U.S. FOOD & DRUG ADMINISTRATION

VIA EMAIL

April 11, 2022

VANELC
3401 Lawson Blvd.
Oceanside, New York 11572-4914

hanson@vanelc.com
support@vanelc.com
service@vanelc.com

Re: FDA Reference Number: COR22000015; Opportunity for Hearing

VANELC, Hanson Mayer

This letter notifies you that the United States ("US") Food and Drug Administration ("FDA"), Center for Devices and Radiological Health ("CDRH") has determined that your business, as a manufacturer, has offered an electronic product, the UV Light Sanitizer Wand, Portable Travel Wand Ultraviolet Disinfection lamp, Ultraviolet Sterilamp, model: PURPLEGLOW (hereafter "PURPLEGLOW", "wand" or "your product"), an Ultraviolet C ("UVC") product, that has a defect under 21 CFR 1003.2(b)(2). This defect was identified on January 27, 2022, through a laboratory evaluation of a sample wand. Our determination that your product has a defect, which relates to the safety of use by reason of the emission of electronic product radiation, is based on the following:

1. PURPLEGLOW is an electronic product whose primary purpose is as a handheld product intended to emit UV radiation for sanitizing purposes. Holding the wand in the hand for the duration of the sanitization process would cause the user to be in close proximity to the source of the radiation for the entirety of the sanitization process. Through laboratory evaluation of the UV radiation emissions from your product, FDA measured the effective (actinic) weighted spectral irradiance in the 200 to 400 nm range as 1.96 W/m^2 (i.e., 0.196 mW/cm^2) at 5 cm from your product. The level of UV radiation emitted by your product presents a risk of injury to the user and nearby persons. The International Commission on Non-ionizing Radiation Protection recommends an exposure limit of 3.0 mJ/cm^2 effective spectrally weighted in the UV range, within an 8-hour period.[1] A person in the vicinity of PURPLEGLOW may receive an injury to their skin (e.g., erythema) and/or eyes (e.g., photokeratitis) from the PURPLEGLOW, in as little as 15.3 seconds (i.e., 3.0 mJ/cm^2 / 0.196 mW/cm^2) at a distance of 5 cm from the light source. In addition, our laboratory evaluation found that the sample PURPLEGLOW exceeded 1000 seconds actinic ultraviolet hazard (Es) Exposure Limit for Risk Group 2 according to subclause 6.1.3 of the Standard IEC 62471:2006 in 170 seconds (2.83 minutes) at a distance of 20 cm from your product. Therefore, your product was classified as a Risk Group 3 product (High Risk). As a result of its design, production or

[1] International Commission on Non-ionizing Radiation Protection: Guidelines on Limits of Exposure to Ultraviolet Radiation of Wavelengths between 180 nm and 400 nm (Incoherent Optical Radiation). Health Physics 87(2):171-186, 2004.

assembly, the PURPLEGLOW causes the user to be in close proximity to a radiation source without shielding and high level of UV radiation, and potentially exposes other persons in the vicinity to emitted radiation, and lacks features to mitigate such exposures, creating a risk of injury. These radiation emissions affecting the user and nearby persons are unnecessary to the accomplishment of the product's primary purpose of sterilizing objects and surfaces, and create a risk of injury to persons.

2. According to the PURPLEGLOW labeling and our laboratory evaluation, the PURPLEGLOW has a built-in timer. Even if the timer goes off, the PURPLEGLOW can be turned on again by pressing the LED switch. As discussed in item #1 above, the internationally accepted exposure limit is based on cumulative exposure over a period of 8 hours. Therefore, the timer system does not eliminate the PURPLEGLOW's emission of electronic product radiation unnecessary to the accomplishment of its primary purpose, which creates a risk of injury to the user and anyone nearby.

Due to the safety hazards presented by the PURPLEGLOW, and the lack of safety features, FDA has concluded, pursuant to 21 CFR 1003.2(b)(2), that the PURPLEGLOW has a defect that relates to the safety of use by reason of the emission of electronic product radiation because it is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, and as a result of its design, production, or assembly, it emits electronic product radiation unnecessary to the accomplishment of its primary purpose, which creates a risk of injury to any person. FDA is thus providing notice under 21 CFR 1003.11(a) of FDA's determination that your product has a defect.

You are required, under 21 CFR 1003.11(b), to immediately provide a written response to FDA with the total number of referenced product units which have been produced and the approximate number of such product units that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas. You have 15 days after you receive this letter to respond in writing using one of the options listed below:

I. Refutation - Under 21 CFR 1003.11(a)(3), you may submit your views and evidence to establish that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

II. Exemption Request - Under 21 CFR 1003.30(a), you may request an exemption from the purchaser and any subsequent transferee and dealer/distributor notification requirements in 21 CFR 1003.10(b) (see item III). If exempted from such notification, you are not required to correct the violative products (as described in 21 CFR 1004.1(a)). Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31) and the information required under 21 CFR 1003.20.

III. Purchaser Notification and Corrective Action - If you neither refute the defect nor request an exemption, then you must: (a) notify purchasers and any subsequent transferee (where known to the manufacturer or where the manufacturer, upon reasonable inquiry to dealers, distributors, or purchasers, can identify the present user) and dealers/distributors of the violative products, as

specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) for approval by FDA, as required by 21 CFR Part 1004, showing how you will fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

b. Corrective Action Plan (CAP) - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and/or 1004.4. Such a plan must expeditiously and effectively correct the defect and must be approved by FDA, as set out in 21 CFR 1004.6.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if you do not take action to address your product defect through one of the options listed above within 15 days, you may be required to proceed with notification to affected persons (see 21 CFR 1003.11(c)). Therefore, you are encouraged to immediately begin your preparation of accurate purchaser and dealer/distributor lists.

Additionally, you have the right to refute the findings in this letter by requesting a regulatory hearing before the FDA. However, a hearing is **not** required to respond to this letter with a refutation. Written submission of your views, along with evidence to refute the alleged defect, in accordance with option I above, is sufficient to assure your refutation will be evaluated. Information about requesting a regulatory hearing before FDA can be found in 21 CFR Part 16. A request for a regulatory hearing, as described in 21 CFR 16.22 and 1003.11(a)(3), must be received by FDA in writing within 15 days from receipt of this letter. Ensure that your request for a regulatory hearing is clearly marked "APPEAL." Please send all materials related to a request for a regulatory hearing to the CDRH Ombudsman via email at CDRHOmbudsman@fda.hhs.gov.

This notice of opportunity for hearing will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest (21 CFR 16.22(d)).

Copies of the Federal Performance Standards, compliance guides, radiation safety product report guides, and other documents are available on FDA's web site at: http://www.fda.gov/Radiation-EmittingProducts/default.htm. FDA's eSubmitter may be used to prepare reports and correspondence, available at http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm.

UVC lamp manufacturers are responsible for compliance with all applicable regulatory requirements. The applicable regulations include 21 CFR parts 1000 through 1004, and certain sections of 21 CFR part 1005, including 21 CFR 1005.25. These regulations include requirements that manufacturers of electronic products (such as UVC lamps) investigate and report Accidental Radiation Occurrences (21 CFR 1000.3(a) and 21 CFR 1002.20), issue notification to the FDA and customers of radiation safety defects and correction of those defects (21 CFR parts 1003 and 1004), and, for non-domestic manufacturers of UVC lamps, designate a U.S. agent (21 CFR 1005.25).

In addition to the information required above, you are requested to include the following information in your response to CDRH: (a) list all models of UVC products your firm manufactures (or imports, or has manufactured, or has imported) that have been, or are intended to be, imported into the United States; and (b) a description of each UVC product's intended use, safety features, intended emission spectrum and intended intensity.

Please email your response to this defect notification (in PDF format) to RadHealthCustomerService@fda.hhs.gov, copying the FDA lead reviewer (identified in the closing paragraph) and including the subject correspondence reference number.

Should you have any questions or comments pertaining to this letter, please contact Pejman Ghassemi by telephone at +1-240-402-0313 or by e-mail at Pejman.Ghassemi@fda.hhs.gov. In any follow-up correspondence, please clearly reference FDA reference number COR22000015 and include a contact email address.

Sincerely,

Robert Ochs, Ph.D.
Deputy Director for Radiological Health
OHT 7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health