Vapotherm Inc.
Michael Webb
VP of Regulatory Affairs
100 Domain Drive
Exeter, New Hampshire 03833

Re: K220869
Trade/Device Name: Vapotherm Aerosol Adapter AAA-2
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: September 29, 2022
Received: September 30, 2022

Dear Michael Webb:

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 James Lee
Director
DHT1C: Division of 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)*
K220869

Device Name
Vapotherm Aerosol Adapter AAA-2

Indications for Use *(Describe)*
The Vapotherm Aerosol Adapter AAA-2 is intended to facilitate the connection between Vapotherm High Velocity Therapy HVT 2.0 and the Aerogen Solo Nebulizer.

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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SECTION 5: 510(k) SUMMARY

Date:	26-October-2022
Company:	Vapotherm, Inc. 100 Domain Drive Exeter, NH 03833
Official Contact:	Michael J. Webb – Vice President of Regulatory Affairs Tel – (844) 381-8276
Proprietary or Trade Name:	AAA-2
Common/Usual Name:	Nebulizer, Accessory to
Classification Name:	21 CFR 868.5630, Class II Product Code: CAF
Predicate Device:	K133360 Aerogen Limited, Aeroneb Solo Adapter (Primary)
Reference Device Predicate:	K162753 Instrumentation Industries, Inc., RTC 26-C Inline Aerosol Adapter

Device Description:
The Vapotherm Aerosol Adapter AAA-2 is an accessory that is intended to facilitate the connection between Vapotherm High Velocity Therapy HVT® 2.0, cleared under K203357, and the Aerogen Aeroneb® Solo Nebulizer System, cleared under K133360, and more recently with K143719, which is intended to aerosolize solutions for inhalation. The AAA-2 facilitates the connection between the noted devices, and therefore aerosolization use is dictated by the Aerogen Aeroneb Solo Nebulizer System labeling.

Indications for Use:
The Vapotherm Aerosol Adapter AAA-2 is intended to facilitate the connection between Vapotherm High Velocity Therapy HVT 2.0 and the Aerogen Solo Nebulizer.

Patient Population:
The AAA-2 shares the same intended patient populations as the Vapotherm HVT 2.0 which are spontaneously breathing adult and pediatric patients (5 kg and up), and the Aeroneb Solo Adapter which includes pediatric patients (29 days or older) as well as adult patients.

Environment of Use:
Hospital, sub-acute facility

Contraindications:
None

Substantial Equivalence:
The AAA-2 is substantially equivalent to the predicate device, K133360 Aeroneb Solo Adapter. The reference predicate device K162753 RTC 26-C Inline Aerosol Adapter, also supports substantial equivalence.

A Benefit-Risk Assessment was completed and concluded that when assessing the minor differences between the subject and predicate device, there is no decrease in the expected benefit or increase in potential risk with the subject device. This assessment supports the conclusion that the minor differences in technological characteristics between the subject device AAA-2 and predicate Aeroneb Solo Adapter do not raise new questions of safety and effectiveness. Additionally, this assessment when considered with the Performance Testing-Bench, supports that the AAA-2 is "as safe and effective" and performs as well as the predicate device. The probable benefit to health from of the use of the AAA-2 outweighs any potential risk of injury or illness from such use.

The tables below present the similarities and differences between the products for substantial equivalence purposes. The differences between the subject device and the predicate device do not raise new questions of safety and effectiveness. Performance data support a substantial equivalence determination.

Table 5.1: Primary Predicate Device Comparison Table and Discussion		
Characteristic	**Primary Predicate:** Aerogen Aeroneb Solo Adapter (K133360)	**Subject Device:** Vapotherm Aerosol Adapter AAA-2
Indications for Use	The Aeroneb® Solo Adapter is an accessory specific to the Aeroneb® Solo Nebulizer. It facilitates intermittent and continuous nebulization and optional supply of supplemental Oxygen to pediatric (29 days or older) and adult patients in hospital use environments via a mouthpiece or aerosol mask. If supplemental oxygen is used, for pediatric patients under 18 years of age, a maximum flow rate of 2 LPM should be used. Note: The mouthpiece should not be used for children under 5 years of age.	**SIMILAR TEXT, SAME INTENDED USE** The Vapotherm Aerosol Adapter AAA-2 is intended to facilitate the connection between Vapotherm High Velocity Therapy HVT®2.0 and the Aerogen Solo Nebulizer. Both are aerosol adapters used with the Aeroneb Solo Nebulizer System, that allow connection to a larger breathing circuit. Because the subject device is only indicated for use with the Aeroneb Solo and HVT 2.0, it carries the same intended patient populations as the two parent devices which are pediatric and adult patients. The pediatric use is limited to 29 days or older and 5kg and up, again, consistent with the parent devices.
Intended Use	To allow use of the Aeroneb Solo Nebulizer System with supplemental oxygen.	**SAME** To allow use of the Aeroneb Solo Nebulizer System with the Vapotherm HVT 2.0, which delivers supplemental oxygen.
Patient Population	Pediatric (29 days or older) and adult patients	**SIMILAR** Pediatric (29 days or older) and adult patients. Pediatric Patients 5kg and up and adult patients. The subject device is only for use with the Aerogen Solo Nebulizer and HVT 2.0 and therefore is subject to their cleared patient populations, which would be pediatric patients 5 kg and up and 29 days or older, as well as adult patients.
Environment of Use	Hospital	**SIMILAR** Hospital, sub-acute facility Environments are similar clinical environments. Sub-acute facility is included given the HVT 2.0 clearance and is not a significant difference.

Table 5.1: Primary Predicate Device Comparison Table and Discussion		
Characteristic	**Primary Predicate:** Aerogen Aeroneb Solo Adapter (K133360)	**Subject Device:** Vapotherm Aerosol Adapter AAA-2
Type & Duration of Use	Single patient use for up to 28 days	**SIMILAR** Single patient use for up to 30 days AAA-2 30 day use is consistent with the HVT 2.0 device it is used with.
Prescriptive	Rx Only	**SAME** Rx Only
Patient Interface – for parent device	Mouthpiece, aerosol mask, nasal cannula, or via ventilator	**SIMILAR** Nasal cannula or TA-22 Both share the same patient interface of nasal cannula or via trach access.
Patient contacting materials	Externally communicating, tissue, prolonged duration	**SAME** Externally communicating, tissue, prolonged duration Both devices are comprised of polymers; Same ISO 10993-1 classification
Sterility	Non-sterile	**SAME** Non-sterile
Operating Principle	Function is to allow access to a breathing circuit for the purpose of the introduction of the aerosolized solution using Aeroneb Solo Nebulizer System.	**SAME** Function is to allow access to a breathing circuit for the purpose of the introduction of the aerosolized solution using Aeroneb Solo Nebulizer System. Both are passive adapters that facilitate the connection of the Aeroneb Solo Nebulizer with a larger breathing circuit that delivers supplemental oxygen.
Compatible Device	Breathing circuit, multiple, not specified Aerogen Aeroneb SOLO Nebulizer	**SAME** Vapotherm HVT 2.0 Aerogen Aeroneb SOLO Nebulizer Aerogen Solo Adapter IFU shows multiple different configurations for attaching the adapter to various breathing circuits. The Subject Device is more specific to HVT 2.0.

Non-clinical performance testing:

Biocompatibility / Materials –
Biocompatibility testing was conducted in accordance with FDA guidance, *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing*

within a risk management process" and ISO 18562-1 - *Biocompatibility evaluation of breathing gas pathways in healthcare applications*. The AAA-2 was determined to possess acceptable biocompatibility risk.

Bench / Performance Testing –
Testing was performed to assure that the proposed design does not raise new questions of safety and effectiveness based on the proposed device intended use. Testing included:

Aerosolized solution output testing was performed utilizing a 500mW green laser to confirm delivery, with a nasal cannula patient and trach adapter interface.

Achievable flow rate consisted of testing the AAA-2 with HVT 2.0 while varying flow rates set to 8, 20, and 45 L/min, with varying cannula sizes which included Infant, Pediatric Small, and Adult XL cannulas, to confirm the set flows were achieved.

Occlusion testing with associated alarm included running the AAA-2 with HVT 2.0 at varying flow rates of 3 and 8 L/min for the infant cannula, 3 and 20 L/min for the Pediatric Small, and 3 and 45 L/min for the Adult XL.

The testing described as 'Volume of liquid exiting the adapter outlet' is to demonstrate that excessive rain-out does not occur. The system passed as the maximum of 5 ml of rainout was not exceeded with the AAA-2 placed in a worst-case orientation.

The physical connections testing included challenging all connection points under varying flow rates and worst-case simulated conditions. The 22mm female port that accommodates the connection to the Aerogen Solo Nebulizer was also demonstrated to be compliant to ISO 5356-1.

Continuous use testing was performed while running the HVT 2.0 at varying flow rates and temperatures and there were no signs of component or material degradation.

Aerosolization performance comparison testing for commonly nebulized solutions was completed to demonstrate similar performance for both the AAA-2 Aerosol Adapter and the Aeroneb Solo Adapter when used with an Aeroneb Solo Nebulizer System. To determine particle size distributions and respirable dose of the nebulized solution, nebulized solution respules were collected using the Next Generation Cascade Impactor (NGI) and demonstrated that the use of HVT 2.0 with AAA-2 did not interfere with the expected performance of the Aeroneb Solo device.

Usability/Human Factors testing was performed with results analyzed to identify potential use errors, close calls, and difficulties associated with the critical tasks. The results of this testing supports a substantial equivalence determination.

Substantial Equivalence Conclusion
The performance testing demonstrates that the subject device is substantially equivalent to the predicate device.