August 25, 2021

Vapotherm Inc.
Dennis Francoeur
Regulatory Manager
100 Domain Drive
Exeter, New Hampshire 03833

Re: K203357
Trade/Device Name: Hvt 2.0
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: July 23, 2021
Received: July 26, 2021

Dear Dennis Francoeur:

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 Blakely, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203357

Device Name
HVT 2.0

Indications for Use *(Describe)*
The HVT 2.0 system is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult patients and pediatric patients (5 kg and up). The device is intended to be used in hospital, sub-acute facility, and home-use settings.

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:	23-August-2021
Company:	Vapotherm, Inc. 100 Domain Drive Exeter, NH 03833
Official Contact:	Dennis Francoeur – Regulatory Manger Tel – 603-658-0491
Proprietary or Trade Name:	HVT 2.0
Common/Usual Name:	Respiratory gas humidifier
Classification Name:	21 CFR 868.5450, Class II Product Code: BTT
Predicate Device:	K191010 – Palladium High Flow Therapy System

Device Description:
The HVT 2.0 system is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult patients and pediatric patients (5 kg and up). The device is intended to be used in hospital, sub-acute facility and home-use settings.

The HVT 2.0 system is intended to be used by qualified medical professionals, such as physicians, nurses, respiratory therapists and by patients in a home-use setting under the supervision of qualified medical professionals.

The HVT 2.0 system consists of the HVT 2.0 main device, a Disposable Patient Circuit (DPC), and a patient interface (nasal cannula). The HVT 2.0 system utilizes an integrated internal blower to deliver warmed and humidified breathing gas at flows up to 45 L/min to spontaneously breathing patients, without the need of wall air or any pressurized air source. The device incorporates a blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently. The addition of an external oxygen source (wall, tank, or oxygen concentrator) enables FiO_2 delivery from 21% to 100%, dependent on the oxygen source.

The HVT 2.0 main device contains all the electrical and electronic components including the electronic blender and flow controllers, and remote sensors to monitor the disposable patient circuit. The main device has no water pathways, and the gas pathway only contains dry gas at room temperature, and consequently does not need internal cleaning or disinfection.

Indications for Use:
The HVT 2.0 system is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult patients and pediatric patients (5 kg and up). The device is intended to be used in hospital, sub-acute facility and home-use settings.

Patient Population:
For pediatric and adult patients
Note: Vapotherm follows the definition of pediatric patients and pediatric subpopulations discussed in Guidance for Industry and Food and Drug Administration Staff "Providing Information about Pediatric Uses of Medical Devices".

Environment of Use:
Hospital, sub-acute and homecare settings

Contraindications:
Not appropriate for patients who are not spontaneously breathing, are unable to protect their airway, or have anatomic or injury induced blockage of the nasal pathway to the nasopharyngeal space.

- Not for treating OSA and snoring.
- HVT 2.0 is not for field transport.
- HVT 2.0 is MRI unsafe. Do not use it in an MR environment.

Substantial Equivalence:
The HVT 2.0 System is substantially equivalent to the predicate device, the Palladium High Flow Therapy System (510(k) K191010). The table below presents the similarities and differences between the products for substantial equivalence purposes. The differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence.

Characteristic	Predicate: Palladium High Flow Therapy System (K191010)	Subject Device: HVT 2.0
Indications for Use	The Palladium High Flow Therapy System is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult and pediatric and patients weighing at least 3.5 kg within hospital, sub-acute and homecare settings.	**SIMILAR – K191010** The HVT 2.0 system is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult patients and pediatric patients (5 kg and up). The device is intended to be used in hospital, sub-acute facility, and home-use settings.
Patient Population	Pediatric, adult	**SAME – K191010** Pediatric, adult
Environment of Use	Hospital, sub-acute and homecare settings	**SAME - K191010** Hospital, sub-acute and homecare settings
Duration of Use	Disposable can be used for up to 30 days single patient use.	**SAME - K191010** Disposable can be used for up to 30 days single patient use.
Prescriptive	Rx Only	**SAME – K191010** Rx Only
Patient Interfaces	Nasal cannula	**SIMILAR – K191010** Nasal cannula, 22mm Tubing Adapter
Flow Range	5 to 40 L/Min (SLPM)	**SIMILAR – K191010** 3-45 L/Min (BTPS)
Patient contacting materials	Externally communicating, tissue, prolonged duration	**SAME - K191010** Externally communicating, tissue, prolonged duration
Temperature Range	33C to 38C	**SIMILAR – K191010** 33C to 39C
Heater	Flat heater element within the capital unit that contacts disposable patient circuit – Flexible Kapton Circuit heater element (Conduction heating)	**SIMILAR - K191010** Flat heater element that is within the disposable patient circuit and powered by an energy source in the capital unit. (Induction heating)
Temperature Alarm	Software controlled; Alarms at 41 °C	**SAME – K191010** Software controlled; Alarms at 41 °C
Temperature Accuracy	± 2 °C	**SAME – K191010** ± 2 °C
Oxygen Range	21 to 95 % O_2	**SIMILAR – K191010** 21 to 100% O_2 Limited by O_2 Concentrator

Characteristic	Predicate: Palladium High Flow Therapy System (K191010)	Subject Device: HVT 2.0
Oxygen Accuracy	±3%	**SIMILAR – K191010** ±3% (when connected to a wall or tank source) ±4% (when connected to an oxygen concentrator source)
Operating Principle	Gas delivery via a blower and humidification via semi-permeable polymer technology which allows for delivery of entrained, humidified gases at constant flow to the patient	**SAME - K191010** Gas delivery via a blower and humidification via semi-permeable polymer technology which allows for delivery of entrained, humidified gases at constant flow to the patient
Alarms	Audible and visual for temperature, low oxygen fraction, blocked tube, water out, disposable water path not present, loss of power and loss of flow	**SAME - K191010** Audible and visual for temperature, low oxygen fraction, blocked tube, water out, disposable water path not present, loss of power and loss of flow
User interface	User set point adjustment via menu system on display for flow rate, temperature, and oxygen fraction	**SAME - K191010** User set point adjustment via menu system on display for flow rate, temperature, and oxygen fraction
Control	Software control	**SAME - K191010** Software control
Modes of operation	Sleep, Standby and Run Modes Sleep: Display is in sleep mode, no gas flow Stand-by: Input parameters can be adjusted, no gas flow Run: Warming to set point temperature, gas flow Unit operating at set point, gas flow	**SAME - K191010** Sleep, Standby and Run Modes Sleep: Display is in sleep mode, no gas flow Stand-by: Input parameters can be adjusted, no gas flow Run: Warming to set point temperature, gas flow Unit operating at set point, gas flow
Gas input	Standard DISS non-interchangeable fitting for medical oxygen, room air via blower	**SAME - K103316** Standard DISS non-interchangeable fitting for oxygen, room air via blower

Characteristic	Predicate: Palladium High Flow Therapy System (K191010)	Subject Device: HVT 2.0
Humidification	Via semi-permeable small-bore tubing	**SAME - K191010** Via semi-permeable small-bore tubing
Power Requirements	100-240 VAC, 50-60 Hz	**SIMILAR – K191010** AC Power: 110-240 VAC, 50-60 Hz External DC Power: 12-24 VDC, 200 VA
Battery	Lithium Ion 2600mAh, 7.26V, 19Wh backup battery	**SIMILAR – K191010** Safety Battery - Lithium ion 14.4V, 6900mAh, 99.4 Wh. Transfer Battery - Lithium-ion battery (VTBP-2.0, 14.4Vdc; 2 x6900mAh; 2 x99.4 Wh)

From the comparison form above, the subject device and predicate device have similar intended use, are both prescription use, and have the same operating principle, gas input and method of humidification. The subject device claims slightly different flow range, patient interface, and temperature range. These differences do not raise different questions of safety or effectiveness.

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"*. Testing of the patient-contacting parts of the HVT 2.0 High Flow Therapy System demonstrates an appropriate biocompatibility profile for the device.

Electrical Safety:
Electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1:2005 Ed.3+A1:2012 and IEC 60601-1-2: 2014 Ed.4 to demonstrate the basic safety, essential performance and emissions and immunity characteristics of the device. The testing demonstrated the appropriate electrical safety and electromagnetic compatibility profile for the device.

Software Verification and Validation Testing:
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern.

Human Factors Testing:
A Human Factors and Usability Engineering validation study was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Medical Devices". The validation study demonstrates that the device has been found to be safe and effective for the intended users, uses, and use environments.

Bench / Performance Testing:
Comparative performance testing included:

- Humidification system output (ISO 80601-2-74 – Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment)
- Temperature output
- Effects of aging on performance
- Environmental Testing

The results demonstrated that the device performance was met after conditioning and was substantially equivalent to the predicate device.

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