Trade/Device Name: AdheResp Smart Breath-actuated Mesh Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: May 19, 2025
Received: May 19, 2025

Dear Paul Dryden:

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,

John S. Bender -S
2025.06.20 10:11:59 -04'00'

for 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)*

K250583

Device Name

AdheResp Smart Breath-actuated Mesh Nebulizer

Indications for Use *(Describe)*

The AdheResp Smart Breath-actuated Mesh Nebulizer is a system to aerosolize liquid medications for inhalation for patients ranging from pediatrics equal to or greater than 5 years old to adults who can coordinate breathing.

The environment of use are 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared:	13-Jun-25
Sponsor:	HCmed Innovations Co., Ltd. Rm.B, 10F., No.319, Sec.2, Dunhua S. Rd. TEL: +886-02-2732-6596
Sponsor Contact:	Michelle Pieh michelle@hcmed-inno.com
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	AdheResp Smart Breath-actuated Mesh Nebulizer
Classification Name:	Nebulizer
Product Code:	CAF
Predicate Device:	Pulmogine® Vibrating Mesh Nebulizer – K202171
Classification Name:	Nebulizer
Product Code:	CAF
Reference Device:	Respironics AAD – K042991
Classification Name:	Nebulizer
Product Code:	CAF
Device Description:	The AdheResp Smart Breath-actuated Mesh Nebulizer consists of a main unit, medication reservoir, mouthpiece, key tag and charging cable, or power adapter. The medication reservoir could be further separated into a medication container and an aerosol chamber.
Principle of Operation:	There are two key features in the AdheResp Smart Breath-actuated Mesh Nebulizer, which are vibrating mesh nebulization and breath-actuation functions.The AdheResp Smart Breath-actuated Mesh Nebulizer is an active mesh nebulizer. Active mesh nebulizers operate by electrically activating a piezoelectric (PZT) ceramic element that rapidly contracts and expands when applied a voltage to it. The vibrations of the PZT are transmitted to the mesh membrane, which is in contact with the liquid medication loaded in the medication container. This vibration pushes the liquid or suspension through the fine conical holes of the mesh, forming aerosol droplets for the user to inhale.
Indications for Use:	The AdheResp Smart Breath-actuated Mesh Nebulizer is a system to aerosolize liquid medications for inhalation for

	patients ranging from pediatrics equal to or greater than 5 years old to adults who can coordinate breathing. The environment of use are Hospital/institutional settings, home care use, schools, and long-term care facilities.
Patient Population:	Pediatrics equal to or greater than 5 years old to Adults who can coordinate breathing.
Environments of use:	Hospital/institutional settings, home care use, schools, and long-term care facilities.

Comparison and Differences vs. Predicate and Reference

	Subject Device AdheResp K250583	Predicate Device HcMed Pulmogine® K202171	Reference Device Respironics AAD K042991	Comment
Classification	21 CFR 868.5630 CAF - Nebulizer - Direct patient interface	21 CFR 868.5630 CAF - Nebulizer - Direct patient interface	21 CFR 868.5630 CAF - Nebulizer - Direct patient interface	Similar
Indications for use	The AdheResp Smart Breath-actuated Mesh Nebulizer is a system to aerosolize liquid medications for inhalation for patients ranging from pediatrics equal to or greater than 5 years old to adults who can coordinate breathing. The environment of use are Hospital/institutional settings, home care use, schools, and long-term care facilities.	The Pulmogine(r) 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.	The intended purpose of the I-neb AAD System is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medication approved for use with the 1-neb AAD System for inhalation by the patient in the home care, nursing home, sub-acute institution, or hospital environment.	Similar
Intended Use Environment	Hospital/institutional settings, home care use, schools, and long-term care facilities.	Hospital/institutional settings, home care use, schools, and long-term care facilities.	Home care, nursing home, sub-acute institution, or hospital environment	Similar
Principle of Operation	Vibrating Mesh	Vibrating Mesh	Vibrating Mesh	Similar
Aerosolization Mode	Breath actuated	Continuous only	Breath actuated	Similar to reference
Breath Actuation	Delivers aerosol during a portion of the inhalation cycle	Continuous only during whole inhalation cycle	Delivers aerosol during a portion of the inhalation cycle	Similar to reference

	Subject Device AdheResp K250583	Predicate Device HcMed Pulmogine® K202171	Reference Device Respironics AAD K042991	Comment
Maximum Fill Volume	8+ml	10 ml	6ml	Similar
Components	Main unit with rechargeable battery Reservoir chamber – multi-use Mouthpiece	Main unit with rechargeable battery Reservoir chamber – multi-use Mouthpiece	Main unit with rechargeable battery Reservoir chamber – multi-use Mouthpiece	Similar
Breath actuation	Pressure drop with sensor	Not applicable	Pressure drop with sensor	Similar to reference
Algorithm for Inhalation Aerosol delivery	Measures breath and averages the cycle, then delivers aerosol during the designated period	Not applicable	Measures breath and averages the cycle, then delivers aerosol during the designated period	Similar to reference
Aerosol delivery Range during Inhalation	40%~80% Default setting - 60%.	Not applicable	50%~80% Up to last 1 second of inhalation	Similar to reference
Nebulization rate	≥0.25 ml/min	≥0.25 ml/min		Similar
Wireless connectivity	Yes	No	Yes	Similar to reference
Biocompatibility	Surface Contact, mucosal and Externally Communicating, Tissue contact, Permanent Duration ISO 10993-1 testing ISO 18562 testing	Surface Contact, mucosal and Externally Communicating, Tissue contact, Permanent Duration ISO 10993-1 testing ISO 18562 testing	Surface Contact, mucosal and Externally Communicating, Tissue contact, Permanent Duration ISO 10993-1 testing ISO 18562 testing	Similar

Breathe Actuated Particle Characterization Performance Comparison to Predicate

Comparative Performance Testing – Breath Actuated 15 LPM and 30 LPM					
		Subject Device 15 LPM	**Predicate 15 LPM**	**Subject Device 30 LPM**	**Predicate 30 LPM**
MMAD [µm]	Albuterol	3.98 ±0.18	4.52 ±0.21	3.48 ±0.15	3.93 ±0.41
	Ipratropium	3.984 ±0.11	4.29 ±0.17	3.39 ±0.21	3.66 ±0.18
	USP Cromolyn	4.07 ±0.14	4.46 ±0.29	3.58 ±0.15	3.77 ±0.35
GSD	Albuterol	1.82 ±0.03	2.01 ±0.12	1.89 ±0.09	1.93 ±0.18
	Ipratropium	1.94 ±0.10	2.15 ±0.14	1.98 ±0.16	2.09 ±0.11
	USP Cromolyn	1.88 ±0.02	2.15 ±0.08	1.90 ±0.07	2.04 ±0.08
Total Delivered Dose (mg)	Albuterol	4.25 ±0.36	4.06 ±0.42	3.83 ±0.29	3.78 ±0.29
	Ipratropium	0.45 ±0.07	0.45 ±0.08	0.40 ±0.04	0.40 ±0.06
	USP Cromolyn	16.23 ±1.35	14.73 ±2.24	14.65 ±1.09	13.69 ±1.75
Respirable Dose <5µm [mg]	Albuterol	2.71 ±0.32	2.16 ±0.21	2.67 ±0.21	2.33 ±0.39
	Ipratropium	0.28 ±0.03	0.24 ±0.04	0.27 ±0.03	0.24 ±0.03
	USP Cromolyn	10 ±0.85	7.7 ±1.08	9.95 ±0.71	8.42 ±0.52
Coarse Particle Dose <4.7µm [mg]	Albuterol	1.47 ±0.10	1.56 ±0.19	1.05 ±0.28	1.20 ±0.39
	Ipratropium	0.15 ±0.02	0.16 ±0.02	0.11 ±0.01	0.12 ±0.02
	USP Cromolyn	5.85 ±0.65	5.51 ±0.09	4.55 ±0.72	4,57 ±1.12
Fine Particle Dose <4.7µm [mg]	Albuterol	2.56 ±0.30	2.01 ±0.19	2.54 ±0.21	2.16 ±0.21
	Ipratropium	0.27 ±0.03	0.23 ±0.04	0.26 ±0.03	0.23 ±0.03
	USP Cromolyn	9.41 ±0.65	7.35 ±0609	9.46 ±0.48	8.00 ±0.47
Ultra-Fine Particle Dose <1µm [mg]	Albuterol	LOD	LOD	0.21 ±0.06	0.20 ±0.04
	Ipratropium	0.01 ±0.00	0.01 ±0.00	0.02 ±0.01	0.03 ±0.01
	USP Cromolyn	LOD	LOD	0.58 ±0.05	0.58 ±0.11

Testing was performed with 3 samples of each device in triplicate with the 3 drugs. Testing was performed at flow rates of 15 L/min and 30 L/min. The above comparative results and performance are similar for both the proposed device and the predicate.

Substantial Equivalence Discussion

Substantial Equivalence Discussion
The tables above compare the key features of the subject device with the identified predicate and reference. The comparison demonstrates that the subject device can be found to be substantially equivalent to the predicate and any differences are addressed with the reference device.

Indications for Use –
The indications for use are similar for the subject device when compared to the predicate.

Technology and construction –
The technology and principle of operation is similar for the subject device when compared to the predicate and reference devices.

Environment of Use –
The environments of use are similar to the predicate device.

Patient Population –
The patient population is similar to the predicate device.

Non-Clinical Testing Summary –

Bench testing
Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:

- Nebulization rate
- Inter- and Intra-sample Variability
- Aerosol Performance
- Comparative (Subject vs. Predicate) Aerosol Performance
- Minimum Breath Actuation Tests

Biocompatibility
Applicable ISO 10993 and ISO 18652 testing was performed.

Reprocessing, Sterility, and Shelf-Life

- Cleaning Validation
- Aging
- Simulated Life (cleaning, aging, drop)

Discussion of Differences

The subject device differs in the following ways from the predicate:

- The predicate device is not breath actuated

- It does not include wireless connectivity
- These have been addressed by use of a reference device

Discussion of Differences
The differences between the subject and predicate and reference devices do not raise new concerns regarding the safety and effectiveness as demonstrated by performance testing.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and non-clinical testing that the subject device and predicate have been found to be substantially equivalent.