October 10, 2019

Vapotherm, Inc.
% Dave Yungvirt
Responsible Third Party Official
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K191010
   Trade/Device Name: Palladium High Flow Therapy System
   Regulation Number: 21 CFR 868.5450
   Regulation Name: Respiratory gas humidifier
   Regulatory Class: Class II
   Product Code: BTT
   Dated: August 13, 2019
   Received: August 16, 2019

Dear Dave Yungvirt:

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.


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,

James J. Lee -S

James J. Lee, Ph.D.
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
Indications for Use

510(k) Number (if known)
K191010

Device Name
Palladium High Flow Therapy System

Indications for Use (Describe)
The Palladium High Flow Therapy System is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult and pediatric patients weighing at least 3.5 kg within hospital, sub-acute and homecare 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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
SECTION 5:  510(k) SUMMARY

Date: 09-October-2019

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

Official Contact: Richelle Helman – Vice President of Regulatory and Quality
Tel – 603-658-0489

Proprietary or Trade Name: Palladium High Flow Therapy System

Common/Usual Name: Respiratory gas humidifier

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

Predicate Device: K103316 – Vapotherm Flowrest®
Reference Device: K072845 – Vapotherm Precision Flow®

Device Description:
The Palladium High Flow Therapy System is designed to heat and humidify respiratory gases and deliver high flow respiratory therapy via a small-bore nasal cannula to spontaneously breathing pediatric and adult patients within hospital, sub-acute and homecare settings.

Palladium is portable, self-contained, AC driven or battery powered with high flow therapy driven by an internal blower room air source and supplied with external oxygen or other gas sources, which is the same as the predicate Vapotherm Flowrest® device.

Palladium utilizes similar semi-permeable small-bore tubing technology for humidification and integrity of a closed, single-use water path disposable as the reference Vapotherm Precision Flow® device.

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 patients weighing at least 3.5 kg within hospital, sub-acute and homecare 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:**
Any situation in which humidification is contra-indicated (see American Association of Respiratory Care Clinical Practice Guidelines).

Specific to the nasal cannula: The system should not be used on patients with occluded or damage nares.

**Substantial Equivalence:**
The Palladium High Flow Therapy System is substantially equivalent to the predicate device, the Vapotherm Flowrest® (510(k) K103316). The table below presents the similarities and differences between the products for substantial equivalence purposes. The reference device, the Vapotherm Precision Flow® (510(k) K072485), is being used to support the effectiveness of the scientific methods for evaluating the effect of the different characteristics on safety and effectiveness. The key differences between the subject device and the predicate device being supported by the reference device are flow range and humidification exchange media. 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.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Predicate: Flowrest® (K103316)</th>
<th>Subject Device: Palladium High Flow Therapy System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The Flowrest® delivers warmed humidified high-flow breathing gases. The Flowrest® is intended for treating spontaneously breathing patients who require warmed and humidified high-flow respiratory gases within the homecare, sub-acute and hospital settings.</td>
<td>SAME – K103316 The Palladium High Flow Therapy System is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult and pediatric patients weighing at least 3.5 kg within hospital, sub-acute and homecare settings.</td>
</tr>
<tr>
<td>Patient Population</td>
<td>Neonate, pediatric, adult</td>
<td>SIMILAR – K103316 Pediatric, adult</td>
</tr>
<tr>
<td>Environment of Use</td>
<td>Homecare, sub-acute and hospital settings</td>
<td>SAME - K103316 Hospital, sub-acute and homecare settings</td>
</tr>
<tr>
<td>Duration of Use</td>
<td>Disposable can be used for up to 30 days single patient use.</td>
<td>SAME - K103316 Disposable can be used for up to 30 days single patient use.</td>
</tr>
<tr>
<td>Prescriptive</td>
<td>Rx Only</td>
<td>SAME - K103316 Rx Only</td>
</tr>
<tr>
<td>Patient Interfaces</td>
<td>Nasal cannula</td>
<td>SAME - K103316 Nasal cannula</td>
</tr>
<tr>
<td>Flow Range</td>
<td>15 to 35 liters per minute</td>
<td>SIMILAR – K103316 5 to 40 liters per minute</td>
</tr>
<tr>
<td>Patient contacting materials</td>
<td>Externally communicating, tissue, prolonged duration</td>
<td>SAME - K103316 Externally communicating, tissue, prolonged duration</td>
</tr>
<tr>
<td>Temperature Setting</td>
<td>31C to 38C</td>
<td>SIMILAR - K103316 33C to 38C</td>
</tr>
<tr>
<td>Heater</td>
<td>Flat heater element that contacts disposable patient circuit – Heatron Platen heater</td>
<td>SAME - K103316 Flat heater element that contacts disposable patient circuit – Flexible Kapton circuit heater element</td>
</tr>
<tr>
<td>Temperature Cutout</td>
<td>Software controlled; Alarms at 43 °C</td>
<td>SIMILAR – K103316 Software controlled; Alarms at 41 °C</td>
</tr>
<tr>
<td>Temperature Accuracy</td>
<td>± 2 °C</td>
<td>SAME - K103316 ± 2 °C</td>
</tr>
<tr>
<td>Operating Principle</td>
<td>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</td>
<td>SAME - K103316Gas 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</td>
</tr>
<tr>
<td>Alarms</td>
<td>Visual for temperature, heater, fan and pressure sensor failure, water empty or canister assembly not in place</td>
<td>SIMILAR - K103316 Audible and visual for temperature, low oxygen fraction, blocked tube, water out, disposable</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Predicate: Flowrest® (K103316)</td>
<td>Subject Device: Palladium High Flow Therapy System</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>water path not present, loss of power and loss of flow</td>
</tr>
<tr>
<td>User interface</td>
<td>User set point adjustment via menu system on display for flow rate, temperature and time</td>
<td><strong>SIMILAR - K103316</strong> User set point adjustment via menu system on display for flow rate, temperature and oxygen fraction</td>
</tr>
<tr>
<td>Control</td>
<td>Software control</td>
<td><strong>SAME - K103316</strong> Software control</td>
</tr>
<tr>
<td>Modes of operation</td>
<td>Run Mode – unit is either on and running or is completely off</td>
<td><strong>SIMILAR - K103316</strong> 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</td>
</tr>
<tr>
<td>Gas input</td>
<td>Medical gases Air / oxygen</td>
<td><strong>SAME - K103316</strong> Medical gases Air / oxygen</td>
</tr>
<tr>
<td>Humidification</td>
<td>Via a semi-permeable flat membrane</td>
<td><strong>SIMILAR - K103316</strong> Via semi-permeable small-bore tubing</td>
</tr>
<tr>
<td>Power Requirements</td>
<td>100-240 VAC, 50-60 Hz No backup battery</td>
<td><strong>SIMILAR – K103316</strong> 100-240 VAC, 50-60 Hz Lithium Ion 2600mAh, 7.26V, 19Wh backup battery</td>
</tr>
<tr>
<td>Connectors</td>
<td>Adapter allows connection to an oxygen source.</td>
<td><strong>SIMILAR – K103316</strong> Oxygen inlet on unit allows connection to an oxygen source.</td>
</tr>
</tbody>
</table>

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 patient population and flow range but these are a subset of the predicate and reference devices. Therefore, these differences do not raise new 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*. Biocompatibility of the gas pathway complies with ISO 18562-1 - Biocompatibility evaluation of breathing gas pathways in healthcare applications and the materials are considered permanent duration due to potential cumulative use. Therefore, the patient contacting materials in the humidified gas pathway are considered to be externally...
communicating, tissue contacting, permanent duration of use (> 30 days). Evaluation and testing were conducted in accordance with the following standards and guidance documents:

- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 18562-1: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
- ISO 18562-4: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate

Testing of the patient-contacting parts of the Palladium High Flow Therapy System demonstrates an appropriate biocompatibility profile for the device.

**Electrical Safety and EMC:**
Electrical safety and electromagnetic compatibility (EMC) 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. Additionally, RFID immunity testing was completed in accordance with FDA recognized standard AIM 7351731:2017, Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers. The testing demonstrated the appropriate electrical safety and electromagnetic compatibility (EMC) 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.

**Bench / Performance Testing** –
Comparative performance testing included:
- Oxygen accuracy
- Temperature accuracy
- Humidification system output (ISO 80601-2-74:2017 – Medical Electrical Equipment Part 2-74: Particular requirements for Basic Safety and Essential Performance of
Respiratory Humidifying Equipment

- Flow rate accuracy
- Patient contacting surface temperature
- Continuous use (Use Lifespan)
- Operating environment
- Nurse call compatibility

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 devices.