March 23, 2023

Vaporox, Inc.
% Allyson Mullen
Hyman, Phelps, & McNamara, P.C.
700 Thirteenth Street NW, Suite 1200
Washington, District of Columbia 20005

Re: K212121
Trade/Device Name: VHT-200 Wound Treatment System
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical Oxygen Chamber For Extremities
Regulatory Class: Class II
Product Code: KPJ
Dated: July 6, 2021
Received: July 7, 2021

Dear Allyson Mullen:

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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212121

Device Name
VHT-200 Wound Treatment System

Indications for Use *(Describe)*
The intended use of VHT 200 wound treatment system is to provide humidified oxygen to open, acute or chronic wounds as an adjunct therapy in wound management and treatment.

The VHT-200 wound treatment system is intended for the following kinds of wounds:
- skin ulcerations due to diabetes, venous stasis, and post-surgical infections, and 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.

510(k) Summary

VHT-200 Wound Treatment System
August 20, 2021

Company: Vaporox, Inc.
7012 S. Revere Pkwy, Suite 100
Centennial, CO 80112

Company Contact: Alan Sage | CEO, Vaporox
(303) 558-5145

Trade Name: VHT-200 Wound Treatment System

Common Name: Topical oxygen chamber for extremities
Classification: Class II
Regulation Number: 21 CFR 878.5650
Product Code: KPJ

Predicate Device: Hyper-Box Topical Wound Oxygen System (K080966)

Device Description:
The VHT-200 Wound Treatment System 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. 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 wound treatment system 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.

Indications for Use:
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 System 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

Substantial Equivalence:
The subject device is substantially equivalent to the predicate Hyper-Box Topical Wound Oxygen System (K080966). The subject device is similar in indications, technological characteristics, and materials to the predicate device. The subject device includes an integrated oxygen concentrator versus the predicate device's use of an external oxygen supply and uses a treatment chamber bag rather than the predicate's sleeve and boot design for the treatment environment. However, neither of these differences in technology raise different questions of safety or effectiveness and performance testing on the subject device has verified it is appropriate for its intended use.

Performance Testing:
The VHT-200 has been evaluated in various conditions and determined to be safe and effective. Testing included software validation, IEC 60601-1, IEC 60601-1-2, IEC 80601-2-69, biocompatibility evaluation, performance testing, cleaning validation, and distribution testing.

Conclusion:
The VHT-200 has equivalent indications for use, similarities in design, and equivalent performance to the predicate device. Therefore, it can be concluded that the subject device is as safe, as effective, and performs at least as safely and effectively as the predicate device.