August 20, 2021

Molekule, Inc.
% Adrienne Lenz
Senior Medical Device Regulation
Hymann, Phelps, & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, District of Columbia 20005

Re: K211194
Trade/Device Name: Molekule Air Pro
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: July 16, 2021
Received: July 19, 2021

Dear Adrienne Lenz:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211194

Device Name
Molekule Air Pro

Indications for Use *(Describe)*
The Molekule Air Pro air purifier is a device intended for medical purposes that is used to capture 95% of particulate matter and destroy bacteria, mold, and viruses by exposure to ultraviolet radiation when operated in Auto Mode Standard or manual mode at fan speed 2 or higher.

The Molekule Air Pro air purifier has been demonstrated to entrain and destroy the following bioaerosols under the following exposure/working conditions:

Test Item		**Average Net Log Reduction / Time @ Fan Speed 6. Room Temperature Test**
Bacteria	Escherichia Coli	4.20 ± 0.11 / 90 minutes
Bacteria Endospores	Bacillus Subtilis	4.02 ± 0.23 / 30 minutes
Mold Spores	Aspergillus Brasiliensis	4.15 ± 0.06 / 60 minutes
Virus	MS2 bacteriophage	4.38 ± 0.15 / 30 minutes
Test Item		Single Pass Mechanical Filtration Efficiency
Particulate Matter	0.3 to 1.0 micron size particles	95% or greater according to ASHRAE 52.2

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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K211194 510(k) Summary

In accordance with 21 C.F.R. § 807.92 the following summary of information is provided:

DATE: July 16, 2021

SUBMITTER:

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San Francisco, CA 94103
T 855-999-9069

PRIMARY CONTACT PERSON:

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Hyman, Phelps, & McNamara, P.C.
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FDA Compliance
Molekule, Inc.
T 925-404-7724

DEVICE:

TRADE NAME: Molekule Air Pro
COMMON/USUAL NAME: Air Purifier
CLASSIFICATION NAMES: Purifier, Air, Ultraviolet, Medical
REVIEW PANEL: General Hospital
PRODUCT CODE: FRA

PREDICATE DEVICE(S):

Molekule Air Mini + Air Purifier, K202339

This predicate has not been subject to a design-related recall.

DEVICE DESCRIPTION:

The Molekule Air Pro air purifier is an ultraviolet air purifier that employs a photo electrochemical oxidation (PECO) ultraviolet air purification technology that destroys bacteria and viruses in air. The Molekule Air Pro may be used in medical facilities and in the home. A fan within the unit draws air up from vents in the bottom of the unit, up through the PECO filter (where it is exposed to low energy UV-A 320 – 400 nm light) and out through the vents on the top of the unit. PECO is an air purification technology that oxidizes microorganisms, including bacteria, molds and viruses. PECO works by shining UV-A light on the surface of the catalytic filter to initiate a chemical reaction that generates hydroxyl radicals. These radicals combine with microbiological contaminants that are captured on the filter. Once combined, a chemical reaction takes place destroying the contaminants.

The Molekule Air Pro is a freestanding device. It is a standalone device with an LCD display and a capacitive touchscreen user interface. Integrated WLAN provides a secondary means for controlling the device from the Molekule Android or iOS application.

Air Pro also includes a particulate matter sensor, particulate matter indicator, and Auto Protect Mode, which controls fan speed based on particulate levels detected in the use environment.

INTENDED USE:

The Molekule Air Pro air purifier is a device intended for medical purposes that is used to capture 95% of particulate matter and destroy bacteria, mold, and viruses by exposure to ultraviolet radiation when operated in Auto Mode Standard or manual mode at fan speed 2 or higher.

The Molekule Air Pro air purifier has been demonstrated to entrain and destroy the following bioaerosols under the following exposure/working conditions:

Test Item		**Average Net Log Reduction / Time @ Fan Speed 6. Room Temperature Test**
Bacteria	Escherichia Coli	4.20 ± 0.11 / 90 minutes
Bacteria Endospores	Bacillus Subtilis	4.02 ± 0.23 / 30 minutes

Test Item		**Average Net Log Reduction / Time @ Fan Speed 6. Room Temperature Test**
Mold Spores	Aspergillus Brasiliensis	4.15 ± 0.06 / 60 minutes
Virus	MS2 bacteriophage	4.38 ± 0.15 / 30 minutes
Test Item		Single Pass Mechanical Filtration Efficiency
Particulate Matter	0.3 to 1.0 micron size particles	95% or greater according to ASHRAE 52.2

TECHNOLOGICAL CHARACTERISTIC COMPARISON:

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

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
510(k) Holder	Molekule	Molekule	Identical
Device Type	Medical Ultraviolet Air purifier	Medical Ultraviolet Air purifier	Identical
Product Code	FRA	FRA	Identical
Classification Regulation	21 C.F.R. § 880.6500	21 C.F.R. § 880.6500	Identical
Class	II	II	Identical
Patient Population	Not specified	Not specified	Identical
Rx/OTC	OTC	OTC	Identical
User	Healthcare Professional Lay User	Healthcare Professional Lay User	Identical

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
Indications for Use	The Molekule Air Pro air purifier is a device intended for medical purposes that is used to capture 95% of particulate matter and destroy bacteria, mold, and viruses by exposure to ultraviolet radiation when operated in Auto Mode Standard or manual mode at fan speed 2 or higher. The Molekule Air Pro air purifier has been demonstrated to entrain and destroy the following bioaerosols under the following exposure/working conditions: Average Net Log Reduction / Time @ Fan Speed 6. Room Temperature Test Escherichia Coli 4.20 +/- 0.11 / 90 mins Bacillus Subtilis 4.02 +/- 0.23 / 30 mins Aspergillus Brasiliensis 4.15 ± 0.06 / 60 mins MS2 Bacteriophage 4.38 ± 0.15 / 30 mins Single Pass Mechanical Filtration Efficiency Particulate Matter 0.3 to 1.0 micron size particles 95% or greater according to ASHRAE 52.2	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 when operated in manual mode at fan speed 3 or higher. 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: Average Maximum Log Reduction / Entrainment Time @ Fan Speed 5. Room Temperature Test MS2 Bacteriophage 4.38 ± 0.15 / 30 mins Single Pass Mechanical Filtration Efficiency Particulate Matter 0.3 to 1.0 micron size particles 95% or greater according to ASHRAE 52.2	Based on additional testing, the indications for use for the Air Pro were updated to include molds, with specific results added for bacteria and mold. Air Pro also has additional testing to support a greater than 4-log reduction of MS2 bacteriophage at fan speed 2, which is also the lowest possible fan speed in Auto Mode Standard. The indications were also revised to clarify that the reductions presented in the table are average net log reductions from the combination of both entrainment and destruction. These differences in indications do not change the intended use of the device. Both devices are used to destroy microorganisms in the air by the same mechanism.
Environment of Use	Hospital and other healthcare setting. Home healthcare.	Hospital and other healthcare setting. Home healthcare.	Identical

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
Placement	Air Pro will work in any room, but giving it space in a central location, is recommended. Placement near the patient is key. It should not be used in surgical suites or in rooms with air separation devices. It is designed for rooms under 1000 ft^2.	Air Mini + will work in any room, but giving it space in a central location, and on a shelf, stand, or table will help maximize air intake. Placement near the patient is key. It should not be used in surgical suites or in rooms with air separation devices. It is designed for rooms under 250 ft^2. We recommend running it in the room, closer to the bed.	The proposed device is designed for larger rooms. They are not placed on shelfs or tables due to the different form factor. These differences do not raise different questions of safety or effectiveness. Both devices meet applicable standards for electrical safety, including home levels, and have been demonstrated to effectively remove and destroy pathogens in the air.
User Control	LCD screen with capacitive touchscreen interface. User Interface includes several dedicated screens for fan speed control, PM sensor readings in addition to other administrative functions. Application controls mimic device touch panel	Touch panel with 5 manual fan settings and one auto protect setting, Application controls mimic device touch panel	The controls on the Air Pro and Air Mini+ are simple and similar to user controls on many other devices that healthcare professionals are accustomed to using. The app has the same functions as the firmware and does not raise different questions of safety or effectiveness as demonstrated by software verification and validation.

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
Software	Basic Firmware and App, 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.	Identical
Mechanism of Action	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.	Identical
Installation	Free standing	Free standing	Identical
Catalytic Filter	• Proprietary multi-layer filter media • Dimensions: 8.1 in (diameter), 11.7 in Height. • Pleats per inch: 2.6 pleats per inch of outer circumference • Total Filter surface area: 1779 in^2 • Filter coated with proprietary photocatalyst and a metal wire mesh • MERV16	• Proprietary multi-layer 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 in^2 • Filter coated with proprietary photocatalyst and a metal wire mesh • MERV16	Filters of both devices are identical in material, coated with the same photocatalyst, and feature identical layers. There are differences in the dimensions related to the sizing requirements for each device. These differences do not raise differences in safety or effectiveness.
Photocatalyst	Proprietary catalyst (same as predicate)	Proprietary catalyst	Identical

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
Light Source	• UV Light Source: LED • Wavelength: 320-400 nm • Total of 20 UV LEDs split amongst 5 PCBs (4 LEDs per PCB) • Total UV Power: 16 W • Filter Irradiance (Minimum): 20 W/m^2	• UV Light Source: LED • Wavelength: 320-400 nm • Total of 12 UV LEDs split amongst 4 PCBs (3 LEDs per PCB) • Total UV Power: 6.8W • Filter Irradiance (Minimum): 20 W/m^2	The UV LEDs in the Molekule Air Mini+ and Molekule Air Pro are identical. Air Pro feature significantly larger filter areas and thus, more LEDs are used and more UV power is needed to achieve the minimum irradiance on the filter.
Air Source	Centrifugal Fan	Centrifugal Fan	Identical
Flow Control	6 speeds (low-high) Provide 25-260 CFM	5 speeds (low-high) Provide 9-86 CFM	All devices achieve the same effect. See discussion of air changes per hour in the next row for additional discussion.
Device Air Changes Per Hour (ACH)	1.83 device air changes per hour on setting 6, roughly 260 CFM, in a 1000 ft^2 room	2.43 device air changes per hour on setting 5, roughly 86 CFM, in a 250 ft^2 room	Air Pro is designed for larger rooms. The effective cleaning rate can be roughly compared by normalizing the device air change for each product. This allows for a quantification of purified air relative to ventilation rate. We see uniformity amongst the products.

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
Particulate Sensor	Optical Particle Matter Sensor	Optical Particle Sensor	Air Pro and Air Mini+ both have a built-in particulate matter sensor that can be used to evaluate the environment the device is in and provide an air quality level that the device can use to ramp up or down fan speed as appropriate. They use different sensors, with Air Pro featuring a sensor capable of binning particles in different sizes, providing additional information. This difference does not raise different quesitons of safety or effectiveness. All devices meet standards for electric fans/EMC and have demonstrated appropriate performance in testing.

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
UV Light Exposure Safety Features	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-A light that would occur without a genuine Molekule Filter being present.	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-A light that would occur without a genuine Molekule Filter being present.	Identical
Fan Exposure Safety Features	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.	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.	Identical
Input Voltage	120 Volt	120 Volt	Identical

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
Current	Up to 1.27 Amps	Up to 0.55 Amps	Increase in current is due to the larger power consumption, given that both units operate off 120V AC. See power consumption row below for more details.
Power Consumption	Up to 152.8 Watts	Up to 55 Watts	Difference in power consumption of the system is largely due to the fan and LEDS. Air Pro utilizes a larger fan and more LEDs than Air Mini+ and thus will consume more power. This difference does not impact safety or effectiveness as both devices comply with applicable safety standards.
Electronic Data Interface	NFC WLAN (2.4 GHZ)	NFC WLAN (2.4 GHZ)	Identical

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
Dimensions	Unit Dimensions: Height: 23.11 in (587 mm) Diameter: 10.83 in (275 mm) Filter Dimensions: Diameter: 8.1 in (206 mm) Height: 11.7 in (296 mm)	Unit Dimensions: Height: 12.04 in (306 mm) Diameter: 8.27 in (210 mm) Filter Dimensions: Diameter: 6.03 in (153 mm) Height: 6.45 in (164 mm)	The Molekule Air Pro has a larger housing to accomodate the larger fan and filter. This is due to the difference in target Air Flow by the device.

	Molekule Air Pro air purifier	Molekule Air Mini+ air purifier (K202339)	Discussion of Differences
Standards	FCC Part 15 C Radio Frequency Devices UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices ASHRAE 52.2-2012 Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size AMCA 210-1999 Laboratory Methods Of Testing Fans For Rating ANSI/AHAM AC-1-2019 Method for Measuring Performance of Portable Household Electric Room Air Cleaners	FCC Part 15 C Radio Frequency Devices UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices ASHRAE 52.2-2012 Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size AMCA 210-1999 Laboratory Methods Of Testing Fans For Rating ANSI/AHAM AC-1-2019 Method for Measuring Performance of Portable Household Electric Room Air Cleaners	Identical

SUMMARY OF NON-CLINICAL TESTS:

The Molekule Air Pro complies with voluntary standards for electrical safety and electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

- Risk Analysis
- Software verification and validation testing and software information recommended by FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
- Electrical safety and electromagnetic compatibility testing per UL 507:2017 Electric Fans and IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests, respectively

- Performance Testing:

Test Methodology	**Purpose**	**Acceptance Criteria**	**Results**
MS2 bacteriophage, Aspergillus Brasiliensis Mold Spores, Bacillus Subtilis Endospores, and Escherichia Coli Bacteria were aerosolized into a sealed environmental bioaerosol chamber containing Molekule® Air Pro device.	To evaluate the efficacy of the Molekule® Air Pro air purification device at reducing aerosolized MS2 bacteriophage, Aspergillus Brasiliensis Mold Spores, Bacillus Subtilis Endospores, and Escherichia Coli Bacteria by a combination of entrainment and destruction.	4 log reduction (99.99%)	Average net log reduction / time MS2 Bacteriophage, 4.38 ± 0.15 / 30 mins Aspergillus Brasiliensis, 4.15 +/- 0.06 / 60 mins Bacillus Subtilis, 4.02 +/- 0.23 / 30 mins Escherichia Coli, 4.20 +/- 0.11 / 90 mins
MS2 bacteriophage was aerosolized into a sealed environmental bioaerosol chamber containing Molekule® Air Pro device running at different fan speeds.	To demonstrate performance at different fan speeds using MS2 bacteriophage as a challenge pollutant.	4 log reduction (99.99%)	Average net log reduction / time Speed 2, 4.54 +/- 0.07 120 mins Speed 3, 4.58 +/- 0.23 60 mins Speed 6, 4.38 ± 0.15 30 mins
Fractional efficiency per ASHRAE 52.2-2012 Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size using three PECO filters. System flow with filter installed according to AMCA 210-1999 Fig.12.	To ensure Air Pro meets Filtration Efficiency Requirements (95% or greater on 0.3 to 1.0 micron size particles) and device flow requirements.	The filter shall achieve 95% or greater on 0.3 to 1.0 micron size particles according to ASHRAE 52.2.	Required filtration efficiency 95% or greater on 0.3 to 1.0 micron size particles was achieved.

SUMMARY OF CLINICAL TESTS:

No clinical tests were required to demonstrate substantial equivalence.

CONCLUSION:

Molekule, Inc. concludes that the nonclinical tests demonstrate that the Molekule Air Pro air purifier is as safe, as effective, and performs as well as or better than the legally marketed predicate device.