Columbia Mill, Bedford St
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26 June 2020

Dear Sir/Madam,

RE: ENFORCEMENT POLICY FOR STERILIZERS, DISINFECTANT DEVICES, AND AIR PURIFIERS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF MARCH 2020

In the context of the COVID-19 public health emergency, the FDA recognizes that it is necessary to maintain an adequate supply of sterilizers, disinfectant devices, and ***air purifiers*** that can facilitate rapid turnaround of sterilized or disinfected medical equipment and that help reduce the risk of viral exposure for patients and health care providers to SARS-CoV-2. FDA believes that certain sterilizers, disinfectant devices, and air purifiers falling within the scope of their guidance (Section III) may help reduce the risk of viral exposure based on their current understanding of these devices and SARS-CoV-2.

In general, manufacturers of sterilizers, disinfectant devices, and ***air purifiers*** are required to submit a marketing application to FDA when seeking to market these devices. However, to help ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, during the declared public health emergency, FDA does not intend to object to the distribution and use of sterilizers, disinfectant devices, and ***air purifiers*** that are intended to be effective at killing the SARS-CoV-2 virus but do not already have FDA marketing authorization, without compliance with the regulatory requirements where such devices do not create an undue risk in light of the public health emergency. The FDA believes such devices will not create such an undue risk where the performance and labeling elements as described in the guidance document, respectively, are met.

This report serves to provide the evaluation/ performance of Radic8's air purifiers – VirusKiller™ range (specifically Hextio, VK401 and VK103).

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FDA 510(k) PREMARKET NOTIFICATION AND ESTABLISHMENT REGISTRATION AND DEVICE LISTING

Although Radic8 plans to submit a 510(k) premarket notification and register its establishment and list its device with the FDA, it currently does not have 510(k) clearance for its air purifiers and is currently not registered with the FDA.

FDA's March 2020 guidance document entitled, " Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" states, "during the declared public health emergency, FDA does not intend to object to the distribution and use of … air purifiers that are intended to be effective at killing the SARS-CoV-2 virus but do not already have FDA marketing authorization, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81 or submission of a PMA Supplement under section 515 of the FD&C Act and 21 CFR 814.39, Registration and Listing requirements in 21 CFR 807..."

PERFORMANCE TESTING AGAINST FDA GUIDANCE CRITERIA

FDA recommends that manufacturers of air purifiers evaluate or perform the following:

1. *Demonstration of a 4-log reduction (through a combination of capture or destruction) of claimed particulates.*

Testing proves 6-log reduction of major airborne viruses (Polio Virus, Influenza Virus, Adeno Virus and Coronavirus DF20). Test results pertain to all three current models in the VirusKiller™ range of air purifiers. Test report is available upon request.

2. *If intended for use against bacteria, effectiveness against representative gram positive and gram-negative species (testing to support the intended use against bacteria)*

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Testing proves effectiveness against bacteria (gram positive and negative), fungi and mould. Test results pertain to all three current models in the VirusKiller™ range of air purifiers. Test report is available upon request.

3. *If intended for use related to SARS-CoV-2, effectiveness against a representative virus (an RNA virus enveloped in a lipid bilayer).*

The Viruskiller technology was tested against Coronavirus DF2 (the same family of SARS virus) by the Institute of Medical Sciences, School of Medicine National Kangwon University. Test results pertain to all three current models in the VirusKiller™ range of air purifiers. Test report and test certificate are available upon request.

4. *If the device generates ozone, the maximum acceptable level of ozone per 21 CFR 801.415.*

The test method used was KOA AS 01 - the test standard for the Korea Air Sterilizer Association which requires "the ozone release shall not exceed an 8-hour average of 0.05×10^{-6} and an 8-hour maximum of 0.1×10^{-6}". This requirement meets 21 CFR 801.415. Our device results indicate -0.014ppm ozone generation – where below "0" means no detection, therefore 0% ozone generation. Test results pertain to all three current models in the VirusKiller™ range of air purifiers. Test reports available upon request.

5. If intended for use in areas that have a sterile field or controlled air flow, a risk assessment to address turbulent air flow and/or potential site contamination.

The areas intended for use of the devices are dental spaces – dental rooms, reception and waiting areas. These spaces do not have a sterile field or controlled air flow. That being said, air flow is very important for the efficiency of an indoor air sterilizer.

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LABELING AGAINST FDA GUIDANCE CRITERIA

This report serves to provide supplementary labeling information relating to Radic8's air purifiers – VirusKiller™ range (specifically Hextio, VK401 and VK103).

The VirusKiller™ range is intended to be placed in medical facilities (e.g. dentists) as a medical countermeasure ("MCM") (refer to the table below for coverage). The VirusKiller™ range does not replace, and is not intended to replace, the use of personal protective equipment ("PPE") or other similar MCMs as prescribed.

	VirusKiller range		
	Hextio	**VK 401**	**VK103**
Area (m_2)	$20m_2$ (*With a standard ceiling height of 2.4m)*	$60m_2$ (*With a standard ceiling height of 2.4m)*	$100m_2$ (*With a standard ceiling height of 2.4m)*
Coverage	Small rooms, bedrooms, hotel rooms, living rooms, dining rooms, kitchens, workspace, small offices, desktop, on-the-go, public transport, private vehicles, elderly homes, childcare spaces, play areas.	Medium rooms, classrooms, public areas, wards, offices, hotel lobbies and rooms, waiting rooms, restaurants, commercial spaces, elderly homes, childcare spaces, mass congregation spaces, medical installations, laboratories, Government buildings, leisure facilities, public toilets.	Large rooms, classrooms, communal areas, wards, offices, hotel lobbies, waiting rooms, restaurants, commercial spaces, elderly homes, childcare spaces, mass congregation spaces, medical installations, laboratories, veterinary surgeries, Government buildings, leisure facilities. It can also create **positive pressure**.

We are available to advise on optimal positioning of units based on room layout and other equipment such as A/C.

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FDA recommends that the devices described above include labelling that helps users better understand the device modifications, such as:

6. ***A clear description of the available data on the device's new indications or functions related to SARS-CoV-2 or co-existing conditions, such as:***
    a) ***Device performance; and***

The Viruskiller™ technology was tested against major airborne viruses (Polio Virus, Influenza Virus, Adeno Virus and Coronavirus DF2 (the same family of SARS virus) by the Institute of Medical Sciences, School of Medicine National Kangwon University. Testing proves 6-log reduction of viruses. The results on airborne pathogens are the same for all of the Viruskiller™ range.

Results Summary

99.9999%	Viruses (Polio Virus, Influenza Virus, Adeno Virus and Coronavirus DF2) killed
99.9999%	Removal of bacteria, mould & fungi
99.9999%	Removal of fine dust and particulate matter
99.9999%	Removal of odor and toxic gas
99.9999%	Removal of Volatile Organic Compounds
0%	Ozone Creation

    b) ***Potential risks (e.g., risk of UV exposure)***

There are no UV risks associated with the devices in use. The UV reactor chambers and fans are sealed to ensure there is no risk of harm and UV exposure. Indoor air quality sensors on the devices also highlight when the filters on units need to be cleaned and replaced.

7. ***A clear distinction delineating FDA-cleared or FDA-approved indications from those that are not FDA-cleared or FDA-approved. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.***

Radic8's VirusKiller™ range is not FDA-cleared / FDA-approved. This is also indicated on Radic8's labeling (website, user manuals and inserts with products).

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8. ***For all disinfectant devices, a clear statement of the level of disinfection.***

Not applicable.

9. ***For UV disinfecting devices:***
    a) ***A caution that UV disinfection will reduce the number of pathogens on the device, but it will not eliminate them completely.***
    b) ***A statement that the device is an adjunct to currently existing reprocessing practices and not a replacement or modification to such practices.***
    c) ***A statement regarding the time, distance, and maximum area over which the device has been evaluated for effectiveness.***
    d) ***An appropriate UV hazard warning label.***
    e) ***Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed.***
    f) ***Procedures to follow if the UV lamp malfunctions or fails.***
    g) ***Description of the preparation of equipment or the room for disinfection***
    h) ***A statement that the equipment intended to be disinfected is UV compatible.***
    i) ***Identification of the UV dose.***

Not applicable.

Kind regards,

Richard Greenwood
Founder: Radic8

HELLOSIGN

Audit Trail

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