June 11, 2021

Guangzhou Ajax Medical Equipment Co., Ltd.
℅ Iris Fung
Specialist
SGS-CSTC Standards Technical Services Co., Ltd.
198 KEZHU Road, SCIENTECH Park Guangzhou Economic &
Technology Deve
Guangzhou, Guangdong
China

Re: K202766
Trade/Device Name: EOS Air Cleaner
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: May 10, 2021
Received: May 14, 2021

Dear Iris Fung:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202766

Device Name
EOS Air Cleaner

Indications for Use *(Describe)*
EOS Air Cleaner is a device intended for medical purposes that is used to destroy bacteria and viruses in the air by exposure to ultraviolet radiation in general medical environment.
The core technology components of the EOS Air Cleaner have been demonstrated to destroy MS2 bacteriophage bioaerosol entrained on the filter to achieve an average 4 log reduction over 4 hours in a 30 cubic meter chamber.

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

510(k) Number: 202766

This 510(K) Summary is being submitted in accordance with the requirement of 21 CFR 807.92. This is a Traditional 510(K) submission, and there were no prior submissions for the subject device.

1. Submitter's Information Sponsor

- Company Name: Guangzhou Ajax Medical Equipment Co., Ltd.
- Address: Building No.2 Dagang industrial zone, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, 511447, P.R. China
- Phone: +86 20 84847938
- Email: ella@ajaxdent.com
- Contact Person (including title): Atwood Lee (General Manager)

Application Correspondent:

- SGS-CSTC Standards Technical Services Co., Ltd.
- Address: 198 KEZHU Road, SCIENTECH Park Guangzhou Economic & Technology Development District, Guangzhou, Guangdong, CHINA
- Contact Person: Ms. Iris Fung
- Tel: +86-20-32136908
- Email: Iris.Fung@sgs.com

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Regulation Name: Medical Ultraviolet Air Purifier
- Trade Name: EOS Air Cleaner
- Review Panel: General Hospital
- Product Code: FRA
- Regulation Number: 21 CFR 880.6500
- Regulation Class: II

3. Date Prepared:

June 9, 2021

4. Predicate Device

- 510(k) number: K200500
- Sponsor: Molekule, Inc.
- Regulation Name: Medical Ultraviolet Air Purifier
- Trade Name: Molekule Air ProRX
- Review Panel: General Hospital
- Product Code: FRA
- Regulation Number: 21 CFR 880.6500

- Regulation Class: II

5. Device Description

EOS Air Cleaner employs an ultraviolet air purification technology that destroys bacteria and viruses in air in hospital, nursing homes, medical facilities, but not in specialized medical place such as operating rooms.

EOS Air Cleaner is a free-standing device, which has a well-sealed metal box including a fine filter, motor, two UV-C lamps, and a HEPA filter. By sucking surrounding air into the device, EOS Air cleaner can suction the air into the device and filtering the air by fine filter and HEPA filter with UV-C light radiation, then the purified air is expelled from the cabinet.

The bacteriophage deposited onto the surface of EOA Air Cleaner's proprietary photocatalytic coated filter media will be killed after exposure to EOS Air Cleaner's UV-C light

UV-C light in 255 nm which is commonly called germicidal kills any remaining bacteria and viruses, as the radiation penetrates the cell walls of bacteria and is absorbed by the organic structures within the bacterial and virus, causing them to decompose and the cell to die.

6. Indications for Use

EOS Air Cleaner is a device intended for medical purposes that is used to destroy bacteria and viruses in the air by exposure to ultraviolet radiation in general medical environment.

The core technology components of the EOS Air Cleaner have been demonstrated to destroy MS2 bacteriophage bioaerosol entrained on the filter to achieve an average 4 log reduction over 4 hours in a 30 cubic meter chamber.

7. Comparison of Technological Characteristics

	Subject Device	**Primary Predicate Device**	**Comparison**
510(k) Number	**K202766**	**K200500**	
Manufacturer	GUANGZHOU AJAX MEDICAL EQUIPMENT CO., LTD.	Molekule, Inc.	--
Product Name	EOS Air Cleaner	Molekule Air Pro RX	--
Classification	Class II, FRA (21 CFR880.6500)	Class II, FRA (21 CFR880.6500)	Same
Indications for Use	EOS Air Cleaner is a device intended for medical purposes that is used to destroy bacteria and viruses in the air by exposure to ultraviolet radiation in general medical environment. The core technology components of the EOS Air Cleaner have been demonstrated to destroy MS2 bacteriophage bioaerosol entrained on the filter to achieve an average 4 log reduction over 4 hours in a 30 cubic meter chamber.	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:	Similar

Light Source	2 UV-C Xenon Flash lamps Wavelength 255 nm	UV Light Source, LED Wavelength, 320-400nm Pow er per Lamp/ String, 11.4W Number of Lamps/ String, 6 Total UV Pow er, 68.4W Filter Irradiance (Minimum), 30W/m^2	Different
MS2 Bacteriophage inactivation	Average Log reduction/exposure time (hours) Speed 1: 4.05 / 4 hours Speed 5: 4.22 / 4 hours Speed 10: 4.45 / 4 hours	Average Maximum log reduction /exposure time (hours) Room temperature test 5.21 / 24 hours	Similar
Environment of Use	Hospital, nursing homes, medical facilities (not surgery setting)	Hospital and general surgery setting	Similar
User Control	4 Buttons to control the device: Power button to turn on/off. Start/Stop button to start/stop device. Higher and Lower button to adjust the air suction velocity.	One knob controls the four speed fan setting One button turns the unit on and off.	Similar
Safety Features	UV lamps and centrifugal fan are contained inside sealed metal box.	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. Grill at outlet and inlet of fan with small enough grating to block user from accessing spinning fan without tools.	Similar
Power Supply	AC110V, 60Hz 12-20A	120 Volt (plugs into standard single phase 120 Volt outlet) Up to 3.72 amps	Similar
Power Consumption	1300 Watts	Up to 450 Watts	Different
Dimensions	Main unit: 12.25” × 10.75”× 40”	22” × 22”× 52”	Similar
Safety and EMC	IEC 60601-1: Pass IEC 60601-1-2 CISPR Group 1A: Pass	UL 507 IEC 60601-1-2	Similar

8. **Summary for non-clinical test**

The non-clinical testing was provided to demonstrate the subject device met the acceptance criteria of the test methodology or standards listed below.

EOS Air Cleaner complies with voluntary standards for electrical safety and electromagnetic compatibility.

Name of Test Methodology	Purpose	Acceptance Criteria	Results
IEC 60601-1	Demonstration of basic safety and	Meets criteria for CISPR Group 1A	Pass

IEC 60601-1-2	essential performance		
Bacteriophage Test	Demonstration of log reduction of viral load	At least 4 log reduction of MS2 bacteriophage	Pass
Aging Test	Demonstration of continued function throughout service life	At least 4 log reduction of MS2 bacteriophage	Pass
Software Validation	Demonstration of software security and good design	Meets design criteria	Pass

9. Clinical Testing

Clinical testing was not performed.

10. Conclusion

The conclusion drawn from the nonclinical testes demonstrates that the subject device in 510(K) submission K202766, EOS Air Cleaner, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202766.