September 15, 2025

UVX Inc.
℅ Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120A
Madison, NJ 07940

Re: K252128
Trade/Device Name: Zener® (model ZEN-001-B1)
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical ultraviolet air purifier
Regulatory Class: Class II
Product Code: FRA
Dated: July 7, 2025
Received: July 7, 2025

Dear Dave Yungvirt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

KATHARINE SEGARS -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252128

Device Name
Zener® (model ZEN-001-B1)

Indications for Use *(Describe)*
Zener® (model ZEN-001-B1) is an ultraviolet (UV) air purifying device intended for the reduction of bacteria in air in medical facilities. Zener has demonstrated the ability to reduce Klebsiella aerogenes in air by 4.73 net log-reduction at 50% ± 10% relative humidity and 23°C ± 3°C (73°F ± 5°F). Zener is non sterile.

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.

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510(k) Summary

ZENER® model ZEN-001-B1

K252128

In accordance with 21 CFR 807.92, the following summary of information is provided:

1. Submission Sponsor

Company Name: UVX Inc.

Address: 049 - 2366 Main Mall, Vancouver, British Columbia, V6T 1Z4, Canada

Website: uvxinc.com

Email: wecare@uvxinc.com

Phone: +1 877 969 2345

Contact and Title: Kunal Sethi, CEO

Date Prepared: 12 September 2025

2. Device Identification

Trade/Proprietary Name:	Zener® (model ZEN-001-B1)
Common/Usual Name:	Medical ultraviolet air purifier
Classification Name:	Purifier, Air, Ultraviolet, Medical
Regulation Number:	21 CFR 880.6500
Product Code:	FRA
Device Class:	Class II
Classification Panel:	General Hospital

3. Predicate Device(s)

Predicate Device

510(k) Number: K133800

Device Name: Odorox® MDU/Rx™

Manufacturer: HGI Industries, Boyton Beach, FL, USA

Reference Device

510(k) Number: K211194

Device Name: Molekule Air Pro

Manufacturer: Molekule, Inc., San Francisco, CA, USA

4. Device Description Summary

Zener is a ceiling-mounted and mains-powered ultraviolet (UV) air purifying device intended to reduce bacteria in air in medical facilities. The device functions autonomously by exposing air in the room to UV light.

Physically, Zener measures 7” x 7” x 3.2”, weighs 2.1 lbs, and mounts to ceilings using its backplate and an included ceiling bracket. The device's exterior surfaces are constructed with quartz glass, metal, and plastic. Device management is supported through a mobile and web application.

5. Intended Use / Indication for Use Statement

Zener® (model ZEN-001-B1) is an ultraviolet (UV) air purifying device intended for the reduction of bacteria in air in medical facilities. Zener has demonstrated the ability to reduce Klebsiella aerogenes in air by 4.73 net log-reduction at 50% ± 10% relative humidity and 23°C ± 3°C (73°F ± 5°F). Zener is non sterile.

6. Comparison of Technological Characteristics

The table below compares technological characteristics of the subject and predicate devices.

The differences identified in the table do not raise different questions of safety or effectiveness as demonstrated by risk analysis, software verification and validation, comparison to the reference device, safety testing and certifications, and performance testing.

A reference device (Molekule Air Pro) has been included to demonstrate wireless communication for devices under product code FRA.

Device & Predicate Device(s):	Subject Device Zener (model ZEN-001-B1) K252128	Predicate Device Odorox MDU/Rx K133800	Reference Device Molekule Air Pro K211194	Comparison
Indications for use	Zener® (model ZEN-001-B1) is an ultraviolet (UV) air purifying device intended for the reduction of bacteria in air in medical facilities. Zener has demonstrated the ability to reduce Klebsiella aerogenes in air by 4.73 net log-reduction at 50% ± 10% relative humidity and 23°C ± 3°C (73°F ± 5°F). Zener is non sterile.	The MDU/Rx™ medical model is an ultraviolet (UV) air purifying device intended for the reduction of bacteria and the MS2 and Phi-X174 virus in air in medical facilities. The MDU/Rx™ medical device is non sterile.	N/A	Similar
Mechanism of action	UV light kills microorganisms.	UV light kills microorganisms.	N/A	Same

Device & Predicate Device(s):	Subject Device Zener (model ZEN-001-B1) K252128	Predicate Device Odorox MDU/Rx K133800	Reference Device Molekule Air Pro K211194	Comparison
Elements of design	UV light irradiates microorganisms in the air already circulating in the room.	Internal fan circulates air through a shielded chamber where UV light irradiates microorganisms. Construction also includes a particulate filter.	N/A	Different. Substantial equivalence demonstrated through safety certifications and performance testing.
Germicidal UV	Yes	Yes	N/A	Same
UV optic type	Quartz UV-C	Quartz UV-C	N/A	Same
Number of optics, power consumption, and number of tubes	One UV-C optic consuming 11 W power. The optic comprises four cylindrical UV-C tubes.	Two UV-C optics consuming 48 W power each. Each optic comprises one U-shaped UV-C tube.	N/A	Different. Substantial equivalence demonstrated through safety certifications and performance testing.
Useful life of UV lamps	10,000 hours of use.	8,000 hours of use.	N/A	Different. Substantial equivalence demonstrated through safety certifications and performance testing.
UV wavelength	200-235 nm	~100-285 nm	N/A	Similar
Catalyst coated surfaces	No	No	N/A	Same
Electric discharge (i.e. Electrostatic precipitation)	No	No	N/A	Same
Chemical additives	No	No	N/A	Same
Types and materials of construction	Quartz UV optics, Metal or plastic structural case.	Quartz UV optics, Metal or plastic structural case and fan powered by electric motor.	N/A	Similar
Performance	4.73 net log reduction of bacteria in 1,060 ft^3 space within 2 hours.	4 - 5 net log reduction of bacteria in 563 ft^3 space within 1 hour.	N/A	Similar

Device & Predicate Device(s):	Subject Device Zener (model ZEN-001-B1) K252128	Predicate Device Odorox MDU/Rx K133800	Reference Device Molekule Air Pro K211194	Comparison
User controls	Software apps used to turn device on or off and show basic device information.	Knob to turn device on or off. LCD display on device shows basic device information.	LCD display and a capacitive touchscreen user interface with integrated WLAN which provides a secondary means for controlling the device from the Molekule Android or iOS software apps.	Different. Substantial equivalence demonstrated through risk analysis and software verification and validation.
Ozone emission	Does not exceed maximum concentration of 0.050 ppm in 21 CFR 801.415.	Does not exceed maximum concentration of 0.050 ppm in 21 CFR 801.415.	N/A	Same
Position	Fixed at minimum 2.25 m (7 ft 5 in) ceiling to floor.	Mobile and positioned such that inlet and outlet vents are free of obstruction.	N/A	Different. Substantial equivalence demonstrated through safety certifications and performance testing.

7. Summary of Non-Clinical Testing

To demonstrate substantial equivalence of Zener to the predicate device, UVX Inc. completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. Zener model ZEN-001-B1 passed the testing in accordance with internal requirements, national standards, and international standards shown below, demonstrating substantial equivalence to the predicate device.

Tests performed and test standards	Purpose	Acceptance criteria	Results (Pass/Fail)
Performance testing to: - ASHRAE 241 (Modified for *Klebsiella aerogenes* which is a bacterium, instead of MS2 which is a virus) - AHAM AC-5 - FDA Good Laboratory Practices (GLP) as defined in 21 CFR, Part 58	Evaluating efficacy at reducing aerosolized bacteria. Specifically, *Klebsiella aerogenes* was tested.	At least 4-log (99.99%) net reduction of *Klebsiella aerogenes* in 150 mins in 30 m^3 (1,060 ft^3) volume of air in 50% ± 10% relative humidity and 23°C ± 3°C (73°F ± 5°F).	Pass

Tests performed and test standards	Purpose	Acceptance criteria	Results (Pass/Fail)
Electrical safety testing to: - UL 1598 - CSA C22.2 No. 250.0	Confirming electrical safety.	Meets acceptance criteria specified in safety standards.	Pass
Photobiological safety testing to: - [12-249] IEC 62471 - ANSI/CAN/UL 8802	Confirming photobiological safety.	Meets acceptance criteria specified in safety standards.	Pass
Ozone safety testing to: - UL 867, Section 40 - CSA C22.2 No. 187, Section 7	Confirming ozone safety.	Meets acceptance criteria specified in safety standards and does not exceed maximum concentration of 0.050 ppm in 21 CFR 801.415.	Pass
Electromagnetic compatibility and interference to: - [19-36] IEC 60601-1-2 - CISPR 11 - FCC Subpart C	Demonstrating electromagnetic compatibility of the device.	Meets acceptance criteria specified in standards.	Pass
Software verification and validation to: - [13-79] IEC 62304 - FDA's Guidance for Industry and FDA Staff, *Content of Premarket Submissions for Device Software Functions*	Demonstrating software security and good design.	Adequate software security and design as per standard and FDA guidance.	Pass
Cybersecurity verification and validation to: - FDA's Guidance for Industry and FDA Staff, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*	Demonstrating cybersecurity and good design.	Adequate cybersecurity and design as per FDA guidance.	Pass
Risk management to: - [5-125] ISO 14971	Demonstrating risk mitigation.	Adequate risk mitigation as per standard.	Pass

8. Summary of Clinical Testing

N/A.

9. Conclusion

Based on the intended use, technological characteristics, and the non-clinical performance tests, the subject device, Zener model ZEN-001-B1, is as safe, as effective, and performs at least as safely and effectively as the predicate device.