June 2, 2023

Genesis Air, Inc.
% Dan Briggs
President
www.genesisair.com
5202 Country Road 7350, Suite D
Lubbock, Texas 79424
Phone Number: (806) 745-7000

Re: K222702
Trade/Device Name: RGS; RGS Mini
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: June 1, 2023
Received: May 5, 2023

Dear Dan Briggs:

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 and Part 809); 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,

Christopher K. Dugard -S

for Clarence W. Murray, III, Ph.D.
Assistant Director
THT4B1:Sterility Devices Team
DHT4B: Division of Infection Control and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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)*
K222702

Device Name
RGS / RGS mini

Indications for Use *(Describe)*
The RGS / RGS mini is a medical ultraviolet air purifier that is intended for medical purposes. It is used to destroy bacteria in the air by exposure to ultraviolet radiation.
The RGS and RGS mini have demonstrated the ability to eliminate Staphylococcus Epidermidis, Bacteriophage MS2, and Escherichia Coli in the air of the test chamber in 60 minutes under the following conditions.

The device with model number RGS and a high fan speed of 600 CFM when tested against Staphylococcus Epidermidis (gram positive) had a log reduction of 4.0 PFU/ft^3. The device with model number RGS and a high fan speed of 600 CFM when tested against Bacteriophage MS2 had a log reduction of 4.02 PFU/ft^3.The device with model number RGS and a high fan speed of 600 CFM when tested against Escherichia Coli had a log reduction of 4.24 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Staphylococcus Epidermidis (gram positive) had a log reduction of 4.04 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Bacteriophage MS2 had a log reduction of 4 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Escherichia Coli had a log reduction of 4.0 PFU/ft^3.

This device is not intended for use in areas with a sterile field or controlled air flow.

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.

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510(k) Summary

RGS / RGS mini

K222702

1. Submission Sponsor As required by 21CFR§807.92(c)

Genesis Air, Inc.

5202 Country Road 7350, Suite D

Lubbock, Texas 79424

United States of America

Phone Number: (806) 745-7000

Contact Person: Dan Briggs

Title: President

2. Submission Correspondent

Genesis Air, Inc.

5202 Country Road 7350, Suite D

Lubbock, Texas 79424

United States of America

Phone Number: (806) 745-7000

Contact Person: Connor Croak

Title: Engineer

Email: connor.croak@genesisair.com

3. Date Prepared

6/1/2023

4. Device Identification

Trade/Proprietary Name:	RGS / RGS mini
Common/usual Name:	Air Purifier
Classification Name:	Medical ultraviolet air purifier
Regulation Number:	21 CR §880.6500
Product Code:	FRA
Device Class:	Class II
Classification Panel:	General Hospital

5. Legally Marketed Predicate Device(s)

K212644, Aura Storm, Invictus Lighting

No reference devices were used in this submission.

6. Indication for Use Statement

The RGS / RGS mini is a medical ultraviolet air purifier that is intended for medical purposes. It is used to destroy bacteria in the air by exposure to ultraviolet radiation.

The RGS / RGS mini have demonstrated the ability to eliminate Staphylococcus Epidermidis, Bacteriophage MS2, and Escherichia Coli in the air of the test chamber in 60 minutes under the following conditions.

The device with model number RGS and a high fan speed of 600 CFM when tested against Staphylococcus Epidermidis (gram positive) had a log reduction of 4.0 PFU/ft^3. The device with model number RGS and a high fan speed of 600 CFM when tested against Bacteriophage MS2 had a log reduction of 4.02 PFU/ft^3.The device with model number RGS and a high fan speed of 600 CFM when tested against Escherichia Coli had a log reduction of 4.24 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Staphylococcus Epidermidis (gram positive) had a log reduction of 4.04 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Bacteriophage MS2 had a log reduction of 4 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Escherichia Coli had a log reduction of 4.0 PFU/ft^3.

This device is not intended for use in areas with a sterile field or controlled air flow.

7. Device Description

The RGS / RGS mini is a medical ultraviolet air purifier that is intended for medical purposes. It is used to destroy bacteria in the air by exposure to ultraviolet radiation.

The device uses a MERV 13 filter for particle filtration. Down upstream of the pre-filter is a PCO component. The PCO consists of a TiO2 coated mesh and UV lights. When the UV lights (UV-C) provide sufficient energy, the TiO2 coated photo catalyst is activated. This component will deactivate microorganisms and viruses through a chemical reaction.

The RGS / RGS mini model numbers RGS and RGS mini have demonstrated the ability to eliminate Staphylococcus Epidermidis, Bacteriophage MS2, and Escherichia Coli in the air of the test chamber in 60 minutes under the following conditions. The device with model number RGS and a high fan speed of 600 CFM when tested against Staphylococcus Epidermidis (gram positive) had a log reduction of 4.0 PFU/ft^3. The device with model number RGS and a high fan speed of 600 CFM when tested against Bacteriophage MS2 had a log reduction of 4.02 PFU/ft^3.The device with model number RGS and a high fan speed of 600 CFM when tested against Escherichia Coli had a log reduction of 4.24 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Staphylococcus Epidermidis (gram positive) had a log reduction of 4.04 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Bacteriophage MS2 had a log reduction of 4 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Escherichia Coli had a log reduction of 4.0 PFU/ft^3.

8. Substantial Equivalence Discussion

The following table compares the RGS / RGS mini to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

Table 5A – Comparison of Characteristics

Traditional 510(k) Premarket Submission
RGS / RGS mini

Manufacturer	Genesis Air, Inc.	Invictus Lighting, LLC	Device Comparison
Trade Name	**RGS / RGS mini**	**Invictus Aura Storm Air Purifier**	
510(k) Number	K222702	K212644	
Panel	General Hospital	General Hospital	
Product Code	FRA	FRA	
Regulation Number	21 C.F.*R.* § 800.6500	21 C.F.*R.* § 800.6500	
Regulation Name	Medical ultraviolet air purifier	Medical ultraviolet air purifier	
Class	II	II	
Rx/OTC	OTC	OTC	
User	Healthcare Professional Lay User	Healthcare Professional Lay User	Same
Environment of Use	General Hospital, Public Schools, Hotels, Restaurants, Casinos	Hospitals, medical facilities, medical clinics, nursing facilities, and dental facilities.	Same
User	Health Care Professionals, School Districts, Hotels, Restaurants, Casinos	Health Care Professional, Lay User	Same
Installation	Free Standing and Wall Mount	Free Standing	
Indications for Use	The RGS / RGS mini is a medical ultraviolet air purifier that is intended for medical purposes. It is used to destroy bacteria in the air by exposure to ultraviolet radiation. The RGS / RGS mini have demonstrated the ability to eliminate Staphylococcus Epidermidis, Bacteriophage MS2, and Escherichia Coli in the air of the test chamber in 60 minutes under the following conditions.	The Aura Storm air purifier is a device intended for medical purposes that is used to capture and destroy bacteria and viruses in the air through the multi-stage filtration system and exposure to ultraviolet radiation. The Aura Storm air purifier has been demonstrated to destroy the following bacteria: Staphylococcus albicans, Staphylococcus aureus, and Escherichia Coli; and virus: A/PR8/34 H1N1 virus entrained on the filter of the subject device under	Similar. The different organisms for each does not affect the safety.

	The device with model number RGS and a high fan speed of 600 CFM when tested against Staphylococcus Epidermidis (gram positive) had a log reduction of 4.0 PFU/ft^3. The device with model number RGS and a high fan speed of 600 CFM when tested against Bacteriophage MS2 had a log reduction of 4.02 PFU/ft^3.The device with model number RGS and a high fan speed of 600 CFM when tested against Escherichia Coli had a log reduction of 4.24 PFU/ft^3. The device with model number RGS mini and a high fan speed of 500 CFM when tested against Staphylococcus Epidermidis. This device is not intended for use in areas with a sterile field or controlled air flow.	the following exposure conditions: Average Maximum log reduction/entrainment time (minutes) at Fan Speed 4. Room Temperature test: Log 4(99.99%) / 60 minutes. Average Maximum log reduction / entrainment time (minutes) at Fan Speed 1. Room Temperature test: Log 4 (99.99%) / 120 minutes	
System Components	- Pre-filter - 6" TiO2 Coated Photocatalyst UV-C Lamp (Approximately 254 nm)	- Pre-filter - HEPA H13+ Filter - TiO2 Photo Catalyst Filter UV-C Sterilization Lamp (253.7 nm)	Similar. Does not affect Safety
Mechanism of Action	UV light (UV-C) of sufficient energy activates the TiO2 coated photocatalyst that deactivates microorganisms and viruses through a	UV light of sufficient energy (UV-C) activates a TiO2 lined photocatalyst that destroys microorganisms	Same

	chemical reaction.	entrained on the filter through a photochemical reaction, plus the addition of a pre-filter and HEPA filter.	
Material	Frame: Galvanized Steel Catalyst Panel: Fiberglass and titanium enriched coating.	N/A	
Temperature Control	N/A	N/A	
Shelf Life	1 year warranty Pre-filter changes every 3 months. UV lamp changes every 12,000 hrs.	Recommended replacement of filers and UV lamps	Same
Light Sources	UV-C Light Source: Mercury Vapor lamps Wavelength: 254nm RGS: (2) 20" UVC Lamps RGS total UV Power: 36 watts RGS mini: (2) 12" UVC lamps RGS mini totals UV power: 14 watts	UV-C Light Source: LED Wavelength: 253.7nm Total of (2) UV-C tubes Lamps: (1 per side) Total UV Power: 8.0 watts	Similar, testing showed no safety or efficacy concerns
User Control	One knob turns the unit on and controls the infinitely variable fans speed.	The unit features a capacitive touch button. Control to operate the On/Off, Fan speed (4 speeds), Auto mode, UV lamp, Anion generator, Child lock, Timer, Filter reset. One button turns the unit on and off.	Same
Software Microprocessor	Analog Controls are used to control the fan speed. Analog safety switches are used to protect the user from UV radiation and impeller blade.	Basic Firmware, used to turn the unit on, off, and change fan speed.	NA
Battery Operated	Not applicable	Not applicable	
AC Powered	RGS: 120 VAC, up to	120 VAC, 0.55 amps, Up	Same

	3.40 amps and 408 watts RGS mini: 120 VAC, up to 3.02 amps and 363 watts.	to 65 watts	
Pre-Filter(s)	MERV 13 Filter is used for particle filtration upstream of the PCO. Dust Spot Efficiency: 89=90% Filter Dimensions: RGS: 12″ x 24″ x 4″ RGS mini : 12″ x 12″ x 2″	Synthetic screen mesh type added prior to HEPA. Designed to trap larger particles and keep them out of the HEPA. Dimensions: 14 in x 15 in x 0.125 in	Same except for proprietary components.
HEPA Filer	HEPA Filter (Optional) 12″ x 24″ x 6″	MERV 13 Dimensions: 14″ x 15″ x 0.125″	Similar, No Safety Concerns.
Catalyst Mesh	Proprietary Catalyst Media Nominal Dimensions: RGS: 12″ x 21″ x 6″ RGS mini: 12″ x 12″ x 6″ Photocatalyst coated with proprietary titanium dioxide coating and wire mesh.	Patent Pending Hybrid Oxidizer with proprietary Dual action Catalyst. Dimensions: N/A	
Photocatalyst	Proprietary Catalyst	Proprietary Catalyst	
Air Source	Centrifugal Fan	Centrifugal Fan	Same
Flow Source	Variable Fan Speeds RGS: 275 - 825 CFM RGS mini: 300 – 500 CFM	4 Speeds (low, medium high, boost) and auto mode provide up to 370 CFM	Same
Air Changes Per Hour (ACH)	RGS: 3 ACH in a 16,000 ft^3 Room RGS mini: 3 ACH in a 10,000 ft^3 room.	5.5 ACH on high fan speed (Speed 4), in a 4,000 ft^3 room.	Similar, no safety concerns
Particulate Sensor	Not applicable	Not applicable	Same
UV Light Exposure Safety Features	The Safety Switch is located on the particle filter door. If the particle filter door is	There are two sets of safety switches on the Aura Storm. The first is on both outer doors	Same

	open, then the device will not operate. This switch is in place to protect the user from UV light exposure and exposure to the moving fan wheel. Safety features confirmed by UL 507.	where the magnetic switch will disengage, and the unit will not turn on. A secondary switch in the Aura Storm filter and if the filter is improperly installed or the filter is missing, the unit will not operate. The unit will not operate with eh generic filter and the Invictus filter must be used for the system to work. These witches have been designed to protect eh user form any possibility of exposure to direct contact with UV light. Safety features confirmed by ETL to UL 507 safety standard.	
Fan Exposure Safety	The outlet grill protects the user from being able to access the spinning fan wheel. Inlet fan grille protects user from being able to access the spinning fan wheel.	Non-removable grill at air output and the switch safety feature at the inlet prevent the user from accessing spinning fan without tools. Safety feature confirmed by ETL tested to UL 507.	
Input Voltage	120-volt single phase AC power at 60 Hz	120-volt	
Current	RGS mini: up to 3.02 amps RGS: up to 3.40 amps	0.55 amps	
Power Consumption	RGS mini: up to 362 watts RGS: up to 408 watts	Up to 65 watts	
Dimensions	RGS mini outer casing dimensions: 19″ x 15″ x 15″ Standard Pre-filter: 12″	Outer frame dimensions: 23 in (H) x 18.2 in (W) x 10.6 in (L)	

	x 12" x 2" Carbon Filter: 12" x 12" x 2" HEPA Filter: 12" x 12" x 6" RGS casing dimensions: 15" x 16.25" x 33.25" Filter dimensions: Standard Pre-filter: 12" x 24" x 4" Alternative Pre-filter: 12" x 24" x 2" Carbon Filter: 12" x 24" x 2" HEPA Filter: 12" x 24" x 6"	Filter dimensions: Pre-Filter: 14 in x 15 in x 0.125 in HEPA Filter: 14 in x 15 in x 0.6875 in Catalytic Filter: 14 in x 15 in x 0.1875 in Carbon/Cold Catalyst Oxidizer Filter: 14 in x 15in x 0.625 in	
Standards	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC EMC for Medical Devices	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC EMC for Medical Devices	

9. Non-Clinical Performance Data

Internal verification and validation testing confirms that product specifications are met which are equivalent in design and technological characteristics as the predicate device. The testing results support that the electrical safety testing, and functional testing of the product were met for the acceptance of the device.

Test Type	Purpose for the Test	Acceptance Criteria and the Source for the Reference	Results
Electrical Safety and Electromagnetic Compatibility Testing	General requirements for basic safety and essential performance including UV light leakage and intensity.	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC EMC for medical devices.	Compliant / Pass
Bacteria Reduction Test	LMS Technologies reduction of Gram Negative (E. Coli) and Gram Positive (Staph. Epidermidis) bacteria.	Log 4 reduction of Gram-Positive and Gram-Negative Bacteria 21 CRF 880.6500	Compliant / Pass Log 4 Reduction of E. Coil and Staphylococcus Epidermidis
Virus Inactivation Test	LMS Technologies Reduction of MS-2 Bacteriophage	Log 4 reduction of representative virus 21 CRF 880.6500	Compliant / Pass Log 4 Reduction of MS-2 Bacteriophage
Filtration Efficiency Testing	LMS Technologies reduction of Gram Negative (E. Coli) and Gram Positive (Staph. Epidermidis) bacteria.	Log 4 reduction of Gram-Positive and Gram-Negative Bacteria 21 CRF 880.6500	Compliant / Pass Log 4 Reduction of E. Coil and Staphylococcus Epidermidis
Shelf Life	Identify the useful life of the UV lamps and pre-filter.	UV lamp life of 12,000 hrs. of continuous operation. Pre-filter life of 3 months of continuous operation.	Compliant / Pass UV lamp life of 12,000 hrs. of continuous operation. Pre-filter life of 3 months of continuous operation.

Biocompatibility testing

This device is not intended to be placed in or on the body. Not applicable.

Electrical safety and electromagnetic compatibility (EMC)

The RGS / RGS mini complies with the applicable voluntary standard which includes IEC 60601-1-2:2014. The overall mechanical, electronic, and safety features of the RGS / RGS mini complies with these voluntary standards including IEC 60601-1-2 for Electromagnetic Compatibility.

Software Verification and Validation Testing

The RGS / RGS mini does not contain any software. Therefore, there is no software documentation to review.

10. Animal Performance Data

Not applicable

11. Clinical Performance Data

Not applicable

12. Conclusions

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 device K212644.