May 26, 2022

Invictus Lighting
Neeraj Lal
Vice President of Engineering and Marketing
1401 Main Ave. SW
Hickory, North Carolina 28602

Re: K212644
Trade/Device Name: Aura Storm
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: April 13, 2022
Received: April 13, 2022

Dear Neeraj Lal:

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, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212644

Device Name
Aura Storm

Indications for Use *(Describe)*
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 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.

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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K212644

510(k) Summary:

Aura Storm

DATE: May 17, 2022

SUBMITTER:

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DEVICE:

- Trade Name: Aura Storm
- Regulation Number: 21 CFR 880.6500
- Regulation Name: Medical Ultraviolet Air Purifier
- Regulatory Class: Class II

- Common Name: Air Purifier
- Classification Name: Purifier, Air, Ultraviolet, Medical
- Review Panel: General Hospital
- Product Code: FRA

PREDICATE DEVICE(S):

Molekule Air Pro RX Air Purifier, K200500
Molekule Air Mini Air Purifier, K202339

DEVICE DESCRIPTION:

The Aura Storm is a multi-stage UV-C air purifier that delivers air purification for rooms up to 2700 square feet (~52ft x 52ft). The Storm inactivates and eliminates bacteria and viruses in the air. The Aura Storm may be used for medical purposes which can include hospitals, medical facilities, medical clinics, nursing facilities, and dental facilities. The Aura Storm is a standalone device that is controlled via buttons on the top of the unit.

The Aura Storm is a dual-sided system with each side consisting of four-stages. The first stage is a pre-filter. The second stage is a HEPA H13+ filter. The third stage is a TiO_2 cold photo-catalyst filter. Finally, the UV-C sterilization lamp emits a 253.7nm designed to activate the photo-catalyst filter and eliminate bacteria and viruses. The anion generator is used strictly to increase the size of the particulate molecules to increase the ability to capture and eliminate the bacteria and viruses. This designed system delivers a third-party tested 99.99% (4-log) sterilization in 60 minutes at the highest fan speed. The Aura storm was also tested at the lowest fan speed and delivered a 99.99% (4-log) sterilization in 120 minutes. The air flow diagram has been submitted in the additional files in the 510(k) submission.

There is an internal fan which draws in air from both sides of the unit, filters it through the multi-stage system and outputs the filtered air through the top of the unit. 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, and filter reset. There is also a particulate matter sensor and color bar to indicate the level of clean air.

INTENDED USE:

The Aura Storm may be used in hospitals, medical facilities, medical clinics, nursing facilities, and dental facilities. The Aura Storm can provide a 99.99% bacterial and virus elimination rate.
The Aura Storm has been third-party certified tested on three bacteria (Staphylococcus albicans, Staphylococcus aureus, and Escherichia Coli) and the A/PR8/34 H1N1 virus. Testing shows our ability to eliminate 99.99% in 60 minutes at the highest fan speed. Data on our low fan speed is included in the Miscellaneous files.

			Control Group			Test Group		
Test Strain	Test Time	Test Number	Original Bacteria Count V_0(cfu/m³)	Original Bacteria Count After Treatment V_t(cfu/m³)	Natural Decay Rate N_t	Original Bacteria Count V_1(cfu/m³)	Original Bacteria Count After Treatment V_2(cfu/m³)	Bacterial Elimination Rate K_t(%)
Staphylococcus albicans	60 min.	1	1.19×10^5	9.07×10^4	23.78	1.16×10^5	7	99.99%
		2	1.11×10^5	8.75×10^4	21.17	1.08×10^5	7	99.99%
		3	1.30×10^5	1.00×10^5	23.08	1.26×10^5	7	99.99%
							Mean	99.99%
Staphylococcus aureus	60 min.	1	1.05×10^5	8.54×10^4	18.67	1.02×10^5	7	99.99%
		2	1.22×10^5	9.76×10^4	20.00	1.18×10^5	7	99.99%
		3	1.09×10^5	8.82×10^4	19.08	1.12×10^5	7	99.99%
							Mean	99.99%
Escherichia Coli	60 min.	1	1.14×10^5	9.07×10^4	20.44	1.17×10^5	7	99.99%
		2	1.25×10^5	9.79×10^4	21.68	1.28×10^5	7	99.99%
		3	1.06×10^5	8.49×10^4	19.91	1.03×10^5	7	99.99%
							Mean	99.99%

			Control Group			Test Group		
Test Strain	Test Time	Test Number	Original Bacteria Count V_0(cfu/m³)	Original Bacteria Count After Treatment V_t(cfu/m³)	Natural Decay Rate N_t	Original Bacteria Count V_1(cfu/m³)	Original Bacteria Count After Treatment V_2(cfu/m³)	Bacterial Elimination Rate K_t(%)
A/PR8/34 (H1N1)	60 min.	1	3.42×10^6	5.06×10^5	85.20	5.06×10^5	/	≥ 99.99%
		2	3.42×10^6	5.55×10^5	83.77	5.06×10^5	/	≥ 99.99%
		3	1.6×10^6	3.42×10^5	78.63	1.60×10^5	/	≥ 99.99%
							Mean	99.99%

CHARACTERISTIC COMPARISON:

The following table summarizes the similarities and differences between the subject and predicate devices

	Invictus Aura Storm Air Purifier	Molekule Air Pro RX (K200500)	Molecule Air Mini (K202339)
510(k) Holder		**Molekule**	**Molekule**
Device Type	Medical Ultraviolet Air Purifier	Medical Ultraviolet Air Purifier	Medical Ultraviolet Air Purifier
Product Code	FRA	FRA	FRA
Classification Regulation	21 C.F.R. § 880.6500	21 C.F.R. § 880.6500	21 C.F.R. § 880.6500
Class	II	II	II
Rx/OTC	OTC	OTC	OTC
User	Healthcare Professional Lay User	Healthcare Professional Lay User	Healthcare Professional Lay User

	Invictus Aura Storm Air Purifier	Molekule Air Pro RX (K200500)	Molecule Air Mini (K202339)
Indications of Use	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 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.	The Molekule Air Pro RX air purifier is a device intended for medical purposes that is used to destroy bacteria and viruses in the air by exposure to ultraviolet radiation. The core technology components of the Molekule Air Pro RX air purifier have been demonstrated to destroy the following MS2 bacteriophage bioaerosol entrained on the filter of the subject device under the following exposure conditions: Average Maximum log reduction/exposure time (hours) Room temperature Virus, MS2 bacteriophage 5.21/24 hours	The Molekule Air Mini air purifier is a device intended for medical purposes that are used to capture 95% of particulate matter and destroy bacteria and viruses by exposure to ultraviolet radiation. 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 conditions: Average maximum log reduction / entrainment time (hours) at Fan Speed 5. Room temperature test for MS2 bacteriophage virus: 5.09 ± 0.42 120 mins Single Pass Mechanical Filtration Efficiency: 95% or greater according to ASHRAE 52.2
Environment of Use	Hospitals, medical facilities, medical clinics, nursing facilities, and dental facilities.	Hospital, including general, surgery, critical care, and radiology. Inpatient and general nursing facilities, diagnostic and radiology rooms.	Hospital and other healthcare setting. Home healthcare.

	Invictus Aura Storm Air Purifier	Molekule Air Pro RX (K200500)	Molecule Air Mini (K202339)
User Control	Touch panel with 4 manual fan settings, auto mode, UV Lamp on/off, Anion on/off, lock and timer.	One knob controls the four-speed fan setting One button turns the unit on and off.	Touch panel with 5 manual fan settings.
Software	Basic Firmware, used to turn the unit on, off, and change fan speed.	Basic Firmware, used to turn the unit on, off, and change fan speed.	Basic Firmware and App, used to turn the unit on, off, and change fan speed.
Mechanism of Action	UV light of sufficient energy (UV-C) activates a TiO_2 lined photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction, plus the addition of a pre-filter and HEPA filter.	UV light of sufficient energy (UV-A) activates photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction.	UV light of sufficient energy (UV-A) activates photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction.
Installation	Free Standing	Free Standing	Free Standing
Pre-Filter	• 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	• Synthetic Media for mechanical filtration upstream of the PECO filter. • Dimensions: 20 in x 20 in x 4 in • Pleats per inch: 1.5 • Total Filter surface area: 4800 in^2	Not Applicable
HEPA Filter	• MERV 13 • Dimensions: 14 in x 15 in x 0.6875 in	Not Applicable	Not Applicable

	Invictus Aura Storm Air Purifier	Molekule Air Pro RX (K200500)	Molecule Air Mini (K202339)
Catalytic Filter	• Patent Pending Hybrid Oxydizer with proprietary Dualaction Catalyst	• Proprietary multi-layer filter media • Dimensions: 20 in x 20 in x 4 in • Pleats per inch: 1.5 • Total Filter surface area: 4800 in2 • Filter coated with proprietary photocatalyst and a metal wire mesh • MERV16	• Proprietary multilayer filter media • Dimensions: 6.18 in (diameter), 6.55 in Height. • Pleats per inch: 3 pleats per inch of outer circumference • Total Filter surface area: 616 in2 • Filter coated with proprietary photocatalyst and a metal wire mesh • MERV16
Carbon/Cold Catalyst Oxidier Filter	• Dimensions: 14' x 15" x 0.625"	Not Applicable	Not Applicable
Photocatalyst	Proprietary Catalyst	Proprietary Catalyst	Proprietary Catalyst
Light Source	• UV-C Light Source: LED • Wavelength: 253.7nm • Total of 2 UV- C tube lamps (1 per side) • Total UV Power: 8.0 W	• UV Light Source: LED • Wavelength: 320-400 nm • Total of 12 UV LEDs split amongst 4 PCBs (3 LEDs per PCB) • Total UV Power: 6.8 W • Filter Irradiance (Minimum): 20 W/m2	• UV Light Source: LED • Wavelength: 320-400 nm • Total of 12 UV LEDs split amongst 4 PCBs (3 LEDs per PCB) • Total UV Power: 6.8 W • Filter Irradiance (Minimum): 20 W/m2
Air Source	Centrifugal Fan	Centrifugal Fan	Centrifugal Fan
Flow Control	4 speeds (low, medium, high, boost) and auto mode provide up to 370 CFM	Four speeds (low, medium, high, boost) provide 300-800 CFM flow.	5 speeds (low-high) Provide 9-86 CFM

	Invictus Aura Storm Air Purifier	Molekule Air Pro RX (K200500)	Molecule Air Mini (K202339)
Air Changes Per Hour (ACH)	5.5 ACH on high fan speed (speed 4), in a 4000 ft^3 room	6-9 ACH when used in room with volume of 4000 cubic feet (a typical Operating Room Volume) with flowrates of 450-650 CFM at settings 2 and 3.	2.43 device air changes per hour on setting 5, roughly 86 CFM, in a 250 ft^2 room
Particulate Sensor	Not applicable	Not Applicable	Not Applicable
UV Light Exposure Safety Features	There are two sets of Safety switches on the Aura Storm. the first is on both outer doors 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 either improperly installed or the filter is missing, the unit will not operate. The unit will not operate with a generic filter and an Invictus filter must be used for the system to work. These switches have been designed to protect the user from any possibility of exposure to direct contact with UV light. Safety feature confirmed by ETL to UL 507 safety standard.	Safety switches exist in the following locations: PECO filter door, pre filter door, PECO filter compartment, and pre filter compartment. Ifany door is open or if a filter is missing, the unit will not operate. The purpose of these switches is to protect the user from any possibility of exposure to direct contact with UV light. Safety feature confirmed by UL 507.	If a validated, serialized, Molekule filter is missing, the unit will not operate. The unit authenticates the filter via NFC, before and during operation. The purpose of this system is to protect the user from any possibility of exposure to direct contact with UV light that would occur without a genuine Molekule Filter being present.

	Invictus Aura Storm Air Purifier	Molekule Air Pro RX (K200500)	Molecule Air Mini (K202339)
Fan Exposure Safety Features	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.	Grill at outlet and inlet of fan with small enough grating to block user from accessing spinning fan without tools. Safety feature confirmed by UL 507.	Vanes at outlet and Honeycomb inlet of fan with small enough grating to block user from accessing spinning fan without tools. Safety feature confirmed by UL 507.
Input Voltage	120 V	120 V	120 V
Current	0.55 Amps	0.55 Amps	3.72 Amps
Power Consumption	Up to 65 W	Up to 450 W	Up to 55 W
Electronic Data Interface	Not Applicable	Not Applicable	NFC WLAN (2.4 GHZ)
Dimensions	Outer frame dimensions: 23 in (H) x 18.2 in (W) x 10.6 in (L) 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 Fitler: 14 in x 15 in x 0.1875 in Carbon/Cold Catalyst Oxidizer Filter: 14 in x 15in x 0.625 in	Outer frame dimensions: 22 in x 22 in x 52 in Filter dimensions: Filter: 20 in x 20 in x 4 in Pre-Filter: 20 in x 20 in x 4 in or 20 in x 20 in x 2 in	Unit Dimensions: Height: 12.04 in Diameter: 8.27 in Filter Dimensions: Diameter: 6.03 in Height: 6.45 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.	FCC Part 15 C Radio Frequency Devices UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices.

SUMMARY OF NON-CLINICAL TESTS:

The Aura Storm air purifier complies with voluntary standards for electrical safety and electromagnetic compatibility. The following were provided in to demonstrate the subject device met the acceptance criteria or the testing specification :

- Biocompatibility Risk Analysis – No relevant concern

Title of the Test	Purpose of the Test	Acceptance Criteria and the Source of References	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	To understand the log reduction rate for Staphylococcus albicans, Staphylococcus aureus, and Escherichia Coli	4 Log reduction of the tested bacteria 3rd party testing at an accredited laboratory	4-LOG reduction in 60 minutes at highest fan speed 4-LOG reduction in 120 minutes at lowest fan speed
Virus Inactivation test	To understand the log reduction rate for the A/PR8/34 H1N1 virus	4 Log activation of the tested virus 3rd party testing at an accredited laboratory	4-LOG reduction in 60 minutes at highest fan speed 4-LOG reduction in 120 minutes at lowest fan speed
Filtration Efficiency Testing	To understand the filtration efficiency of the HEPA filter	ISO 29463 H13 ISO 35H ≥ 99.975% filtration for particles ≥ 0.3 microns 3rd party testing at an accredited laboratory	99.98% filtration efficiency for particles greater than or equal to 0.3 microns
Shelf Life	Recommended replacement of filters and UV lamps	Manufacturer's information	Filters should be replaced every 6 months if being run continuously UV Lamps should be replaced every 12 months if being run continuously

SUMMARY OF CLINICAL TESTS:

No clinical tests were required to demonstrate substantial equivalence.

CONCLUSION:

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