November 19, 2024

CerroZone LLC
% Erin Gontang
Senior Consultant
RQM+
2790 Mosside Blvd., Suite 800
Monroeville, Pennsylvania 15146

Re: K242102
Trade/Device Name: CerroZone Mini
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: FRF
Dated: July 18, 2024
Received: October 18, 2024

Dear Erin Gontang:

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)*
K242102

Device Name
CerroZone Mini

Indications for Use *(Describe)*
The CerroZone Mini is intended as a room recirculating air cleaner. The system is used for filtering out and inactivating airborne particles (i.e., bacteria and viruses) from the air for medical purposes.

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.

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510(k) Summary

DATE PREPARED
November 19, 2024

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DEVICE INFORMATION

Proprietary Name/Trade Name:	CerroZone Mini
Common Name:	Medical Recirculating Air Cleaner
Regulation Number:	21 CFR 880.5045
Class:	II
Product Code:	FRF
Premarket Review:	Infection Control Devices (DHT4C)
Review Panel:	General Hospital

PREDICATE DEVICE IDENTIFICATION
The CerroZone Mini is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K220298	CerroZone Mobile / CerroZone LLC	✓

DEVICE DESCRIPTION
The CerroZone Mini is a medical recirculating air cleaner that uses multiple inactivation processes, including use of reactive oxidizing species (ozone) and ultraviolet radiation, to inactivate bacteria and viruses in the air. The CerroZone Mini may be used in medical facilities. Once turned on, inlet air is passed through CerroZone Mini's inline flow-through design which inactivates bacteria and viruses in a single pass flow-through. The device generates 110 cubic feet of air per minute (CFM), or 2.00 air changes per hour (ACH) in a standard 5,600 cubic foot

room. The process of air being inlet, purified, then outlet, lasts approximately 1.2 seconds. A 4 LOG reduction, or 99.99% reduction, of airborne particles in a standard 579 cubic foot room is achieved in 45 minutes or less.

INDICATIONS FOR USE

The CerroZone Mini is intended as a room recirculating air cleaner. The system is used for filtering out and inactivating airborne particles (i.e., bacteria and viruses) from the air for medical purposes.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

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

	Subject Device	**Predicate Device**	**Comparison**
	CerroZone LLC CerroZone Mini K242102	**CerroZone LLC CerroZone Mobile K220298**	
Indications for Use	The CerroZone Mini is intended as a room recirculating air cleaner. The system is used for filtering out and inactivating airborne particles (i.e., viruses and bacteria) from the air for medical purposes.	The CerroZone Mobile is intended as a room recirculating air cleaner. The system is used for filtering out and inactivating airborne particles (i.e., viruses and bacteria) from the air for medical purposes.	Identical
Product Code / Regulation Number	FRF/ 21 CFR 880.5045	FRF/ 21 CFR 880.5045	Identical
Regulation Description	Medical recirculating air cleaner	Medical recirculating air cleaner	Identical
Type of Use	Over-the-Counter Use	Over-the-Counter Use	Identical
Mechanism of Action	Microorganisms including viruses and bacteria, are inactivated by the device via damage by multiple inactivation processes: Reactive Oxidizing Species (ozone) Ultraviolet Radiation Also, a filter to trap the resulting virus/bacteria particulates: Particulate Filter Activated Carbon Filter	Microorganisms including viruses and bacteria, are inactivated by the device via damage by multiple inactivation processes: Reactive Oxidizing Species (ozone) Ultraviolet Radiation Also, a filter to trap the resulting virus/bacteria particulates: Particulate Filter Activated Carbon Filter	Identical
Reduction of Biological Agents	MS2 phage reduced by 4 log reduction in 45 minutes or less when operating at full fan speed in a standard room	MS2 phage reduced by 4 log reduction in 30 minutes or less and 5.67 log reduction in 45 minutes or less when	Similar

	of 579 ft^3 (16 m^3)	operating at full fan speed in a std. room of 579 ft^3 (16 m^3)	
Ozone Emitted	Within the maximum acceptable level of ozone given in 21 CFR 801.415	Within the maximum acceptable level of ozone given in 21 CFR 801.415	Identical
Installation	Free standing	Free standing	Identical
Reactive Oxidizing Species (Ozone) Source	Activated Carbon Filter Proprietary Catalyst Substrate	Activated Carbon Filter Proprietary Catalyst Substrate	Identical
Reactive Oxidizing Species (Ozone) Removal	Activated Carbon Filter Proprietary Catalyst Substrate	Activated Carbon Filter Proprietary Catalyst Substrate	Identical
Air Source	Centrifugal Fan	Centrifugal Fan	Identical
Device Air Changes Per Hour (ACH)	2.00 device air changes per hour in a 5,600 ft^3 room	2.36 device air changes per hour in a 5,600 ft^3 room	Similar
UV Light or Reactive Oxidative Species (Ozone) Exposure Safety Features	A catalyst substrate converts any ozone generated back into oxygen. An activated carbon filter absorbs any remaining ozone. If > 0.03 ppm of ozone is measured the external ozone sensors, the CerroZone Mini will automatically shut down. The CerroZone Mini also utilizes a second and redundant external ozone sensor that runs on a different circuit. As such, if one external ozone sensor were to stop functioning, another sensor will be active. Safety feature confirmed by UL 867 & CSA C22.2 No.187.	A catalyst substrate converts any ozone generated back into oxygen. An activated carbon filter absorbs any remaining ozone. If > 0.03 ppm of ozone is measured the external ozone sensors, the CerroZone Mini will automatically shut down. The CerroZone Mini also utilizes a second and redundant external ozone sensor that runs on a different circuit. As such, if one external ozone sensor were to stop functioning, another sensor will be active. Safety feature confirmed by UL 867 & CSA C22.2 No.187.	Identical
Input Voltage	120 Volt	120 Volt	Identical
Dimensions	Unit Dimensions: Height: 36 in Width: 21 in Depth: 17 in	Unit Dimensions: Height: 59 in Width: 29 in Depth: 17 in	Different

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

Electromagnetic Compatibility and Electrical Safety: The subject device is equivalent to CerroZone Mobile that tested in compliance to EN/IEC 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests* and UL 867 & CSA C22.2 No.187 *Electrostatic Air Cleaners*.

Ozone Emissions: Ozone Emissions of the CerroZone Mini have been assessed per Section 40 of UL 867 & CSA C22.2 No.187 *Electrostatic Air Cleaners*. Results of the test show that the CerroZone Mini emits between 0.000 and 0.002 ppm of Ozone with a measured absolute max of 0.002 ppm. All Ozone emissions measured fall within the maximum acceptable level of ozone, 0.050 ppm, given in 21 CFR 801.415.

Test Methodology	Purpose	Acceptance Criteria	Results
MS2 bacteriophage were aerosolized into a sealed environmental bioaerosol chamber containing the CerroZone Mini.	To evaluate the efficacy of the CerroZone Mini at reducing viability of aerosolized MS2 bacteriophage by a combination of entrainment and destruction.	Greater than 4 log reduction (99.99%).	Average net log reduction / time, MS2 bacteriophage, 5.76 ± 0.20 / 45 mins.
Methicillin Resistant *Staphylococcus epidermidis* (MRSE) were aerosolized into a single-pass flow through chamber that modeled the CerroZone Mini.	To evaluate the efficacy of the CerroZone Mini at reducing viability of aerosolized bacteria by a combination of entrainment and destruction.	Greater than 3 log reduction (99.99%) in single-pass testing.	Demonstrated effectiveness against *Staphylococcus epidermidis*.

SUMMARY OF CLINICAL TESTING

No clinical data were provided in order to demonstrate substantial equivalence.

CONCLUSION

CerroZone concludes that the non-clinical tests demonstrate that the CerroZone Mini is as safe, as effective, and performs as well as or better than the legally marketed predicate device.