April 15, 2020

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: K200500
Trade/Device Name: Molekule Air Pro RX
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: February 27, 2020
Received: February 28, 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,

CAPT Elizabeth F. Claverie, MS
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)*

K200500

Device Name

Molekule Air Pro RX

Indications for Use *(Describe)*

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:

Organism	Name	Average Maximum log reduction /exposure time (hours)
		Room temperature test
Virus	MS2 bacteriophage	5.21 / 24 hours

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

MOLEKULE AIR PRO RX

510(k) Summary

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

DATE: April 15, 2020

SUBMITTER:

Molekule, Inc.
1301 Folsom St
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 Pro RX
COMMON/USUAL NAME: Air Purifier
CLASSIFICATION NAMES: Purifier, Air, Ultraviolet, Medical
REVIEW PANEL: General Hospital
PRODUCT CODE: FRA

PREDICATE DEVICE(S):

Transformair Indoor Air Purifier, K161468

Molekule Inc. is the current holder of the Transformair 510(k). This predicate has not been subject to a design-related recall. The ABRACAIR (K052732) is used as a reference device as, like the Molekule Air Pro RX, it is a freestanding device.

DEVICE DESCRIPTION:

The Molekule Air Pro RX air purifier employs a photo-electrochemical oxidation (PECO) ultraviolet air purification technology that destroys bacteria, viruses and mold in air in medical facilities. The Molekule Air Pro RX air purifier includes a pre-filter and low energy ultraviolet lights (UV-A 320-400 nm), and a catalytic filter.

INTENDED USE:

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:

Organism	**Name**	**Average Maximum log reduction /exposure time (hours)**
		Room temperature test
Virus	MS2 bacteriophage	5.21 / 24 hours

TECHNOLOGY:

The Molekule Air Pro RX air purifier employs a photo-electrochemical oxidation (PECO) ultraviolet air purification technology that destroys bacteria in air in medical facilities. It is designed using the technology platform from the Transformair Air Purifier. The Molekule Air Pro RX air purifier includes a pre-filter, low energy ultraviolet lights (UV-A 320-400 nm), and a catalytic filter.

PECO is an air purification technology that fully oxidizes bacteria, viruses, and mold. 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, viruses, and mold spores that are captured on the filter. Once combined, a chemical reaction takes place killing the contaminants.

Unlike the Transformair Air Purifier which is installed in a vent, the Molekule Air Pro RX air purifier is a freestanding device. The following table summarizes the similarities and differences between the subject and predicate devices.

<table>
<tr><th></th><th colspan="3">Transformair air purifier (K161468)</th><th>Molekule Air Pro RX air purifier (K200500)</th></tr>
<tr><td>Product Name</td><td colspan="3">Transformair Air purifier</td><td>Molekule Air Pro RX Air purifier</td></tr>
<tr><td>Device Type</td><td colspan="3">Medical Ultraviolet Air purifier</td><td>Medical Ultraviolet Air purifier</td></tr>
<tr><td>Product Code</td><td colspan="3">FRA</td><td>FRA</td></tr>
<tr><td>Classification Regulation</td><td colspan="3">21 C.F.R. § 880.6500</td><td>21 C.F.R. § 880.6500</td></tr>
<tr><td>Class</td><td colspan="3">II</td><td>II</td></tr>
<tr><td>Patient Population</td><td colspan="3">General Hospital</td><td>General Hospital</td></tr>
<tr><td>User</td><td colspan="3">Healthcare Professional</td><td>Healthcare Professional</td></tr>
<tr><td rowspan="9">Indications for Use</td><td colspan="3">The Transformair Indoor Air Purifier, In Duct Model 16108 is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation.

Transformair Indoor Air Purifier, In Duct Model 16108 has been demonstrated to destroy Staphylococcus epidermidis, Escherichia coli, MS2, Phi-X174, Aspergillus Niger and Bacillus globigii entrained on the filter of the subject device under the following exposure conditions:</td><td rowspan="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:</td></tr>
<tr><td colspan="3">Average Maximum log reduction /exposure time (hours)</td></tr>
<tr><td colspan="3">Test temperature</td><td>Room temperature</td></tr>
<tr><td>45 ºF</td><td>72 ºF</td><td>110 ºF</td><td></td></tr>
<tr><td colspan="3">Virus, MS2 bacteriophage</td><td>Virus, MS2 bacteriophage</td></tr>
<tr><td>4.13 / 24 hours</td><td>4.25 / 24 hours</td><td>5.51 / 24 hours</td><td>5.21 / 24 hours</td></tr>
<tr><td colspan="3">Bacteria, Staphylococcus epidermidis</td><td></td></tr>
<tr><td>4.88 / 24 hours</td><td>4.02 / 0.33 hours</td><td>4.20 / 0.33 hours</td><td></td></tr>
</table>

	Transformair air purifier (K161468)			Molekule Air Pro RX air purifier (K200500)
	Bacteria, Escherichia coli			
	4.31 / 24 hours	4.79 / 24 hours	4.40 / 0.33 hours	
	Virus, Phi-X174 bacteriophage			
	4.37 / 24 hours	4.37 / 24 hours	4.37 / 24 hours	
	Mold endospore, Aspergillus Niger			
	3.91 / 72 hours	3.99 / 72 hours	4.22 / 72 hours	
	Bacterial endospore, Bacillus globigii			
	4.11 / 72 hours	4.41 / 72 hours	4.41 / 72 hours	
Environment of Use	Hospital and general surgery setting			Hospital and general surgery setting
User Control	HVAC fan speed controls the air flow			One knob controls the four-speed fan setting One button turns the unit on and off.
Software	None. The device is on whenever power is connected.			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.
Installation	In-duct			Free standing
Pre-Filter(s)	• Synthetic Media for mechanical filtration upstream of the PECO filter. • Dimensions 21.25 in. x 26 in. x 2 in. • Pleats per inch 1.25 • Total Filter surface area 2800 sq. 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 sq. in.

	Transformair air purifier (K161468)	Molekule Air Pro RX air purifier (K200500)
Catalytic Filter	• Proprietary filter media • Dimensions 21.25 in. x 26 in. x 2 in. • Pleats per inch 1.25 • Total Filter surface area 2800 sq. in. • Filter coated with proprietary photocatalyst and a wire-mesh	• Proprietary filter media • Dimensions 20 in. x 20 in. x 4 in. • Pleats per inch 1.5 • Total Filter surface area 4800 sq. in. • Filter coated with the proprietary photocatalyst and a wire-mesh
Photocatalyst	Proprietary catalyst	Same proprietary catalyst
Light Source	• UV Light Source, black light fluorescent bulbs • Wavelength, 320-400nm (See Figure 13.3) • Power per Lamp/ String, 17W • Number of Lamps/ String, 6 • Total UV Power, 102W • Filter Irradiance (Minimum), 25W/m^2	• UV Light Source, LED • Wavelength, 320-400nm • Power per Lamp/ String, 11.4W • Number of Lamps/ String, 6 • Total UV Power, 68.4W • Filter Irradiance (Minimum), 30W/m^2
Air Source	HVAC fan	Centrifugal Fan
Flow Control	Building HVAC system	Four speeds (low, medium, high, boost) provide 300 - 800 CFM flow.
Air Changes Per Hour	Standard building HVAC of 2-3 ACH (air changes per hour) when used in building volume of 45600 cubic feet with flowrates of 1300-1950 CFM.	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.

	Transformair air purifier (K161468)	Molekule Air Pro RX air purifier (K200500)
UV Light Exposure Safety Features	Installed in duct away from user, none required.	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 UL507.
Fan Exposure Safety Features	Installed in duct without fan, none required.	Grill at outlet and inlet of fan with small enough grating to block user from accessing spinning fan without tools. Safety feature confirmed by UL507.
Voltage	120 Volt (plugs into standard outlet: no switch, always on)	120 Volt (plugs into standard single phase 120 Volt outlet)
Current	Up to 1.25 amps	Up to 3.72 amps
Power Consumption	Up to 240 Watts	Up to 450 Watts
Dimensions	Outer frame dimensions: 28.5” x 21” x 12.25” Filter dimensions : Filter: 7-20” x 7-26” x 5” Pre-Filter: 7-20” x 7-26” x 2”	Outer frame dimensions: 22” x 22” x 52” Filter dimensions: Filter: 20” x 20” x 4” Pre-Filter: 20” x 20” x 4" or 20" x 20" x 2"

	Transformair air purifier (K161468)	Molekule Air Pro RX air purifier (K200500)
Standards	ANSI/UL 1995-2011 & CAN-CSA C22.2 No. 236-11, Heating and Cooling Equipment and UL 2043, Heat and Visible Smoke Release For Discrete Products and Their Accessories Installed in Air-Handling Spaces.	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices.

SUMMARY OF NON-CLINICAL TESTS:

The Molekule Air Pro RX air purifier complies with voluntary standards for electrical safety and electromagnetic compatibility. The following 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 tests for UV light leakage and light intensity
- Fluid modeling to confirm the system does not impact laminar flow systems
- Testing to demonstrate filtration performance and destruction of bacteria
- Third party testing was performed to characterize the kill rate kinetics for MS2 bacteriophage deposited onto the surface of Air Pro RX's proprietary photocatalytic coated filter media after exposure to Air Pro RX's UV-A light. The Air Pro RX Catalytic media effectively kills viable MS2 bacteriophage at room temperature. After one hour of UV exposure, an average of 3.41 LOG reduction was observed. After 24 hours of exposure, a 5.21 LOG reduction was observed.

SUMMARY OF CLINICAL TESTS:

Not applicable.

CONCLUSION:

Based on the intended uses, technological characteristics and non-clinical performance data, the Molekule Air Pro RX is as safe, as effective, and performs at least as well as the predicate,Transformair air purifier, cleared under K161468.