November 26, 2021

Samsung Electronics Co., Ltd.
% Kyoungju Kim
Consultant
MDLab Inc.
Room 804, 161-17, Magokjungang-ro,
Gangseo-gu
Seoul, 07788
Korea, South

Re: K211139
Trade/Device Name: CUBE Air Purifier
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: October 14, 2021
Received: October 20, 2021

Dear Kyoungju Kim:

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)*

K211139

Device Name
CUBE Air Purifier

Indications for Use *(Describe)*
The CUBE 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 CUBE Air Purifier has been demonstrated to destroy the following MS2 bacteriophage, Phi-Xl74 bacteriophage, Staphylococcus epidermidis, Escherichia coli entrained on the filter of the subject device under the following exposure conditions:

Organisms	Name	Average Maximum log reduction/ exposure time (hours)
		Room temperature test
Virus	MS2 bacteriophage	5.33±0.23 /60 mins
Virus	Phi-X174 bacteriophage	5.34±0.11 /60 mins
Bacteria	*Staphylococcus epidermidis*	5.36±0.28 /60 mins
Bacteria	*Escherichia coli*	5.17±0.05 /60 mins

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

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Device Information

- Trade Name: CUBE Air Purifier
- Common Name: Medical ultraviolet air purifier
- Classification Name: purifier, air, ultraviolet, medical
- Product Code: FRA
- Panel: General Hospital
- Regulation Number: 21 CFR §880.6500
- Device Class: Class II
- Date prepared: 10/14/2021

Predicate Device

Primary Predicate
K161468, Transformair Indoor Air Purifier by Transformair, LLC.

Reference Device
K200500, Molekule Air Pro RX by Molekule, Inc.

Indications for use

The CUBE 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 CUBE Air Purifier has been demonstrated to destroy the following MS2 bacteriophage, Phi-X174 bacteriophage, *Staphylococcus epidermidis*, *Escherichia coli* entrained on the filter of the subject device under the following exposure conditions:

Organisms	Name	Average Maximum log reduction/ exposure time (hours)
		Room temperature test
Virus	MS2 bacteriophage	5.33±0.23 /60 mins
Virus	Phi-X174 bacteriophage	5.34±0.11 /60 mins
Bacteria	*Staphylococcus epidermidis*	5.36±0.28 /60 mins
Bacteria	*Escherichia coli*	5.17±0.05 /60 mins

Device Description
The CUBE Air Purifier employs a photocatalytic oxidation (PCO) ultraviolet air purification technology that destroys bacteria and viruses in air in medical facilities. The CUBE Air Purifier includes a pre-filter, a dust collecting filter, UV-A LED lights (320-400 nm), and a catalytic filter.

The device is intended to be placed in medical and healthcare facilities.

Summary of Technological Characteristics
The subject and primary predicate device (K161468) are similar in indications, design, technology, functions, and principle of operation.
The major differences between the subject and primary predicate are as follows:

1) Differences of technical characteristics
   - Unlike the Transformair Air Purifier, which is installed in a vent, the CUBE Air Purifier is a freestanding device.
   - The CUBE Air Purifier, usually used indoor, is therefore deals with room temperature while the Transformair Air Purifier deals with the air of wide-ranged temperature, from 45 °F to 110 °F.
   - The CUBE Air Purifier and the predicate Transformair air purifier use the action of UV light on a Titanium Oxide (TiO_2) photocatalyst to destroy microbiological contaminates in the air. Both devices use conventional UV-light and TiO_2 catalytic material but, unlike the predicate, the CUBE Air Purifier uses UV-A LED instead of UV-A lamps. Also, the CUBE Air Purifier uses TiO_2 in a shape of spherical bead while the predicate device utilizes it as coating on a wire-mesh. Both devices are designed to operate in a medical facility.
   - Unlike the Transformair Air Purifier, the CUBE Air Purifier can be optionally controlled with a mobile application. The user interface CUBE Air Purifier includes buttons and LED indicators on the top of the device. Power supply (on/off) and fan speed can be controlled with the buttons. In addition, there is an integrated WLAN in the body of the device enabling the control of the device with the SmartThings application optionally.

To Support these differences, we added the Molekule Air Pro RX Air Purifier (K200500), which is a freestanding device at the room temperature with UV-A LED.

2) Differences of Indications for Use
   The primary predicate, Transformair air purifier (K161468) covers larger range of the indications than the subject device. However, since the indications of the subject device are included in the indications of the predicate device.

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

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate</th><th>Reference Device</th></tr>
<tr><td>K number</td><td>NA</td><td>K161468</td><td>K200500</td></tr>
<tr><td>Device Name</td><td>CUBE Air Purifier</td><td>Transformair Air Purifier</td><td>Molekule Air Pro RX</td></tr>
<tr><td>Classification Name</td><td>Medical Ultraviolet Air purifier</td><td>Medical Ultraviolet Air purifier</td><td>Medical Ultraviolet Air purifier</td></tr>
<tr><td>Product Code</td><td>FRA</td><td>FRA</td><td>FRA</td></tr>
<tr><td>Regulation</td><td>21 C.F.R. § 880.6500</td><td>21 C.F.R. § 880.6500</td><td>21 C.F.R. § 880.6500</td></tr>
<tr><td>Class</td><td>II</td><td>II</td><td>II</td></tr>
<tr><td>Patient Population</td><td>General Hospital</td><td>General Hospital</td><td>General Hospital</td></tr>
<tr><td>User</td><td>Healthcare Professional</td><td>Healthcare Professional</td><td>Healthcare Professional</td></tr>
<tr><td>Indications for Use</td><td>The CUBE 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 CUBE Air Purifier has been demonstrated to destroy the following MS2 bacteriophage, Phi-X174 bacteriophage, Staphylococcus epidermidis, Escherichia coli entrained on the filter of the subject device under the following exposure conditions:
<table>
<tr><th rowspan="2">Organisms</th><th rowspan="2">Name</th><th>Average Maximum log reduction/ exposure time (hours)</th></tr>
<tr><th>Room temperature test</th></tr>
<tr><td>Virus</td><td>MS2 bacteriophage</td><td>5.33±0.23 /60 mins</td></tr>
<tr><td>Virus</td><td>Phi-X174 bacteriophage</td><td>5.34±0.11 /60 mins</td></tr>
<tr><td>Bacteria</td><td>Staphylococcus epidermidis</td><td>5.36±0.28 /60 mins</td></tr>
<tr><td>Bacteria</td><td>Escherichia coli</td><td>5.17±0.05 /60 mins</td></tr>
</table></td><td>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:
<table>
<tr><th colspan="3">Average maximum log reduction /exposure time (hours)</th></tr>
<tr><td colspan="3">Test temperature</td></tr>
<tr><td>45 °F</td><td>72 °F</td><td>110 °F</td></tr>
<tr><td colspan="3">Virus, MS2 bacteriophage</td></tr>
<tr><td>4.13/24 hours</td><td>4.25/24 hours</td><td>5.51/24 hours</td></tr>
<tr><td colspan="3">Bacteria, Staphylococcus epidermidis</td></tr>
<tr><td>4.88/24 hours</td><td>4.02/24 hours</td><td>4.20/0.33 hours</td></tr>
<tr><td colspan="3">Bacteria, Escherichia coli</td></tr>
</table></td><td>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:
<table>
<tr><th rowspan="2">Organism</th><th rowspan="2">Name</th><th>Average Maximum log reduction/ exposure time (hours)</th></tr>
<tr><th>Room temperature test</th></tr>
<tr><td>Virus</td><td>MS2 bacteriophage</td><td>5.21 / 24 hours</td></tr>
</table></td></tr>
</table>

	Subject Device	Primary Predicate	Reference Device
		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	Hospital and general surgery setting
User Control	Two buttons for controlling power and modes (Adjusted fan speed by smart, high, wind-free, sleep mode)	HVAC fan speed controls the air flow	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.	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.	UV light of sufficient energy (UV-A) activates photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction.
Installation	Free Standing	In-duct	Free Standing
Pre-Filter(s)	• Synthetic Media for mechanical filtration upstream of the PCO filter. • Dimensions Pre-filter: 13 in. x 13.7 in. x 0.2 in. Dust collecting filter: 12.6 in. x 13.4 in. x 1.6 in. • Pleats per inch 0.16 (Dust collecting filter only) Total Filter surface area 3610 sq. in.	• 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.
Catalytic Filter	• Proprietary filter media • Dimensions 12.4 in. x 12.7 in. x 0.8 in.	• Proprietary filter media • Dimensions 21.25 in. x 26 in. x 2 in.	• Proprietary filter media • Dimensions 20 in. x 20 in. x 4 in.

	Subject Device	Primary Predicate	Reference Device
	• Filter contains 4 mm spherical photocatalytic beads	• Pleats per inch 1.25 • Total Filter surface area 2800 sq. in. • Filter coated with the proprietary photocatalyst and a wire-mesh	• 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	Proprietary catalyst	Proprietary catalyst
Light Source	• UV-A Light Source, LED • Wavelength, 320-400 nm • Power per Lamp/String, 9.6 W • Number of Lamps/ String, 3 • Total UV Power, 28.8 W • Filter Irradiance (Minimum), 1 W/m^2	• UV Light Source, black light fluorescent bulbs • Wavelength, 320-400 nm • Power per Lamp/ String,17 W • Number of Lamps/ String, 6 • Total UV Power, 102 W • Filter Irradiance (Minimum), 25 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	Turbo Fan	HVAC fan	Centrifugal Fan
Flow Control	Four speeds (low, medium, high, wind-free) provide 35.7-148 CFM flow.	Building HVAC system	our speeds (low, medium, high, boost) provide 300 - 800 CFM flow.
Air changes per hour	0.5-2.2 ACH when used in room with volume of 4000 cubic feet (a typical operating room volume) with flowrates of 35.7- 148 CFM at settings low and high.	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.
UV Light Exposure Safety Features	Safety switches exist in the rear panel. If the rear panel is removed, the unit will not operate. The purpose of these switches is to protect the users from any possibility of exposure to direct contact with UV light. Safety feature confirmed by UL 507.	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 UL 507.
Fan Exposure Safety Features	Safety switches exist in the rear panel. If the rear panel is removed, the unit will not operate. The purpose of these switches is to protect the user from any possibility of exposure to direct contact with spinning fan. Safety feature confirmed by UL 507.	Installed in duct away from user, 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 UL 507.
Voltage	Input: 120 Volt (plugs into standard single phase 120 Volt outlet) Output: 24 Vdc (System In 24 Vdc)	120 Volt (plugs into standard outlet: no switch, always on)	120 Volt (plugs into standard single phase 120 Volt outlet)

	Subject Device	Primary Predicate	Reference Device
Current	Up to 2.3 amps	Up to 1.25 amps	Up to 3.72 amps
Power Consumption	Up to 55 Watts	Up to 240 Watts	Up to 450 Watts
Dimensions	• Outer frame dimensions: 15 in. x 16 in. x 17.3 in. • Pre-Filter: 13 in. x 13.7 in. x 0.2 in. • Dust Collecting Filter: 12.6 in. x 13.4 in. x 1.6 in.	• 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 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.
Mobile App (Optional)	If the mobile App (SmartThings) is installed on smartphone, the user can control the device with a smartphone.	None	None
Standard	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices.	ANSI/UL 1995-2011 & CANCSA 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.

Non-clinical Testing

The CUBE Air Purifier complies with voluntary standards for electrical safety and electromagnetic compatibility.
The following were provided:

- 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.
- UV light exposure and UV irradiance testing according to UL 507:2017.
- Fluid modeling to confirm the system does not impact laminar flow systems. The CUBE Air Purifier does not provoke back flow and the pressure change in AII rooms.
- Performance Testing:

Test Methodology	Purpose	Acceptance Criteria	Results
Performance study for removal efficiency by particle size using dust collecting filter materials, DB63-04081A / DB63-04081D.	To ensure the CUBE Air Purifier meets filtration efficiency Requirements (95 % or greater on 0.3 to 1.0 micron size particles).	The filter material 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
The estimate of the catalytic filter lifetime based on performance and stability evaluation.	To ensure the sustainability of photocatalytic activity and durability of the catalytic filter after 10 years of operation under constant UVA irradiation.	The photocatalytic activity (CADR against toxic gas) shall maintain more than 50 % of initial activity after accelerating test simulating 10 years of operation.	Photocatalytic activity (CADR against toxic gas) after accelerating test was above 50 % compared to initial activity.
Performance evaluation for the estimate of UVA LED Lifetime based on acceleration test.	To estimate the usable lifetime of UVA LED lamp	L50/B50	111,638 hours (12.7 years) to reach L50/B50.

MS2 bacteriophage, Phi-X174 bacteriophage, *Staphylococcus epidermidis, Escherichia coli* were aerosolized into a sealed environmental bioaerosol chamber containing the CUBE Air Purifier.	To evaluate the efficacy of the CUBE Air Purifier at reducing viability of aerosolized MS2 bacteriophage, Phi-X174 bacteriophage, *Staphylococcus epidermidis, Escherichia coli* by a combination	4 log reduction (99.99 %)	Average net log reduction / time MS2 bacteriophage, 5.33 ± 0.23 / 60 mins Phi-X174 bacteriophage, 5.34 ± 0.11 / 60 mins *Staphylococcus epidermidis*, 5.36 ± 0.28 / 60 mins *Escherichia coli*, 5.17 ± 0.05 / 60 mins
Efficacy of the CUBE Air Purifier Device against MS2 Bacteriophage After 10 Years of Simulated Use	To evaluate the efficacy of the CUBE Air Purifier after 10 years of simulated use at reducing viability of aerosolized MS2 bacteriophage.	4 log reduction (99.99 %)	Average net log reduction / time MS2 Bacteriophage, 5.35 ± 0.26 / 60 mins

Clinical Testing

Not applicable.

Conclusion

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