



February 16, 2024

Airgle Corporation  
Jet Li  
Regulation manager  
1170 Lincoln Avenue Unit 2  
Holbrook, New York 11741

Re: K232645  
Trade/Device Name: Airgle Room Air Purifier  
Regulation Number: 21 CFR 880.6500  
Regulation Name: Medical Ultraviolet Air Purifier  
Regulatory Class: Class II  
Product Code: FRA  
Dated: January 16, 2024  
Received: January 16, 2024

Dear Jet Li:

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.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Christopher K. Dugard -**

**S**

Christopher K. Dugard, M.S.

Assistant Director

DHT4B: Division of Infection Control

and 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

## Indications for Use

510(k) Number (if known)  
K232645

Device Name

Airgle Room Air Purifier

Indications for Use (Describe)

The Airgle Room 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 and virus in medical facilities and occupied spaces. The Airgle® Air Purifier has been demonstrated to destroy MS2 bacteriophage bioaerosol entrained on the filter of the subject device in the following exposure/working conditions:

Test Item(s)	Test Results (Average Maximum Log Reduction / Entrainment Time at Fan Speed 5)
MS2 Bacteriophage	Model AG300: >4.0 Logs / 120 minutes Model AG600: >4.0 Logs / 120 minutes Model AG900: >4.0 Logs / 120 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**



## **K232645**

### **510(k) Summary**

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a Traditional 510(K) submission, and there were no prior submissions for the subject device.

**Date of the summary prepared: February 15, 2024**

#### **1. Submitter's Information**

##### **Sponsor**

- ◆ Applicant: Airgle Corporation
- ◆ Address: 1170 Lincoln Avenue Unit 2 Holbrook, NY 11741 USA
- ◆ Manufacturer: Shenzhen Airgle Corporation Limited
- ◆ Factory address: Zone A&B, The 11th Floor, KeChuang Building, QuanZhi Science & Technology Innovation Park, Houting Mao zhoushan Industrial Park, ShaJing Street, Baoan District, Shenzhen Guangdong, CN 518000
- ◆ Phone: +86-755-86726696
- ◆ Email: jerry@airgle.com.cn
- ◆ Contact Person (including title): Jerry Liu (CTO)

##### **Application Correspondent:**

- ◆ . Airgle Corporation
- ◆ Address: 1170 Lincoln Avenue Unit 2 Holbrook, NY 11741 USA
- ◆ Contact Person: Mr. Jet Li
- ◆ Title: Regulation Manager
- ◆ Tel: +86-18588874857
- ◆ Email: jianda-lee@foxmail.com

## 2. Subject Device Information

- ◆ Type of 510(k) submission: Traditional
- ◆ Classification: Medical Ultraviolet Air Purifier
- ◆ Trade Name: Airgle Room Air Purifier
- ◆ Model: AG300 /AG600 /AG900
- ◆ Review Panel: General Hospital
- ◆ Product Code: FRA
- ◆ Regulation Number: 21 CFR 880.6500
- ◆ Regulation Class: 2

## 3. Predicate / Reference Device Information

	<b>Predicate Device</b>	<b>Reference Device</b>
510(k) number	K202339	K212824
Sponsor	Molekule, Inc..	Bluezone Products, Inc.
Classification	Medical Ultraviolet Air Purifier	Medical Ultraviolet Air Purifier
Trade Name	Molekule Air Mini	Bluezone Model RX-450 Air Purifier
Review Panel	General Hospital	General Hospital
Product Code	FRA	FRA
Regulation Number	21 CFR 880.6500	21 CFR 880.6500
Regulation Class	2	2

## 4. Device Description

Airgle Room Air Purifier is an air purification device that employs an ultraviolet air purification technology to inactivate viral aerosols. It is a free-standing device, which has a sealed main housing including a Carbon filter, a cHEPA filter and Titanium Pro (UV-C) module. Model AG300 use a 2-in-1 filter which combine the Carbon filter and cHEPA filter.

The operation of the device is as follows:

- 1) Room air is drawn into the device via the rear grill.

- 2) The process begins when air moves through the Carbon filter, which captures the large particles
- 3) Next, the air moves through the cHEPA filter, which captures a particle size greater than 0.3 microns. The filter is an ultra-high performance cHEPA filter, which filters respirable particulate matter with an efficiency reaching 99.3% at least.
- 4) Then the air moves through the Titanium Pro® module, where viral organisms are inactivated by UV-C light.
- 5) Purified air is then returned to the room via the front grill.

**5. Intended Use / Indications for Use (For models: AG300/AG600/AG900)**

The Airgle Room 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 and virus in medical facilities and occupied spaces.

The Airgle® Air Purifier has been demonstrated to destroy the following MS2 bacteriophage bioaerosol entrained on the filter of the subject device under the following exposure/working conditions:

Test Item(s)	Test Results (Average Maximum Log Reduction / Entrainment Time at Fan Speed 5)
MS2	Model AG300: >4.0 Logs / 120 minutes
Bacteriophage	Model AG600: >4.0 Logs / 120 minutes
	Model AG900: >4.0 Logs / 120 minutes

**6. Comparison to predicate device and conclusion**

The technological characteristics, features, specifications, materials, and intended use of Airgle Room Air Purifier are shown below in tabular form.

<b>Device</b>	<b>Proposed Device</b>	<b>Primary Predicate Device 1</b> K202339	<b>Reference Device 1</b> K212824	<b>Comment</b>
<b>Manufacturer</b>	Airgle Corporation	Molekule, Inc.	Bluezone Products, Inc.	None
<b>Product Name</b>	Airgle Room Air Purifier AG300/AG600/AG900	Molekule Air Mini,	Bluezone Model RX-450 Air Purifier	None
<b>Device type</b>	Medical Ultraviolet Air Purifier	Purifier, Air, Ultraviolet, Medical	Medical Ultraviolet Air Purifier	Same
<b>Classification</b>	Class II, FRA (21 CFR880.6500)	Class II, FRA (21 CFR880.6500)	Class II, FRA (21 CFR880.6500)	Same
<b>Use type</b>	OTC	OTC	OTC	Same
<b>Intended Use</b>	Destroy bacteria and viruses by exposure to ultraviolet radiation.	Destroy bacteria and viruses by exposure to ultraviolet radiation.	Kill bacteria and virus in the air	Same

<p><b>Indications for use</b></p>	<p>The Airgle Room Air Purifier is a free standing, air purifying device utilizing germicidal ultraviolet light intended for inactivation of indoor airborne aerosols including bacteria and virus in medical facilities and occupied spaces.</p> <p>The Airgle® Air Purifier has been demonstrated to destroy the following MS2 bacteriophage bioaerosol entrained on the filter of the subject device under the following exposure/working conditions:</p>	<p>The Molekule Air Mini air purifier is a device intended for medical purposes that is used to capture 95% of particulate matter and destroy bacteria and viruses by exposure to ultraviolet radiation.</p> <p>The Molekule Air Mini air purifier has been demonstrated to destroy the following MS2 bacteriophage bioaerosol entrained on the filter of the subject device under the following exposure/working conditions:</p>	<p>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.</p> <p>The Bluezone Model Rx-450 Air Purifier has been demonstrated to entrain and destroy the following exposure/working conditions:</p>	<p>Subject and Predicate Devices tested against the same organism</p> <p>Reference Device tested against additional organisms</p>
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<b>Device</b>	<b>Proposed Device</b>	<b>Primary Predicate Device 1</b> K202339	<b>Reference Device 1</b> K212824	<b>Comment</b>
<b>Mechanism of Action</b>	UV-C inactivation of microorganisms	UV light of sufficient energy (UV-A) activates photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction.	UV-C inactivation of microorganisms	Subject, Predicate and Reference Devices all reduce viable and non-viable aerosols by entrainment onto filter media and biocidal action of UV Light
<b>Installation</b>	Free standing	Free standing	Free standing	Same
<b>Elements of design</b>	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	Fan circulates air through a shielded chamber where UV light irradiates microbial aerosols	Same
<b>Filter</b>	Yes	Yes	Yes	Same
<b>Filtration type</b>	Particle filter	Particle filter	Particle filter	Same

<b>Device</b>	<b>Proposed Device</b>	<b>Primary Predicate Device 1</b> K202339	<b>Reference Device 1</b> K212824	<b>Comment</b>
<b>Internal Fan</b>	Yes	Yes	Yes	Same
<b>Fan speed</b>	5 speeds	5 Speeds	2 Speeds	No new safety or efficacy questions raised by differences. Any performance differences mitigated by test results
<b>Germicidal UV</b>	Yes	Yes	Yes	Same
<b>UV Optic type</b>	Quartz tube with low pressure mercury vapor	UV Light Source: LED	Quartz tube with low pressure mercury vapor	No new safety or efficacy questions raised by differences. Any performance differences mitigated by test results.
<b>UV wavelength</b>	254nm	320-400 nm	254nm	No new safety or efficacy questions raised by differences. Any

<b>Device</b>	<b>Proposed Device</b>	<b>Primary Predicate Device 1</b> K202339	<b>Reference Device 1</b> K212824	<b>Comment</b>
				performance differences mitigated by test results.
<b>Ozone Emission</b>	Does not exceed a concentration of 0.050 ppm according to UL 867	Does not exceed a concentration of 0.050 ppm according to UL 867	Does not exceed a concentration of 0.050 ppm according to UL 867	Same
<b>Removal of bacterial spores</b>	Not claimed	Not Claimed	99.99%	No new safety or efficacy questions raised by differences. Performance differences mitigated by labeling claims.
<b>Removal of mold spores</b>	Not claimed	Not claimed	99.99%	No new safety or efficacy questions raised by differences. Performance differences mitigated by labeling claims

<b>Device</b>	<b>Proposed Device</b>	<b>Primary Predicate Device 1</b> K202339	<b>Reference Device 1</b> K212824	<b>Comment</b>
<b>Removal of Aerosolized MS2 Bacteriophage</b>	4.0 net LOG reduction in a 30 m <sup>3</sup> space at 120 minutes	4 log reduction (99.99%)	4.0 net LOG reduction in a 16m <sup>3</sup> space at 35 minutes.	No new safety or efficacy questions raised by differences. Performance differences mitigated by labeling claims
<b>UV radiance and leakage in occupied spaces</b>	None	None	Effective irradiance <0.1 uW/cm <sup>2</sup>	Same
<b>Chemical Additives</b>	No	No	No	Same
<b>Electrical safety</b>	IEC 60601-1 AAMI TIR69:2017 ANSI C63.27-2017	UL 507	UL 507	No new safety or efficacy questions raised by differences in Standards applied.
<b>EMC</b>	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same

## 7. Summary for non-clinical test

The non-clinical testing was provided to demonstrate the subject device met the acceptance criteria of the test methodology or standards listed below. Airgle Room Air Purifier complies with voluntary standards for electrical safety and electromagnetic compatibility.

Name of test methodology	Purpose	Acceptance Criteria	Results
IEC 60601-1 IEC 60601-1-2	Demonstration of basic safety and essential performance	Meets criteria for CISPR Group 1A	PASS
AAMI TIR69:2017 ANSI C63.27-2017	wireless coexistence test	Wireless System ability to coexist with interfering networks in the 2.4G band.	PASS
Bacteriophage Test	Demonstration of log reduction of viral load	At least 99.99% reduction of MS2 bacteriophage after 2 hours	PASS
ANSI/ASHRAE Standard 52.2	Demonstration of filter efficiency	At least 99.3% for 0.3-10 um	PASS
Software validation	Demonstration of software security and good design	Meets design criteria	PASS

## 8. Summary for clinical test

Not applicable

## 9. Conclusion

The Conclusion drawn from the non-clinical testing demonstrates that the subject device, Airgle Room Air Purifier, is as safe, as effective, and performs as well for the documented intended use as the legally marketed predicate device cleared under K202339 and the reference device cleared under K212824.