June 1, 2022

AeroClean Technologies, LLC
% Rita King
CEO
MethodSense, Inc.
One Copley Pkwy, Ste. 410
Morrisville, North Carolina 27560

Re: K213753
Trade/Device Name: Purgo
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: April 29, 2022
Received: May 2, 2022

Dear Rita King:

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)*
K213753

Device Name
Pūrgo

Indications for Use *(Describe)*
Pūrgo is a combination UV and air filtration device, equipped with UV-C LEDs and a True HEPA filter intended for the reduction of bacteria, virus, fungal spores, and particles in air for use in medical facilities and other indoor spaces. Pūrgo is non-sterile.

Pūrgo has been demonstrated to remove the following organisms under the following exposure conditions:

Organism	**Name**	**Avg. max log reduction / exposure time (min)**
Gram + Bacteria	Methicillin resistant Staphylococcus epidermidis	*4.6 (45) at normal speed*
Gram + Bacteria	Bacillus globigii endospore	*4.1 (60) at normal speed*
Gram - Bacteria	Escherichia coli	*5.4 (45) at normal speed*
RNA Virus	MS2 bacteriophage	*5.4 (60) at normal speed*
DNA Virus	Phi-X174 bacteriophage	*4.4 (45) at normal speed*
Fungal Spore	Aspergillus brasiliensis spore	*4.3 (90) at normal speed*

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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K213753 510(k) Summary

AeroClean Technologies, LLC.

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: AeroClean Technologies, LLC.
10455 Riverside Drive, Suite 100
Palm Beach Gardens, FL 33410

Primary Contact: Rita King, CEO
MethodSense, Inc.
Email: ritaking@methodsense.com
Phone: (919) 313-3961
Fax: (919) 313-3979

Company Contact: Richard Foster
Title: Senior Director, Quality and Regulatory Affairs
Email: rfoster@aeroclean.com
Phone: (773) 791-6198

Date Prepared: June 1, 2022

Trade Name: Pūrgo™

Common Name: Purifier, Air, Ultraviolet, Medical

Classification: Class II

Regulation Number: 21 CFR 880.6500

Classification Panel: General Hospital

Product Code: FRA

Predicate Device(s):

	Primary Predicate	Secondary Predicate
Trade Name	Molekule Air Pro	Molekule Air Pro RX
510(k) Submitter / Holder	Molekule, Inc.	Molekule, Inc.
510(k) Number	K211194	K200500
Regulation Number	21 CFR 880.6500	21 CFR 880.6500
Classification	Class II	Class II
Classification Panel	General Hospital	General Hospital
Product Code	FRA	FRA

The primary predicate device and secondary predicate device have not been subject to a design-related recall.

Device Description

Pūrgo is a free-standing air disinfection system employing two technologies for purifying air: HEPA filtration and UV-C light irradiation, removing or destroying bacteria and viruses in air. Pūrgo may be used in medical facilities and commercial home healthcare environments. Pūrgo's main components consist of

- LED UV-C lamps that generate irradiation to destroy microorganisms that are not filtered;
- a proprietary SteriDuct chamber that intensifies the UV-C light to destroy microbiological material;
- a filtration system with pre-filter, activated carbon filter, and HEPA filter;
- a motor/impeller to move air through the filtration system;
- sensors to monitor UV irradiance and airflow;
- an electronic control system to power and control the device; and
- a touch panel interface equipped with LEDs to indicate the working status of the device.

Pūrgo has several built-in safety features that will prevent operation of the unit if the filter cartridge is not in place or if the filter door is not closed. The unit also incorporates UV and airflow sensors that provide warnings to the user if the device is not performing as designed to purify air.

Pūrgo pulls air through a filter cartridge and then passes the filtered air through a chamber containing UV-C light to neutralize remaining airborne microorganisms (such as bacteria, viruses, and fungi). The filter cartridge contains a series of three filters, the first of which is a pre-filter that removes physically large particulate matter (such as dust) and protects the finer particle filters downstream. This is followed by an Activated Carbon filter. Finally, a HEPA (high-efficiency particulate air) filter that removes 99.995% of the remaining airborne particles above a particle size of 0.1 µm.

Any microbes that still manage to make it through the filters, pass through the SteriDuct chamber where they are subjected to Ultraviolet Radiation at 265 nm (UV-C). UV radiation at this wavelength is particularly effective at destroying microbes. UV-C irradiation has been shown to damage the microbe's RNA and DNA genetic materials sufficiently to prevent the microbe's ability to reproduce.

After passing through the filtration and SteriDuct UV-C chamber, the purified air then exits back into the room. The exit air does not destroy laminar air flow in a typical operating room environment.

Indications for Use

Pūrgo is a combination UV and air filtration device, equipped with UV-C LEDs and a True HEPA filter intended for the reduction of bacteria, virus, fungal spores, and particles in air for use in medical facilities and other indoor spaces. Pūrgo is non-sterile.

Pūrgo has been demonstrated to remove the following organisms under the following exposure conditions:

Organism	Name	Avg. max log reduction / exposure time (min)
Gram + Bacteria	Methicillin resistant Staphylococcus epidermidis	*4.6 (45) at normal speed*
Gram + Bacteria	Bacillus globigii endospore	*4.1 (60) at normal speed*
Gram - Bacteria	Escherichia coli	*5.4 (45) at normal speed*
RNA Virus	MS2 bacteriophage	*5.4 (60) at normal speed*
DNA Virus	Phi-X174 bacteriophage	*4.4 (45) at normal speed*
Fungal Spore	Aspergillus brasiliensis spore	*4.3 (90) at normal speed*

Summary of Technological Characteristics compared to Predicate Device

Item	**Pūrgo (K213753)** *Subject Device*	**Molekule Air Pro (K211194)** *Primary Predicate*	**Molekule Air Pro RX (K200500)** *Secondary Predicate*	**Comparison**
Intended Use	To remove and destroy, by exposure to UV radiation, bacteria and viruses in interior spaces.	To remove and destroy, by exposure to UV radiation, bacteria and viruses in interior spaces.	To remove and destroy, by exposure to UV radiation, bacteria and viruses in interior spaces.	**Identical**
Indications for Use	Pūrgo is a combination UV and air filtration device, equipped with UV-C LEDs and a True HEPA filter intended for the reduction of bacteria, virus, fungal spores, and particles in air for use in medical facilities and other indoor spaces. Pūrgo is non-sterile. Pūrgo has been demonstrated to remove the following organisms under the following exposure conditions: Avg. max log reduction / exposure time (min): Methicillin resistant Staphylococcus epidermidis 4.6 (45) at normal speed Bacillus globigii endospore 4.1 (60) at normal speed Escherichia coli 5.4 (45) at normal speed MS2 bacteriophage	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	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	**Similar** The indications for use of the devices are equivalent. The devices have different performance metrics for the chosen microorganisms.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
	5.4 (60) at normal speed Phi-X174 bacteriophage 4.4 (45) at normal speed Aspergillus brasiliensis spore 4.3 (90) at normal speed	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		
User	Healthcare Professional Lay User	Healthcare Professional Lay User	Healthcare Professional	**Identical**
Environment of Use	Hospital and other healthcare setting. General Surgery Setting. Home healthcare.	Hospital and other healthcare setting. Home healthcare.	Hospital and general surgery setting	**Similar** The Environment of Use of the Pūrgo is identical to that of the primary predicate as both can be used in a hospital and other healthcare setting and the home healthcare environments. The Environment of Use of the Pūrgo is identical to that of the secondary predicate device as both can be used in the hospital and general surgery setting.

Item	**Pūrgo (K213753)** *Subject Device*	**Molekule Air Pro (K211194)** *Primary Predicate*	**Molekule Air Pro RX (K200500)** *Secondary Predicate*	**Comparison**
Placement	Pūrgo will work in any room, but giving it a space in a central location is recommended. Placement near the patient is key. Pūrgo may be used in surgical suites. Pūrgo is designed for rooms up to 3000 ft^3.	Air pro will work in any room, but giving it a 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.	*Specific information on placement not available* *Device can be used in surgical suites.*	**Similar** The Placement of Pūrgo is equivalent to that of the primary predicate in a central location and that of the secondary predicate device in a surgical suite.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
User Control	Touch panel with selections for 3 fan speeds, power button, timer, and UV and airflow indicators.	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.	One knob controls the four speed fan setting One button turns the unit on and off.	**Similar** The User Controls of the devices are equivalent, as all provide a user interface allowing the user control of major functions of the device. The devices differ as the primary predicate uses an LCD screen with an associated software application and the secondary predicate device uses a knob and button while Pūrgo has a static interface on a touch panel. This difference does not affect the intended use or safety and effectiveness of the device.
Software	Basic Firmware; used to turn the unit on, off, change fan speed, and other administrative functions (timer, UV and airflow status).	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.	**Similar** All devices utilize firmware which provides equivalent functionality. The primary predicate has an additional software application in addition to its device firmware. This difference does not affect the intended use or safety and effectiveness of the device.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
Mechanism of Action	Air is pulled through a multi-layer filter (pre-filter, activated carbon, HEPA) to remove microorganisms and then into a UV chamber (SteriDuct) containing UV-C light with sufficient energy to kill any remaining microorganisms.	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.	**Similar** The mechanisms of action of the devices are similar as all devices utilize filtration and UV irradiation to remove microorganisms from air. The devices differ as the Pūrgo device first filters the air and then separately applies UV-C light to any microorganisms which are able to pass through the filter while the predicates use technology which first captures microorganisms on a catalytic filter and applies UV-A light to the filter to destroy microorganisms via a photochemical reaction. This difference does not affect the intended use of the device and safety and effectiveness has been confirmed via performance testing.
Installation	Free standing	Free standing	Free standing	**Identical**

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison

Filter	Pūrgo Filter:
	• Multi-layer filter with 1/8" thick pre-filter, 1/8" thick activated carbon filter, and HEPA filter media
	• Dimensions: 16.5" x 19.5" x 2.5"
	• HEPA filter:
	  ○ Number of pleats: 140
	  ○ Depth of pleats: 42mm
	  ○ Minimum filter media area: 61 sq ft
		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
			Pre-Filter:
			• 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.
			
			Catalytic Filter:
			• 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
				Similar
				All devices utilize multi-layer filter(s). The devices differ as the Pūrgo filter utilizes HEPA and activated carbon filtration while the primary and secondary predicate devices utilize a proprietary multi-layer catalytic PECO filter. This difference does not affect the intended use of the device and safety and effectiveness has been confirmed via performance testing.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
Photocatalyst	None	Proprietary catalyst	Proprietary catalyst	**Different** Pūrgo does not use a photocatalyst as its mechanism of action is achieved via filtration and UV-C irradiation, unlike the predicate devices which rely on a photo-catalytic reaction for microorganism destruction. This difference does not affect the intended use of the device and safety and effectiveness has been confirmed via performance testing.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
Light Source	• UV Type: UV-C • UV Light Source: LED • Wavelength: 265 nm • Total of 4 UV LEDs • Total UV Power: 110 mW • SteriDuct Irradiance (Minimum): 0.24 mW/cm^2	• UV Type: UV-A • UV Light Source: LED • Wavelength: 320-400 nm • Total of 20 UV LEDs • Total UV Power: 16 W • Filter Irradiance (Minimum): 20 W/m^2	• UV Type: UV-A • UV Light Source: LED • Wavelength: 320-400 nm • Power per Lamp / String: 11.4W • Number of Lamps / String: 6 • Total UV Power: 68.4W • Filter Irradiance (Minimum): 30 W/m^2	**Similar** All devices utilize a UV light source for the purpose of destroying microorganisms. The Pūrgo differs from the predicates as the Pūrgo device uses UV-C light at 265 nm in order to destroy microorganisms while the primary and secondary predicate devices use UV-A light at 320 to 400 nm to destroy microorganisms. This difference does not affect the intended use of the device and safety and effectiveness has been confirmed via performance testing.
Air Source	Centrifugal Fan	Centrifugal Fan	Centrifugal Fan	**Identical**

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
Flow Control	Three speeds (sleep, normal, boost) provide minimum 125-315 CFM flow.	6 speeds (low-high) Provide 25-260 CFM	Four speeds (low, medium, high, boost) provide 300 - 800 CFM flow.	**Similar** All devices allow for the user to control flow by providing an adjustable speed setting. The Pūrgo airflow range reaches a max of 315 CFM compared to the primary predicate's max of 260 CFM. This difference does not affect the intended use of the device and safety and effectiveness has been confirmed via performance testing.
Device Air Changes Per Hour (ACH)	1.875 – 2.36 device air changes per hour on Boost, 250 – 315 CFM, in a 1000 ft^2 room.	1.83 device air changes per hour on setting 6, roughly 260 CFM, in a 1000 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.	**Similar** Both Pūrgo and the primary predicate achieve around 1.8 ACH on the maximum speed setting. Pūrgo achieves slightly higher ACH during optimal performance. This difference does not affect the intended use of the device and safety and effectiveness has been confirmed via performance testing.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
Particulate Sensor	None	Optical Particle Sensor	None	**Similar to Secondary Predicate** Neither Pūrgo nor the secondary predicate device utilize a particulate sensor that the primary predicate has. This difference does not affect the intended use of the device or safety and effectiveness.
Fan Exposure Safety Features	Diffuser panel on side of device and SteriDuct cover behind filter door 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 UL507.	**Similar** All devices provide protection from the spinning fan for users. The safety features have been confirmed with UL 507 testing.
UV Light Exposure Safety Features	Safety interlock switch exists in filter door to ensure if the 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-A 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 UL507.	**Similar** All devices provide protection from the exposure to UV light. The safety features have been confirmed with UL 507 testing.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
Input Voltage	120 Volt	120 Volt	120 Volt (plugs into standard single phase 120 Volt outlet)	**Identical**
Current	Up to 1.00 Amps	Up to 1.27 Amps	Up to 3.72 amps	**Different** The Pūrgo and predicates differ due to the technical specifications of the devices (i.e. the Pūrgo uses fewer LEDs, fan power consumption may differ) which results in lower power and current consumption. This difference does not affect the intended use or safety and effectiveness of the device.
Power Consumption	Up to 120 Watts	Up to 152.8 Watts	Up to 450 Watts	**Different** The Pūrgo and predicates differ due to the technical specifications of the devices (i.e. the Pūrgo uses fewer LEDs, fan power consumption may differ) which results in lower power and current consumption. This difference does not affect the intended use or safety and effectiveness of the device.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
Electronic Data Interface	None	NFC WLAN (2.4 GHz)	None	**Similar to Secondary Predicate** Neither Pūrgo nor the secondary predicate device utilize an electronic interface that the primary predicate has. This difference does not affect the intended use of the device or safety and effectiveness.
Dimensions	Unit Dimensions: 25.8”H (27.5” with casters) x 19.5”W x 10.6”D Filter Dimensions: 16.5” x 19.5” x 2.5”	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: Length: 22 in Width: 22 in Height: 52 in Area = 25,168 Filter Dimensions: 20in x 20in x 4in	**Similar** All devices are able to be moved to authorized locations without the need for door size accommodations and all filters are able to be replaced by the intended user without the need for special tools or accommodations related to size. The minor differences in dimensions do not affect the intended use or safety and effectiveness of the device.

Item	Pūrgo (K213753) *Subject Device*	Molekule Air Pro (K211194) *Primary Predicate*	Molekule Air Pro RX (K200500) *Secondary Predicate*	Comparison
Standards	UL 507 Standard for Electrical Fans IEC 60601-1 Basic Safety and Essential Performance IEC 60601-1-2 EMC. EMC for Medical Devices IEC 60601-1-11 Home Healthcare Environment IEST-RP-CC001.6 HEPA and ULPA Filters	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	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices.	**Similar** All devices were tested to UL 507 and IEC 60601-1-2 for electrical and EMC safety. Pūrgo was tested to the more stringent IEST-RP-CC001.6 standard instead of ASHRAE 52.2 as the primary predicate was since Pūrgo utilizes a HEPA filter. For other performance testing, Pūrgo was tested using validation protocols to verify safety and effectiveness.

Summary of Non-Clinical Testing

The Pūrgo was verified and validated in accordance with documented Verification & Validation plans and protocols to ensure conformance with established performance criteria. See below for the type of tests performed. AeroClean has completed the following testing:

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Microorganism Performance	Internal Standards	Testing was performed to evaluate the Pūrgo's efficacy against aerosolized biologicals. Testing was performed with the Pūrgo device in accordance with the normal use of the system (i.e. both the filtration and UV systems active at the normal speed) with six (6) different aerosolized biologicals. Testing was performed with two aerosolized biologicals (MS2 and Bacillus globigii as they are representative of the more difficult biologicals to filter and destroy) at the sleep and boost fan speeds to demonstrate that the efficacy of the device isn't compromised by changes in fan speed.	4 log reduction (99.99%)	<u>Average net log reduction / time</u> *Methicillin resistant Staphylococcus epidermidis*, 4.6 / 45 mins at normal *Bacillus globigii endospore*, 4.1 / 60 mins at normal, 4.4 / 60 mins at sleep, 4.2 / 45 mins at boost *Escherichia coli,* 5.4 / 45 mins at normal *MS2 bacteriophage*, 5.4 / 60 mins at normal, 4.3 / 60 mins at sleep, 4.5 / 45 mins at boost *Phi-X174 bacteriophage*, 4.4 / 45 mins at normal *Aspergillus brasiliensis spore*, 4.3 / 90 mins at normal

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Fractional Efficiency	IEST-RP-CC001.6 – HEPA and ULPA Filters	Fractional efficiency testing was performed on the Pūrgo filter and the Pūrgo device itself per IEST-RP-CC001.6 TypeH test to determine the fractional efficiency percentage of particles of varying size ranges.	Per Standard	*Filter*: fractional efficiency percentage of 99.995% at 0.1-0.2 µm *Pūrgo Unit with Filter*: fractional efficiency percentage of 99.990% at 0.1-0.2 µm
UV Intensity	Not Applicable	The UV intensity performance of the Pūrgo units was verified to ensure the appropriate amount of UV irradiance is achieved in the SteriDuct.	≥ 0.240 mW/cm^2	Pass
UV Irradiance Exposure	American Conference of Governmental Industrial Hygienists (ACGIH) 2019 Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents and Biological Exposure Indices (BEIs)	UV radiation testing and evaluation was performed to measure the irradiance values at each wavelength between 200-400nm and determine the effective irradiance of the UV radiation to ensure UV exposure from the device is within safe limits.	Per Standard	Testing demonstrated that when operating in the normal condition (filter in place), the unit meets daily exposure limits (less than 0.1 $\mu W/cm^2$ for an 8 hour duration) and is considered part of the ANSI/IENSA RP-27.3-07 Exempt Risk Group
Ozone	UL 867 - Electrostatic Air Cleaners UL ECVP 2998 Zero Ozone Emissions for Air Cleaners, 3rd edition – 2020	Ozone testing was performed per UL 867 by monitoring the ozone concentration in a test chamber at the highest fan speed and lowest fan speed.	Per Standard	Testing demonstrates the Pūrgo unit is able to operate at less than 0.005 ppm at its highest and lowest fan speed.
Airflow Performance Evaluation	Not Applicable	The airflow performance of the Pūrgo units was verified at the three fan speeds available to the user.	Sleep: min. 125 CFM Normal: min. 200 CFM Boost: min. 315 CFM	Pass

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Laminar Airflow Evaluation	Internal Standards	Computational fluid dynamics (CFD) was performed to evaluate airflow from the Pūrgo unit in a prototypical surgery room with the aim of determining combinations of Pūrgo unit positions and operating conditions that preserves the stable air curtain over the surgery table (i.e. does not disturb laminar flow). Flow rate, placement, and HVAC return duct position were considered in the analysis and	Pūrgo does not disturb laminar flow	Testing determined that optimal placement was near the outer wall of room (8' from the surgery table) for Pūrgo flow rates of 230 to 315 CFM. This is true regardless of whether HVAC return ducts were located near the ceiling or floor of the room.
Home Healthcare Environments	FDA Guidance "Design Considerations for Devices Intended for Home Use" (November 24, 2014) IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; 2012 IEC 60601-1-11: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment; 2015	FDA's Guidance "Design Considerations for Devices Intended for Home Use" (November 24, 2014) was followed for the design and development of Pūrgo to ensure the home use device complies with applicable standards of safety and effectiveness and other regulatory requirements.	Per Standards	Pass

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Electrical Safety	UL 507: Standard for Electric Fans IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; 2012	Electrical safety testing was performed in accordance with UL 507 and IEC 60601-1.	Per Standard	Pass
Electromagnetic Compatibility	IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests; Edition 4.0	Electromagnetic Compatibility testing was performed in accordance with IEC 60601-1-2.	Per Standard	Pass
Software Validation	FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” (May 11, 2005)	Software verification and validation testing was performed for the Pūrgo device firmware.	Meet defined specifications	Pass

Summary Clinical Testing

No clinical tests were required to demonstrate substantial equivalence.

Conclusion

The conclusions drawn from the nonclinical testing demonstrate that the subject device, Pūrgo is as safe, as effective, and performs as well as or better than the legally marketed predicate, K211194 Class II (21 CFR 880.6500), product code FRA.