



April 13, 2026

Vapotherm, Inc.  
Michael Webb  
Vice President of Regulatory Affairs  
100 Domain Dr.  
Exeter, New Hampshire 03833

Re: K254078  
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: December 17, 2025  
Received: December 18, 2025

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Ethan L. Nyberg -S**

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

## Indications for Use

510(k) Number (if known)

K254078

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 neonate/infant, pediatric and adult patients. The device is intended to be used in hospital and sub-acute facility settings. HVT 2.0 is not for use during field transport. The flow rates may be from 2 to 45 liters per minute (BTPS).

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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## 510(k) Summary and Certification

**Date:** 11-March-2026

**Company:** VapoTherm, Inc.  
100 Domain Drive  
Exeter, NH 03833, USA

**Official Contact:** Michael J. Webb, VP of Regulatory Affairs  
Tel: 866-410-9986

**Proprietary or Trade Name:** HVT 2.0

**Common/Usual Name:** Respiratory gas humidifier

**Classification:** Class II  
21 CFR 868.5450, Product Code: BTT

**Predicate Devices:** K072845 VapoTherm Precision Flow (Primary)  
K203357 VapoTherm HVT 2.0 (Secondary)

**Reason for submission:** Align indications with VapoTherm Precision Flow

### Device Description:

The HVT 2.0 System is designed to deliver high velocity respiratory therapy via a small-bore nasal cannula to spontaneously breathing neonate/infant, pediatric and adult patients. HVT 2.0 heats and humidifies respiratory gases to provide comfortable, safe, and effective therapy.

The HVT 2.0 System consists of the HVT 2.0 Main Device, also referred to as the capital unit, and a Disposable Patient Circuit (DPC). The HVT 2.0 main unit is portable, self-contained, AC (line voltage) or battery powered with high velocity therapy driven by an internal blower using room air source and supplied with external oxygen. It facilitates patient transfer, while maintaining the levels of heated humidified gas delivered through a small-bore cannula. The unit maintains the integrity of a closed, single-use water path disposable. The main unit contains all the electrical and electronic components and measures and controls water temperature, flow rate and oxygen percentage to reach the user-set target values. The main unit has no water pathway, and the gas pathway contains only gas at room temperature, and consequently does not need internal cleaning or disinfection.

The DPC consists of the Vapor Transfer Cartridge (VTC), Disposable Water Path (DWP) and multi-lumen delivery tubing. The VTC uses semi-permeable small-bore tubing technology to transfer heat and humidity to the inspired gases. Finally, multi-lumen tubing is used to circulate warmed water to provide humidity and body temperature gas from the VTC to the patient. This is the same as the predicate devices.

**Indications for Use:**

The HVT 2.0 system is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing neonate/infant, pediatric and adult patients. The device is intended to be used in hospital and sub-acute facility settings.

HVT 2.0 is not for use during field transport. The flow rates may be from 2 to 45 liters per minute (BTPS).

**Intended Patient Population:**

Neonate/infant, pediatric and adult patients

**Environment of Use:**

Hospital and sub-acute facility 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.
- Not for use with an Oxygen Concentrator (when treating respiratory distress).

**Basis for Determination of Substantial Equivalence:**

The expansion in indications for the proposed device falls within the already cleared indications for the primary predicate. The subject device and predicate have the same intended use, and any minor differences in technological characteristics do not raise different questions of safety and effectiveness based on the performance data. The devices are substantially equivalent.

The following table compares the technological characteristics of the HVT 2.0 subject device to the Vapotherm primary predicate Precision Flow, and where appropriate, to itself as the secondary predicate.

<b>Predicate Devices Comparison Table and Discussion</b>				
<b>Characteristic</b>	<b>Primary Predicate:</b> Precision Flow K072845	<b>Secondary Predicate:</b> HVT 2.0 K203357	<b>Subject Device:</b>	<b>Discussion:</b>
Indications for Use	Precision Flow® HVNI is intended for use to add warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital, subacute institutions settings, and home settings. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.	The HVT 2.0 system is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult 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 deliver warmed and humidified high-flow respiratory gases to spontaneously breathing neonate/infant, pediatric and adult patients. The device is intended to be used in hospital and sub-acute facility settings.  HVT 2.0 is not for use during field transport. The flow rates may be from 2 to 45 liters per minute (BTSP).	<b>Equivalent</b>  Patient populations are equivalent to K072845.  Flow rate range is a subset of K072845.  Environments of use for subject device are a subset of the predicates.
Patient Population	Neonate, Infant, Pediatric, Adult	Adult and pediatric (5 kg and up)	Neonate, Infant, Pediatric, Adult	<b>Identical</b> to K072845
Product Codes	BTT	BTT	BTT	<b>Identical</b>
Environment of Use for BTT	Hospital, sub-acute and homecare settings	Hospital, sub-acute and homecare settings	Hospital and sub-acute settings	<b>Equivalent</b> Subject device is a subset of the predicate
Patient Consciousness	Spontaneously breathing patients	Spontaneously breathing patients	Spontaneously breathing patients	<b>Identical</b>
Duration of Use	Disposable can be used for up to 30 days single patient use.	Disposable can be used for up to 30 days single patient use.	Disposable can be used for up to 30 days single patient use.	<b>Identical</b>
Prescriptive	Rx Only	Rx Only	Rx Only	<b>Identical</b>
Patient Interface	Small bore nasal cannula or Trach Adapter	Vapotherm ProSoft small bore nasal cannula or Trach Adapter	Vapotherm ProSoft small bore nasal cannula or Trach Adapter	<b>Equivalent</b> to both predicates

<b>Predicate Devices Comparison Table and Discussion</b>				
<b>Characteristic</b>	<b>Primary Predicate:</b> Precision Flow K072845	<b>Secondary Predicate:</b> HVT 2.0 K203357	<b>Subject Device:</b>	<b>Discussion:</b>
Flow Range	1 to 40 L/Min (SLPM), converted as: 1.1 to 45 L/Min (BTPS) per ISO 80601-2-74	3-45 L/Min (BTPS)	2-45 L/Min (BTPS)	<b>Equivalent</b> Subject Device flow range falls within cleared predicate K072845
Patient contacting materials	Externally communicating, tissue, permanent duration	Externally communicating, tissue, permanent duration	Externally communicating, tissue, permanent duration	<b>Identical</b>
Temperature Range	33°C to 39°C	33°C to 39°C	33°C to 39°C	<b>Identical</b>
Temperature Alarm	Alarms if 2°C above set point.	Alarms if 2°C above set point.	Alarms if 2°C above set point.	<b>Identical</b>
Temperature Accuracy	±2 °C	± 2 °C	± 2 °C	<b>Identical</b>
FiO <sub>2</sub> Range	0.21 to 1.00	0.21 to 1.00	0.21 to 1.00	<b>Identical</b>
Oxygen Source	Wall or tank	Wall, tank, or Oxygen Concentrator	Wall, tank, or Oxygen Concentrator	<b>Identical to K203357</b>
Oxygen Accuracy	±2%	±2% (wall or tank) ±4% Oxygen Concentrator	±2% (wall or tank) ±4% Oxygen Concentrator	<b>Identical to K203357</b>
Operating Principle	Air flow via a compressor and humidification via semi-permeable polymer technology which allows for delivery of entrained, humidified gases at constant flow to the patient	Air flow via a blower and humidification via semi-permeable polymer technology which allows for delivery of entrained, humidified gases at constant flow to the patient	Air flow via a blower and humidification via semi-permeable polymer technology which allows for delivery of entrained, humidified gases at constant flow to the patient	<b>Identical to K203357</b>
Alarms	Extensive audible and visual alarms to ensure essential performance of the device is maintained.	Extensive audible and visual alarms to ensure essential performance of the device is maintained.	Extensive audible and visual alarms to ensure essential performance of the device is maintained.	<b>Identical to K203357</b>
User interface settings	User sets flow rate, temperature, and oxygen fraction F <sub>i</sub> O <sub>2</sub>	User sets flow rate, temperature, and oxygen fraction F <sub>i</sub> O <sub>2</sub>	User sets flow rate, temperature, and oxygen fraction F <sub>i</sub> O <sub>2</sub>	<b>Identical to K203357</b>
Control	Software control	Software control	Software control	<b>Identical</b>
Modes of operation	Sleep, Standby and Run Modes	Sleep, Standby and Run Modes	Sleep, Standby and Run Modes	<b>Identical</b>
Gas/Air input	Standard DISS non-interchangeable fitting for oxygen, room air	Standard DISS non-interchangeable	Standard DISS non-interchangeable	<b>Identical to K203357</b>

<b>Predicate Devices Comparison Table and Discussion</b>				
<b>Characteristic</b>	<b>Primary Predicate:</b> Precision Flow K072845	<b>Secondary Predicate:</b> HVT 2.0 K203357	<b>Subject Device:</b>	<b>Discussion:</b>
	via wall source or compressor	fitting for oxygen, room air via blower	fitting for oxygen, room air via blower	
Humidification	Via semi-permeable small-bore tubing	Via semi-permeable small-bore tubing	Via semi-permeable small-bore tubing	<b>Identical to K203357, Complies with ISO 80601-2-74</b>
Power Requirements	100-240 VAC, 50-60Hz Back-up power: 4.8V nickel-metal hydride battery pack  Back-up power with Vapotherm Transfer Unit (VTU): Medipower™ unit, one hour limited use	110 to 240VAC, 50 to 60Hz Back-up power (Safety Battery): Li-Ion Battery 14.4V, 2900mAh, 99.Wh.  Back-up power with Transfer Battery: Li-Ion Battery Pack consisting of 2X (14.4V, 2900mAh, 99.4Wh), one hour limited use	110 to 240VAC, 50 to 60Hz Back-up power (Safety Battery): Li-Ion Battery 14.4V, 2900mAh, 99.Wh.  Back-up power with Transfer Battery: Li-Ion Battery Pack consisting of 2X (14.4V, 2900mAh, 99.4Wh), one hour limited use	<b>Identical to K203357</b>

From the comparisons above, the subject and predicate devices have the same intended use. Any minor differences do not raise different questions of safety or effectiveness.

### **Non-clinical performance testing**

The subject device was designed and validated in accordance with the application recommendations of FDA guidance documents and requirements of international standards including:

### **Biocompatibility / Materials:**

Biocompatibility was assessed 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*”, including the ISO 18562 series *Biocompatibility evaluation of breathing gas pathways in healthcare applications*. Testing of the patient-contacting parts of the HVT 2.0 System demonstrates an appropriate biocompatibility profile for the device.

### **Electrical Safety, Alarms, RFID:**

Electrical safety and electromagnetic compatibility testing was conducted in accordance with IEC 60601-1:2005 +AMD1:2012, +AMD2:2020, and IEC 60601-1-2: 2014, +A1:2020 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. Alarms testing was performed compliant with IEC 60601-1-8:2006 +AMD1:2012, +AMD2:2020. RFID testing was successfully completed in accordance with AIM 7351731.

### **Software Verification, Validation Testing, and Hazard Analysis**

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions”, as well as “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”. Hazard Analysis/Risk Management activities for the device comply with ISO 14971:2019 Medical Devices – Application of risk management to medical devices.

### **Bench / Performance Testing –**

Comparative performance testing was performed to demonstrate substantial equivalence to the predicate device. Given the HVT 2.0 was previously cleared under K203357 and K221318, prior performance testing continues to apply and includes:

- Oxygen accuracy/Blender Performance
- Temperature accuracy/Thermal Stability
- Flow rate accuracy
- Humidification output ISO 80601-2-74
- Patient contacting surface temperature/Thermal Safety
- Volume of liquid exiting the humidification chamber outlet
- Continuous use (Use Lifespan)
- Operating environment
- Nurse call compatibility
- Usability/Human Factors
- Cleaning Validation (for hardware)

### **Substantial Equivalence Conclusion**

The intended use of the subject and predicate devices are the same and the technological characteristics are similar or equivalent. Any minor differences do not raise different questions of safety and effectiveness. The testing performed and documentation provided demonstrates that the subject device is substantially equivalent to the predicate devices.