July 1, 2022

CerroZone
% Matthieu Kirkland
Regulatory Specialist
Rqm+
2251 San Diego Avenue, Ste B-257
San Diego, California 92110

Re: K220298
Trade/Device Name: CerroZone Mobile
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: FRF
Dated: May 23, 2022
Received: May 24, 2022

Dear Matthieu Kirkland:

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)*
K220298

Device Name
CerroZone Mobile

Indications for Use *(Describe)*
The CerroZone Mobile 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
K220298

DATE PREPARED
July 01, 2022

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	CerroZone Mobile
Common Name:	Medical Recirculating Air Cleaner
Regulation Number:	21 CFR 880.5045
Class:	II
Product Code:	FRF
Premarket Review:	Infection Control and Plastic Surgery Devices (DHT4B)
Review Panel:	General Hospital

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

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*	*Reference Device*
K200321	Novaerus NV1050 / Novaerus US Inc	✓	
K203189	AEROCURE-MD / Aerobiotix, Inc.		✓

The predicate and reference devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The CerroZone Mobile is a medical recirculating air cleaner that uses multiple inactivation processes consisting of reactive oxidizing species (ozone) and ultraviolet radiation to inactivate bacteria and viruses in the air. The CerroZone Mobile may be used in medical facilities. Once turned on, inlet air is passed through CerroZone Mobile's inline flow-through design which inactivates bacteria and viruses in a single pass flow-through. The device generates 220 cubic feet of air per minute (CFM), or 2.36 air changes per hour (ACH) in a standard 5,600 cu. Ft room. This process of air being inlet, purified, then outlet, lasts approximately 1.2 seconds. A 4 LOG reduction of airborne particles in a standard 579 cu. Ft room is achieved in 30 minutes or

less. A 5.67 LOG, or 99.9998%, reduction is achieved in 45 minutes or less.

INDICATIONS FOR USE

The CerroZone Mobile 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	***Primary Predicate Device***	***Comparison***
	CerroZone CerroZone Mobile Current	Novaerus US Inc. Novaerus NV1050 K200321	
Image			
Indications for Use	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	The Novaerus NV1050 is intended as a room recirculating air cleaner. The system is used for filtering out and inactivating airborne particles from the air for medical purposes	Similar
Product Codes / 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 Ions Electrons High Electric Fields Also, a filter to trap the resulting virus/bacteria particulates: Particulate Filter Activated Carbon Filter	Similar
Reduction of Biological Agents	MS2 phage reduced by 4 log reduction in 30 minutes or less and 5.67 log reduction in 45 minutes or less when operating at full fan speed in a standard room of 579 ft^3 (16 m^3)	MS2 phage reduced by 3 log reduction in 10 minutes and 4 log reduction in 15 minutes when operating at full fan speed in a room of 580ft^3 (16.4 m^3)	Similar
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	High-output UVC generating lamp elements	High-output Plasma Field generating coil elements	Similar
Reactive Oxidizing Species (Ozone) Removal	Activated Carbon Filter Proprietary Catalyst Substrate	Activated Carbon Filter	Similar
Air Source	Centrifugal Fan	Centrifugal Fan	Identical
Device Air Changes Per Hour (ACH)	2.36 device air changes per hour in a 5,600 ft^3 room	2 device air changes per hour in a 3,200 – 16,000 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 Mobile will automatically shut down. The CerroZone Mobile also utilizes a second and redundant external	An activated carbon filter absorbs any ozone generated.	Similar

	ozone sensor that runs on a different circuit. As such, if one external ozone senor were to stop functioning, another sensor will be active. Safety feature confirmed by UL 867 & CSA C22.2#187		
Input Voltage	120 Volt	110 Volt	Different
Dimensions	Unit Dimensions: Height: 59 in Width: 29 in Depth: 17 in	Unit Dimensions: Height: 59 in Width: 27.5 in Diameter: 8.27 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 was 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#187 *Standard for Electrostatic Air Cleaners.*

Determination of Turbulent Air Flow and/or Site Contamination: Risk of turbulent air flow and/or potential site contamination in areas that have a sterile field or controlled air flow has been assessed via computational fluid dynamics per ASHRAE/ASHE Standard 170-2017 *Ventilation of Health Care Facilities.*

Ozone Emissions: Ozone Emissions of the CerroZone Mobile have been assessed per Section 40 of UL 867 & CSA C22.2#187 *Electrostatic Air Cleaners.* Results of the test show that the CerroZone Mobile emits between 0.000 and 0.010 ppm of Ozone with a measured absolute max of 0.036 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 Mobile.	To evaluate the efficacy of the CerroZone Mobile 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, 5.67 ± 0.19 / 60 mins
Methicillin Resistant *Staphylococcus epidermidis* (MRSE) were aerosolized into a single-pass flow through chamber connected to the CerroZone Mobile.	To evaluate the efficacy of the CerroZone Mobile at reducing viability of aerosolized bacteria by a combination of entrainment and destruction	Greater than 3 log reduction (99.9%) 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 Inc. concludes that the nonclinical tests demonstrate that the CerroZone Mobile is as safe, as effective, and performs as well as or better than the legally marketed predicate device.