



April 10, 2018

Vapotherm, Inc.
% Paul Dryden
22 Industrial Dr.
Exeter, NH 03833 USA

Re: DEN170001

Trade/Device Name: Precision Flow® HVNI
Regulation Number: 21 CFR 868.5454
Regulation Name: High flow humidified oxygen delivery device
Regulatory Class: Class II
Product Code: QAV
Dated: December 30, 2016
Received: January 3, 2017

Dear Paul Dryden:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Precision Flow HVNI, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Precision Flow HVNI, and substantially equivalent devices of this generic type, into Class II under the generic name high flow humidified oxygen delivery device.

FDA identifies this generic type of device as:

High flow humidified oxygen delivery device. A high flow humidified oxygen delivery device is a prescription device that delivers high flow oxygen with humidification for patients who are suffering from respiratory distress and/or hypoxemia.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On January 3, 2017, FDA received your De Novo requesting classification of the Precision Flow HVNI. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Precision Flow HVNI into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Precision Flow HVNI can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1: Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Method
Adverse tissue reaction	Biocompatibility evaluation Non-clinical performance testing Labeling
Interference with other devices	Electromagnetic compatibility testing Radiofrequency identification (RFID testing) Labeling
Infection	Cleaning validation Labeling
Device software failure leading to delayed initiation of therapy	Software verification, validation, and hazard analysis Labeling
Device failure/malfunction leading to ineffective treatment	Non-clinical performance testing Labeling
Electrical shock injury from device failure	Electrical safety, thermal safety, and mechanical safety testing
Use error/improper device use leading to hypoxia or worsening hypercarbia	Labeling

In combination with the general controls of the FD&C Act, the high flow humidified oxygen delivery device is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, including the following:
 - a. Alarm testing must be performed.
 - b. Continuous use thermal stability testing must be performed.
 - c. Humidity output testing must be performed.
 - d. Blender performance testing must evaluate fraction of inspired oxygen (FiO_2) blending accuracy.
3. Performance data must validate cleaning instructions for any reusable components of the device.
4. Electrical safety, thermal safety, mechanical safety, electromagnetic compatibility, and radiofrequency identification (RFID) testing must be performed.
5. Software verification, validation, and hazard analysis must be performed.
6. Labeling must include the following:
 - a. A description of available FiO_2 ranges for different flowrates and inlet gas pressures;
 - b. Instructions for applicable flowrates for all intended populations;
 - c. A warning that patients on high flow oxygen are acute and require appropriate monitoring, to include pulse oximetry;
 - d. A warning regarding the risk of condensation at low set temperatures and certain flows; and
 - e. A description of all alarms and their functions.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the high flow humidified oxygen delivery device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Derya Coursey at 240-402-6130.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health