February 17, 2022

Bluezone Products, Inc.
% Maureen O'connell
President
O'Connell Regulatory Consultant, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K212824
Trade/Device Name: Bluezone Model RX-450 Air Purifier
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: January 7, 2022
Received: January 10, 2022

Dear Maureen O'connell:

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,

Clarence W. Murray, III, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212824

Device Name
Bluezone Model Rx-450 Air Purifier

Indications for Use *(Describe)*
The Bluezone Model Rx-450 Air Purifier is a free standing, air purifying device utilizing germicidal ultraviolet light (UV-C wavelengths near 254nm) intended for inactivation of indoor airborne aerosols including bacteria, mold, and virus in medical facilities and occupied spaces.

The Bluezone Model Rx-450 Air Purifier has been demonstrated to entrain and destroy the following exposure/working conditions:

Test Item		Average Net Log Reduction/Time @ High Fan Speed. Room Temperature Test
Bacteria	Bacillus atrophaeus	4.95 / 60 minutes
Bacteria	Bacillus atrophaeus	4.00 / 48 minutes
Mold	Penicillium rocqueforti	4.40 / 60 minutes
Mold	Penicillium rocqueforti	4.00 / 52 minutes
Virus	MS-2 bacteriophage	5.32 / 60 minutes
Virus	MS-2 bacteriophage	4.00 / 40 minutes

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.

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K212824 510(k) SUMMARY

Bluezone Products, Inc.
Bluezone Model RX-450 Air Purifier

510(k) Owner
Bluezone Products, Inc.
225 Wildwood Avenue
Woburn, MA 01801

Submission Correspondent
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: February 15, 2022

Trade Name of Device
Bluezone Model RX-450 Air Purifier

Common or Usual Name
Air Purifier

Classification Name
Medical UV Air Purifier, 21 C.F.R. §880.6500
Class II
Product Code: FRA

Review Panel
General Hospital

Predicate Device
ECO-Rx Air Purifier with UV Light Model Rx-400 cleared in K062716

Device Description
The Bluezone Model RX-450 is an air purification device that uses germicidal UV bulbs to inactivate viral, bacterial or fungal aerosols. The operation of the device is as follows: ambient air containing microbial aerosols is drawn into the air purifier through a prefilter and two angled aluminum honeycomb light baffles. The infective aerosols in the air are then exposed to high intensity, germicidal, ultraviolet light where the contaminants receive a UV dose of at least 10 mW*second/cm^2. The bacterial, fungal and viral aerosols are inactivated through the breakdown of the microbial DNA or RNA. The cleaned air is exhausted back into the room from the Bluezone Model RX-450 through an axial fan.

Indications for Use
The Bluezone Model RX-450 Air Purifier is a free standing, air purifying device utilizing germicidal ultraviolet light (UV-C wavelengths near 254nm) intended for inactivation of indoor airborne aerosols including bacteria, mold, and virus in medical facilities and occupied spaces.

The Bluezone Model Rx-450 Air Purifier has been demonstrated to entrain and destroy the following exposure/working conditions:

Test Item		**Average Net Log Reduction/Time @ High Fan Speed. Room Temperature Test**
Bacteria	Bacillus atrophaeus	4.95 / 60 minutes
Bacteria	Bacillus atrophaeus	4.00 / 48 minutes
Mold	Penicillium rocqueforti	4.40 / 60 minutes
Mold	Penicillium rocqueforti	4.00 / 52 minutes
Virus	MS-2 bacteriophage	5.32 / 60 minutes
Virus	MS-2 bacteriophage	4.00 / 40 minutes

Technological Characteristics Comparison

Table 1
Bluezone Model RX-450 Air Purifier Technological Characteristics Comparison

Characteristic	**Bluezone Model RX-450 Air Purifier**	**ECO-Rx Air Purifier with UV Light Model Rx-400**	**Comparison**
510(k) Number	-	K062716	-
Device Type	Medical Ultraviolet Air Purifier	Medical Ultraviolet Air Purifier	Same
Product Code	FRA	FRA	Same
Class	II	II	Same
Use Type	OTC	OTC	Same
Intended Use	Kill bacteria and virus in the air	Kill bacteria and virus in the air	Same
Indications for Use	The Bluezone Model RX-450 Air Purifier is a free standing, air purifying device utilizing germicidal ultraviolet light (UV-C wavelengths near 254nm) intended for inactivation of indoor airborne aerosols including bacteria, mold, and virus in	The ECO-Rx Air Purifier with UV Light, Model Rx-400 is a flow-through indoor air-purification system for the inactivation of indoor airborne bacteria.	Minor differences in wording of indications for use statement do not impact the intended use

	medical facilities and occupied spaces. The Bluezone Model Rx-450 Air Purifier has been demonstrated to entrain and destroy the following bioaerosols under the following exposure/working conditions: (see indications for use)		
Mechanism of Action	UV-C inactivation of microorganisms	UV-C inactivation of microorganisms	Same
Installation	Free standing	Free standing	Same
Elements of Design	Fan circulates air through a shielded chamber where UV light irradiates microbial aerosols	Fan circulates air through a shielded chamber where UV light irradiates microbial aerosols	Same
Filter	Yes	Yes	Same
Internal Fan	Yes	Yes	Same
Germicidal UV	Yes	Yes	Same
UV Optic Type	Quartz tube with low pressure mercury vapor	Quartz tube with low pressure mercury vapor	Same
UV Wavelength	254 nm	254 nm	Same
Ozone Emission	No	No	Same
Chemical Additives	No	No	Same
Standards Compliance			
Electrical Safety	Per UL 507	Per UL 507	Same
EMC	Per IEC 60601-1-2	Per IEC 60601-1-2	Same

Summary of Non-Clinical Testing

Table 2 shows the non-clinical testing that was performed.

Table 2
Non-Clinical Testing for the Bluezone Model RX-450 Air Purifier

Test Completed	Standard Followed	Acceptance Criteria	Result
Electrical Safety	UL 507: 2017 Ed. 10+R: 06Nov2018 Fans and Ventilators	Per Standard	Passed

	CSA C22.2#113:2018 Ed. 11		
Electromagnetic Compatibility	IEC 60601-1-2:2014 (4th Edition) General Requirements for Safety-Collateral Electromagnetic Compatibility Requirements and Tests Medical Electrical Equipment	Per Standard	Passed
Safety of air-cleaning appliances	IEC 60335-2-65 Safety of household and similar electrical appliances Part 2: Particular requirements for air-cleaning appliances	Per Standard	Test specifications were met
Ozone Emissions Testing of Household Electrostatic Air Cleaners	Electrostatic Air Cleaners, UL 867 Section 40, Fifth Edition CSA 22-2 No. 187-15, Section 7	Emittance of ozone not exceeding a concentration of 0.050 ppm	Found in compliance with criteria
Zero Ozone Emission	UL 2998 Section 6	Ozone <0.005 ppm	Passed. Ozone <0.001 ppm
UV Irradiance and Leakage in Occupied Spaces	UL 507-2017: Heating and Cooling Equipment	Effective irradiance <0.1 uW/cm^2	Passed. Location 1 Effective irradiance 6.55E-02 uW/cm^2 and Location 2 3.13E-03 uW/cm^2
Removal of Aerosolized MS2 Bacteriophage	Not applicable	4.0 net LOG reduction	Produced a rapid reduction in viable MS2 within the 60-minute test period. The Bluezone RX-450 is estimated to reach a 4.0 net LOG reduction of viable MS2 bioaerosol in a 16m^3 chamber at 35 minutes.
Removal of Bacterial Spores	Not applicable	99.99% reduction in active aerosolized bacterial spores	Achieved 99.99% reduction in active aerosolized bacterial spores in less than 48 minutes in a 735 cubic foot test chamber
Removal of Mold Spores	Not applicable	99.99% reduction in active aerosolized molds	Achieved 99.99% reduction in active aerosolized molds in less then 1 hour in a

			735 cubic foot test chamber

Summary of Clinical Testing
Not applicable

Conclusion
The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.