March 10, 2025

Vaporox, Inc.
% Adrienne Lenz
Principal Medical Device Regulatory Expert
Hyman, Phelps & McNamara P.C.
8375 Willow St Ste. 500
Lone Tree, CO 80124

Re: K250188
Trade/Device Name: Wound Treatment System (VHT-200)
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical oxygen chamber for extremities
Regulatory Class: Class II
Product Code: KPJ
Dated: January 22, 2025
Received: January 22, 2025

Dear Adrienne Lenz:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Wilmarie Flores -S

Wilmarie Flores Ph.D.
Assistant Director *(Acting)*
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250188

Device Name
VHT-200 Wound Treatment System (VHT-200)

Indications for Use *(Describe)*
VHT-200 is intended to provide ultrasonically generated mist and concentrated oxygen to open, acute and chronic wounds as an adjunct therapy in wound management and treatment.

The VHT-200 is intended for the following kinds of wounds:
- Skin ulcerations due to diabetes, venous stasis, and post-surgical infections
- Gangrenous lesions
- Decubitus ulcers
- Amputations / infected stumps
- Skin grafts
- Burns
- Frostbite

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Vaporox VHT-200 Wound Treatment System
510(k) Summary

In accordance with 21 C.F.R. § 807.92 the following summary of information is provided:

DATE: March 10, 2025

COMPANY: Vaporox, Inc.
8375 Willow St Ste. 500
Lone Tree, CO 80124

COMPANY CONTACT: Alan Sage, CEO
(303) 558-5145, alan.sage@vaporox.com

PRIMARY CONTACT PERSON: Adrienne R. Lenz
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Allyson B. Mullen
Director, Hyman, Phelps, & McNamara, P.C.
(202) 737-9639, amullen@hpm.com

DEVICE/TRADE NAME: VHT-200 Wound Treatment System
COMMON/USUAL NAME: Chamber, oxygen, topical, extremity
REGULATION NUMBER: 21 C.F.R. § 878.5650
REGULATION NAME: Topical oxygen chamber for extremities
PRODUCT CODE: KPJ
REVIEW PANEL: General & Plastic Surgery

PREDICATE DEVICE: VHT-200 Wound Treatment System (K212121)

DEVICE DESCRIPTION:

The VHT-200 Wound Treatment System (VHT-200) is a prescription medical device. This system is designed for most topical skin injuries that can benefit from the properties of oxygen and moisture therapy treatments. The VHT-200 operates by generating vapor/mist using non-contact, low-frequency ultrasonic crystals. Concentrated oxygen is generated using a pump compressor and oxygen concentrator. All the benefits of oxygen and moisture modalities are self-contained into one system and applied without the need

of switching applications. The VHT-200 is made for clinical office use. The VHT-200 is designed for the medical provider to add oxygen flow rate and frequency of the treatments based on experience and professional assessment of the individual patient's medical need.

INDICATION FOR USE:

VHT-200 is intended to provide ultrasonically generated mist and concentrated oxygen to open, acute and chronic wounds as an adjunct therapy in wound management and treatment.

The VHT-200 is intended for the following kinds of wounds:

- Skin ulcerations due to diabetes, venous stasis, and post-surgical infections
- Gangrenous lesions
- Decubitus ulcers
- Amputations / infected stumps
- Skin grafts
- Burns
- Frostbite

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The table below compares the intended use and technological characteristics of the subject and predicate device.

TABLE 1: COMPARISON OF MODIFIED DEVICE TO PREDICATE DEVICE

	VHT-200	**Predicate VHT-200 (K212121)**
Product Name	VHT-200 Wound Treatment System	VHT-200 Wound Treatment System
Manufacturer	Vaporox, Inc.	Vaporox, Inc.
Product Code	KPJ	KPJ
Regulation No.	878.5650	878.5650
Class	II	II
Description	The VHT-200 provides ultrasonically generated mist and concentrated oxygen to open, acute or chronic wounds as an adjunct therapy in wound management and treatment.	The VHT-200 provides ultrasonically generated mist and concentrated oxygen to open, acute or chronic wounds as an adjunct therapy in wound management and treatment.

	VHT-200	Predicate VHT-200 (K212121)
Indications for Use	VHT-200 is intended to provide ultrasonically generated mist and concentrated oxygen to open, acute and chronic wounds as an adjunct therapy in wound management and treatment. The VHT-200 is intended for the following kinds of wounds: • Skin ulcerations due to diabetes, venous stasis, and post-surgical infections • Gangrenous lesions • Decubitus ulcers • Amputations / infected stumps • Skin grafts • Burns • Frostbite	VHT-200 is intended to provide humidified oxygen to open, acute and chronic wounds as an adjunct therapy in wound management and treatment. The VHT-200 is intended for the following kinds of wounds: • Skin ulcerations due to diabetes, venous stasis, and post-surgical infections • Gangrenous lesions • Decubitus ulcers • Amputations / infected stumps • Skin grafts • Burns • Frostbite
Intended Use	To deliver oxygen to a patient's wound in a humidified environment.	To deliver oxygen to a patient's wound in a humidified environment.
Contraindications	Contraindications for the VHT-200 include: • Patients with active infections of cellulitis or osteomyelitis in the treated limb • Patients with diagnosed malignant ulcers in the treated limb • Not for respiratory use	Contraindications for the VHT-200 include: • Patients with active infections of cellulitis or osteomyelitis in the treated limb • Patients with diagnosed malignant ulcers in the treated limb • Not for respiratory use
Environment of Use	Healthcare environment	Healthcare environment
Oxygen Form	Oxygen Concentrator and Vaporizer	Oxygen Concentrator and Vaporizer
Oxygen Concentration at Source (%)	95% +/- 5%	95% +/- 5%
Flowrate	4 – 7 L/minute	4 – 7 L/minute
Vapor Humidity	90 – 98%	90 – 98%
Pressure at wound	1 ATM	1 ATM
Oxygen Delivery Duration	20 minutes / session; twice a week at clinician office	20 minutes / session; twice a week at clinician office
Mode of operation	Continuous, alternating vapor and oxygen delivery in timed cycles	Continuous, alternating vapor and oxygen delivery in timed cycles
Alerts / Indicators	Visible messages and audible tone: Refill fluid, Vaporizer not installed and System Fault	Visible messages and audible tone: Refill fluid, Vaporizer not installed and System Fault

The subject device and the predicate device have the same intended use: to deliver concentrated oxygen to a patient's wound in a humidified environment. The only difference between the subject and predicate versions of the VHT-200 is the Indications for Use statement. The Indications for Use statement has been updated to clarify that the device delivers ultrasonically generated mist and concentrated oxygen separately within the treatment cycle. The device has always alternated delivery of mist and concentrated oxygen. This clarification does not change the intended use of the device.

The subject and predicate device have identical technological features, including identical materials, hardware, and software.

SUMMARY OF PERFORMANCE TESTING:

There are no differences in the materials, hardware, and software between the VHT-200 and predicate device. This 510(k) introduces labeling changes that did not require clinical or non-clinical performance testing.

CONCLUSION:

The VHT-200 is as safe and effective as the predicate device. The justification provided for the revisions to the Indications for Use statement supports a determination of substantial equivalence.