December 13, 2022

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

Re: K221318
Trade/Device Name: HVT 2.0
Regulation Number: 21 CFR 868.5454
Regulation Name: High Flow Humidified Oxygen Delivery Device
Regulatory Class: Class II
Product Code: QAV
Dated: November 10, 2022
Received: November 14, 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,

Ethan L. Nyberg -S

for James Lee, Ph.D.
Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221318

Device Name
HVT 2.0

Indications for Use *(Describe)*

The HVT 2.0 system provides high velocity nasal insufflation (HVNI) with simultaneous warmed and humidified respiratory gas delivery to augment breathing of spontaneously breathing adult and pediatric patients (5 kg and up) suffering from respiratory distress and/or hypoxemia in the hospital setting, via a small bore nasal cannula. HVT 2.0 is not intended to provide total ventilatory requirements of the patient and not for use during field transport. The flow rates may be from 5 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.

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510(k) SUMMARY

Date: 12-Dec-2022

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

Official Contact: Michael J. Webb
Tel: 866-410-9986

Proprietary or Trade Name: HVT 2.0

Common/Usual Name: High Flow Humidified Oxygen Delivery Device

Classification: 21 CFR 868.5454, Class II
Product Code: QAV

Predicate Device: DEN170001 Vapotherm Precision Flow HVNI

Reference Device: K203357 Vapotherm HVT 2.0

Device Description:
The HVT 2.0 System is comprised of hardware containing software, and single use disposables that are designed to deliver the same High Velocity Nasal Insufflation (HVNI) as the Vapotherm Precision Flow HVNI.

The HVT 2.0 system consists of the HVT 2.0 hardware containing software, 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 5 to 45 L/min (BTPS) to spontaneously breathing patients, without the need of wall air or any pressurized air source. The addition of an external oxygen source (wall or tank for QAV indication) enables FiO_2 delivery from 21% to 100%. The device incorporates a blender and flow sensors that allow the oxygen percentage and total gas flow to be set independently.

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

Indications for Use:
The HVT 2.0 system provides high velocity nasal insufflation (HVNI) with simultaneous warmed and humidified respiratory gas delivery to augment breathing of spontaneously breathing adult and pediatric patients (5 kg and up) suffering from respiratory distress and/or hypoxemia in the hospital setting, via a small bore nasal cannula. HVT 2.0 is not intended to provide total ventilatory requirements of the patient and not for use during field transport. The flow rates may be from 5 to 45 liters per minute (BTPS).

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 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

Substantial Equivalence:
The technological characteristics that define HVNI and achieve the flush of expired CO_2 from the accessible extrathoracic anatomic dead space are equivalent for HVT 2.0 and the predicate Precision Flow HVNI DEN170001. Therefore HVT 2.0 possesses the same clinical utility as Precision Flow HVNI (Product Code QAV). Bench testing has further demonstrated substantial equivalence of the devices.

Characteristic	**Predicate:** Precision Flow HVNI **DEN170001**	**Subject Device:** HVT 2.0
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 and subacute institutions 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. Precision Flow® HVNI provides high velocity nasal insufflation (HVNI) with simultaneous oxygen delivery to augment breathing of spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting. Precision Flow® HVNI is not intended to provide total ventilatory requirements of the patient and not for use during field transport.	**SIMILAR** QAV Indications: The HVT 2.0 system provides high velocity nasal insufflation (HVNI) with simultaneous warmed and humidified respiratory gas delivery to augment breathing of spontaneously breathing adult and pediatric patients (5 kg and up) suffering from respiratory distress and/or hypoxemia in the hospital setting, via a small bore nasal cannula. HVT 2.0 is not intended to provide total ventilatory requirements of the patient and not for use during field transport. The flow rates may be from 5 to 45 liters per minute (BTPS).
Patient Population	Pediatric, adult	**DIFFERENT** Pediatric (≥5kg), adult
Environment of Use for QAV	Hospital setting	**SAME** Hospital setting
Duration of Use	Disposable can be used for up to 30 days single patient use.	**SAME** Disposable can be used for up to 30 days single patient use.
Prescriptive	Rx Only	**SAME** Rx Only
Patient Interface for QAV	Small bore nasal cannula	**SAME** Small bore nasal cannula
Flow Range	1 to 40 L/Min (SLPM), converted as: 1.1 to 45 L/Min (BTPS)	**DIFFERENT** 5-45 L/Min (BTPS)
Patient contacting materials	Externally communicating, tissue, permanent duration	**SAME** Externally communicating, tissue, permanent duration
Temperature Range	33ºC to 39ºC	**SAME** 33ºC to 39ºC
Temperature Alarm	Alarms if 2ºC above set point.	**SAME** Alarms if 2ºC above set point.
Temperature Accuracy	±2 °C	**SAME** ± 2 °C

Characteristic	**Predicate:** Precision Flow HVNI **DEN170001**	**Subject Device:** HVT 2.0
FiO2 Range	0.21 to 1.00	**SAME** 0.21 to 1.00
Oxygen Accuracy	±2% Wall/tank	**SAME** ±2% Wall/tank
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	**DIFFERENT** 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
Alarms	Extensive audible and visual alarms to ensure essential performance of the device is maintained.	**SAME** Extensive audible and visual alarms to ensure essential performance of the device is maintained.
User interface settings	User sets flow rate, temperature, and oxygen fraction F_iO_2	**SAME** User sets flow rate, temperature, and oxygen fraction F_iO_2
Control	Software control	**SAME** Software control
Modes of operation	Sleep, Standby and Run Modes	**SAME** Sleep, Standby and Run Modes
Gas/Air input	Standard DISS non-interchangeable fitting for oxygen, room air via wall source or compressor	**DIFFERENT** Standard DISS non-interchangeable fitting for oxygen, room air via blower
Humidification	Via semi-permeable small-bore tubing	**SAME** Via semi-permeable small-bore tubing
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	**DIFFERENT** 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

From the comparison above, the subject device and predicate device have the same intended use, are both prescription use, and have the same operating principle, gas input and method of humidification. Any differences do not raise different questions of safety or effectiveness.

Non-clinical performance testing

Biocompatibility / Materials:

Biocompatibility testing is leveraged from the prior testing performed as part of K203357, whereby the 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 System demonstrates an appropriate biocompatibility profile for the device.

Electrical Safety, Alarms, RFID:
Electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1:2012 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. Alarms testing was performed compliant with IEC 60601-1-8:2006, ed 2.1. RFID testing was successfully completed in accordance with AIM 7351731.

Software Verification, Validation Testing, and Hazard Analysis
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 is considered as a "moderate" level of concern. 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 and to meet the Special Controls requirements of 21 CFR 868.5454 High flow humidified oxygen delivery device, and included:

- Precision Flow and HVT 2.0 Comparison Testing to demonstrate the same High Velocity Nasal Insufflation (HVNI) technological characteristics and performance
- 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
HVT 2.0 is substantially equivalent to the predicate device based on the intended use and comparison of the technological characteristics and performance testing.

Any differences in technological characteristics of the devices do not raise different questions of safety and effectiveness based on the performance testing, further supported by the prior clearance of the Reference Device HVT 2.0, cleared under K203357. The devices are substantially equivalent.