February 23, 2021

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

Re: K202339
Trade/Device Name: Molekule Air Mini, Molekule Air Mini +
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: August 14, 2020
Received: August 17, 2020

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,

for Clarence W. Murray, III, Ph.D.
Acting 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)*

K202339

Device Name

Molekule Air Mini

Indications for Use *(Describe)*

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.

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:

Test Item		Test Result
Virus	MS2 bacteriophage	**Average maximum log reduction / entrainment time (hours) at Fan Speed 5. Room temperature test.** 5.09 ± 0.42 / 120 mins
Particulate matter	0.3 to 1.0 micron size particles	**Single Pass Mechanical Filtration Efficiency** 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K202339

Device Name

Molekule Air Mini +

Indications for Use *(Describe)*

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:

Test Item		Test Result
Virus	MS2 bacteriophage	**Average maximum log reduction / entrainment time (hours) at Fan Speed 5. Room temperature test.** 5.09 ± 0.42 / 120 mins
Particulate matter	0.3 to 1.0 micron size particles	**Single Pass Mechanical Filtration Efficiency** 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)

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510(k) Summary

K202339

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

DATE: February 22, 2021

SUBMITTER:

Molekule, Inc.
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San Francisco, CA 94103
T 855-999-9069

PRIMARY CONTACT PERSON:

Adrienne R. Lenz
Senior Medical Device Regulation Expert
Hyman, Phelps, & McNamara, P.C.
T 202-737-4292

SECONDARY CONTACT PERSON:

Frank Bianco
FDA Compliance
Molekule, Inc.
T 925-404-7724

DEVICE:

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

PREDICATE DEVICE(S):

Molekule Air Pro RX Air Purifier, K200500

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

DEVICE DESCRIPTION:

The Molekule Air Mini and Air Mini + air purifiers are ultraviolet air purifiers that employ a photo electrochemical oxidation (PECO) ultraviolet air purification technology that destroys bacteria and viruses in air. The Molekule Air Mini and Air Mini + may be used in medical facilities and in the home. The Molekule Air Mini and Air Mini + air purifiers includes a low energy ultraviolet light (UV-A 320 – 400 nm) and a catalytic filter. They are standalone devices that can be controlled via a button on the device and may also be controlled using the Molekule Android or iOS application.

PECO is an air purification technology that oxidizes bacteria 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, such as bacteria and viruses, that are captured on the filter. Once combined, a chemical reaction takes place destroying the contaminants.

The Molekule Air Mini and Air Mini + are freestanding devices. 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 UV-A light), and out through the vents on the top of the unit.

The Molekule Air Mini and Air Mini + user interface includes a capacitive touch button and LED indicators on the top of the device. Power (on/off) and fan speed are controlled via the capacitive touch button. Integrated WLAN provides a secondary means for controlling the device from the Molekule Android or iOS application.

Air Mini + additionally 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:

Molekule Air Mini

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.

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:

Test Item		Test Result
Virus	MS2 bacteriophage	**Average maximum log reduction / entrainment time (hours) at Fan Speed 5. Room temperature test.** 5.09 ± 0.42 / 120 mins
Particulate matter	0.3 to 1.0 micron size particles	**Single Pass Mechanical Filtration Efficiency** 95% or greater according to ASHRAE 52.2

Molekule Air Mini +

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:

Test Item		Test Result
Virus	MS2 bacteriophage	**Average maximum log reduction / entrainment time (hours) at Fan Speed 5. Room temperature test.** 5.09 ± 0.42 / 120 mins
Particulate matter	0.3 to 1.0 micron size particles	**Single Pass Mechanical Filtration Efficiency** 95% or greater according to ASHRAE 52.2

CHARACTERISTIC COMPARISON:

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

	Molekule Air Mini air purifier (K202339)	**Molekule Air Mini + air purifier (K202339)**	**Predicate Device Molekule Air Pro RX air purifier (K200500)**
510(k) Holder	Molekule	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

	Molekule Air Mini air purifier (K202339)	Molekule Air Mini + air purifier (K202339)	Predicate Device Molekule Air Pro RX air purifier (K200500)
Indications for Use	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	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 in the air 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 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	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

	Molekule Air Mini air purifier (K202339)	**Molekule Air Mini + air purifier (K202339)**	**Predicate Device Molekule Air Pro RX air purifier (K200500)**
Environment of Use	Hospital and other healthcare setting. Home healthcare.	Hospital and other healthcare setting. Home healthcare.	Hospital, including general, surgery, critical care, and radiology. Inpatient and general nursing facilities, diagnostic and radiology rooms.
User Control	Touch panel with 5 manual fan settings. Application controls mimic device touch panel	Touch panel with 5 manual fan settings and one auto protect setting. Application controls mimic device touch panel	One knob controls the four-speed fan setting One button turns the unit on and off.
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.	Basic Firmware, used to turn the unit on, off, and change fan speed.
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.	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(s)	• Not applicable	• Not applicable	• 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

	Molekule Air Mini air purifier (K202339)	**Molekule Air Mini + air purifier (K202339)**	**Predicate Device Molekule Air Pro RX air purifier (K200500)**
Catalytic Filter	• 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	• 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	• Proprietary multi-layer filter media • Dimensions: 20 in x 20 in x 4 in • Pleats per inch: 1.5 • Total Filter surface area: 4800 in^2 • Filter coated with proprietary photocatalyst and a metal wire mesh • MERV16
Photocatalyst	Proprietary catalyst (same as predicate)	Proprietary catalyst (same as predicate)	Proprietary catalyst

	Molekule Air Mini air purifier (K202339)	**Molekule Air Mini + air purifier (K202339)**	**Predicate Device Molekule Air Pro RX air purifier (K200500)**
Light Source	• 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/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	• UV Light Source: LED • Wavelength: 320-400 nm • Power per Lamp/ String: 11.4 W • Number of Lamps/ String: 6 • Total UV Power: 68.4 W • Filter Irradiance (Minimum): 30 W/m^2
Air Source	Centrifugal Fan	Centrifugal Fan	Centrifugal Fan
Flow Control	5 speeds (low-high) Provide 9-86 CFM	5 speeds (low-high) Provide 9-86 CFM	Four speeds (low, medium, high, boost) provide 300-800 CFM flow.
Device Air Changes Per Hour (ACH)	2.43 device air changes per hour on setting 5, roughly 86 CFM, in a 250 ft^2 room	2.43 device air changes per hour on setting 5, roughly 86 CFM, in a 250 ft^2 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.
Particulate Sensor	Not applicable	Optical Particle Sensor	Not applicable

	Molekule Air Mini air purifier (K202339)	**Molekule Air Mini + air purifier (K202339)**	**Predicate Device Molekule Air Pro RX air purifier (K200500)**
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 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 light that would occur without a genuine Molekule Filter being present.	Safety switches exist in the following locations: PECO filter door, pre filter door, PECO filter compartment, and pre filter compartment. If any 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.
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.	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.
Input Voltage	120 Volt	120 Volt	120 Volt
Current	0.55 Amps	0.55 Amps	Up to 3.72 Amps
Power Consumption	Up to 55 Watts	Up to 55 Watts	Up to 450 Watts
Electronic Data Interface	NFC WLAN (2.4 GHZ)	NFC WLAN (2.4 GHZ)	Not applicable

	Molekule Air Mini air purifier (K202339)	**Molekule Air Mini + air purifier (K202339)**	**Predicate Device Molekule Air Pro RX air purifier (K200500)**
Dimensions	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)	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)	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
Standards	FCC Part 15 C Radio Frequency 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.	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices.

SUMMARY OF NON-CLINICAL TESTS:

The Molekule Air Mini and Air Mini + 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 was aerosolized into a sealed environmental bioaerosol chamber containing Molekule® Air Mini device. •	To evaluate the efficacy of the Molekule® Air Mini air purification device at reducing aerosolized MS2 bacteriophage by a combination of entrainment and destruction.	4 log reduction (99.99%)	4.18 ±0.56 net log reduction at 90 mins 5.09 ± 0.42 net log reduction at 120 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 Mini 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. considers the Molekule Air Mini and Air Mini + air purifiers to be substantially equivalent to the predicate device.