December 28, 2020

Novaerus US Inc
Declan Kiely
International Quality Director
35 Melrose Place
Stamford, Connecticut 06902

Re: K200321
Trade/Device Name: Novaerus NV1050
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: FRF
Dated: December 21, 2020
Received: December 28, 2020

Dear Declan Kiely:

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, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200321

Device Name
Novaerus NV1050

Indications for Use *(Describe)*
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.

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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510K SUMMARY
K200321

1. SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

Novaerus US Inc
35 Melrose Place
Stamford
CT 06902
USA

Contact Person: Declan Kiely

Phone: +1 203 662 0800

Date Prepared: 06th February 2020

2. DEVICE

Name of Device

Novaerus NV1050

Common or Usual Name

Air Filtration System, HEPA Air Filtration System

Classification Name/Product Code/CFR Reference

Medical recirculating air cleaner,
Product Code: FRF
CFR Reference: 21 CFR 880.5045

3. PREDICATE DEVICE

Predicate: Plasmair Model T2006 [K070722], Commercial name: Sentinel
This predicate has not been subject to a design-related recall

No reference devices were used in this submission

4. DEVICE DESCRIPTION

The Novaerus NV1050 (NV1050) is a free-standing cabinet of a size that can be maneuvered into position by a single person. The NV1050 is powered from an AC wall outlet.

The NV1050 circulates the room air through its cabinet. The air is drawn in through the front of the cabinet, passes through a pre-filter then a Dielectric Barrier Discharge Plasma generator ("plasma generator") stage, and a further two filters (HEPA, Carbon) The cleaned air is exhausted out of the top panel of the cabinet.

The device has simple controls: On/Off and fan speed setting from 1 to 5. There is a button to initiate a filter blockage test to check and inform the user if the filters are getting close to requiring changing. The only routine maintenance is a calendar-based filter change schedule indicated in the User Manual; the indicator light on the front panel acts as a reminder that the filters will soon need attention.

The airflow path through the NV1050 is:

- A general pre- filter to remove particles from the input air flow.
- A bank of three (3) plasma generators, each Plasma Generator consists of two (2) plasma Coils. Micro-Organisms, including virus and bacteria, are inactivated by the plasma generator. This occurs through damage by plasma constituents (ions, electrons, reactive oxidizing species, ultraviolet radiation, high electric fields)
- A HEPA (High-efficiency Particulate Air) filter to trap the resulting virus/bacteria particulates.
- An activated carbon filter to trap any ozone in the airstream before it is output to the environment.

Examples of the individual performance of these elements are:

- The general air pre-filter captures over 85% of particles between 0.4 µm and 10 µm per ISO16890:2016.
- A single plasma generator produced a 4.4. log reduction in *MS2 bacteriophage* in five (5) hours in a sealed room of 580ft^3 (16.4m^3). The NV1050 has three (3) such plasma generators.
- The HEPA filter captures over 99.95% of particles of 0.18µm
- The carbon filter has an expected life of 3000 hours.

The combined performance of these elements in the reduction of micro-organisms is stated on the labelling as, "*Bacillus Globigii* endospores and *MS2 bacteriophage* reduced by 99.99% (4 log reduction) in 15 minutes when operating at full fan speed in a room of 580ft3 (16.4m3)". The testing that produced these results is detailed at section 7.

5. INTENDED USE / INDICATIONS FOR USE

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

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the Novaerus NV1050 and the Plasmair Model T2006 are free-standing cabinets that can be moved to a location to provide localized air-cleansing. The NV1050 and T2006 both use a plasma discharge as the method of neutralizing biological contaminants. Both devices use a HEPA filter as the primary method of then trapping the debris and particles.

The generation of a plasma field creates extra ozone in the airflow as a byproduct of the electrical discharge. Both devices have a final stage of filtration to remove any residual ozone in the airflow. The predicate device uses a catalytic converter to absorb the ozone. The NV1050 uses an activated carbon filter for this purpose. They are alternative methods to achieve the same objective of removing any residual ozone. The use of an activated carbon filter in the NV1050 is a design choice that makes the device cheaper to manufacture and assists in reducing the cabinet size. It does mean that the carbon filter will have to be changed in a maintenance schedule, but there is already a HEPA filter in both the NV1050 and the predicate device. A HEPA filter will require periodic changes. The additional Carbon filter to be changed in the NV1050 is just an additional item on the maintenance schedule.

A table to compare the technical characteristics is below.

Feature	Novaerus NV1050 (K200321)	Plasmair T2006 (K070722)	Comparison
Device illustration			Similar
Intended Use/ Indications for Use	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	The Plasmair Model T2006 is intended as a room air purifier/recirculating air cleaner. The system is used for filtering out and inactivating airborne particles from the air for medical purposes. The Plasmair T2006 is designed to treat indoor air to supplement existing building air treatment and/or provide air treatment where none exists	Similar
Use location	Medical Facilities	Medical Facilities	Same
Technology	Air from the room is passed through a plasma field to inactivate airborne micro-organisms. A HEPA filter traps the resulting debris and an activated carbon filter absorbs any ozone generated as a byproduct of the plasma field	Air from the room is passed through a plasma-ion field to neutralize airborne micro-organisms. A HEPA filter traps the resulting debris and a third catalytic converter stage absorbs any oxidants, odors and volatile organic compounds.	Similar
Device size (inches)	36.5 (h) x 19.0 (w) x 19.1 (d)	59 (h) x 27.5 (w) x 17.5 (d)	Similar

Feature	Novaerus NV1050 (K200321)	Plasmair T2006 (K070722)	Comparison
Device weight	112lb (51 kg)	220lb (100 kg)	
Power source	110V AC	110V AC	Identical
Air change rates	6,400 to 31,925 ft^3/h (180 to 904 m^3/h) in 5 steps	14,125 to 30,000 ft^3/h (400 to 850 m^3/h) in 3 steps	Similar
Reduction of biological agents	*Bacillus Globigii* endospores and *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 580ft3 (16.4m^3)	Predicate claims a decontamination of 35m^3 room from ISO9 to ISO7 in 10 minutes	Similar
Filtration of particles	NV1050 produces a 4 log reduction in 0.5 to 2.0 µm sized particles in 10 minutes in a 580ft3 (16.4m^3) sealed room	Produces a 4 log reduction of particles at 12 ACH at 600 m^3/h.	Similar
Ozone emitted	Ozone emissions below 10 ppb (1/5th FDA limit for medical devices)	No specific claim made, but must be below FDA limit of 50 ppb	Same
Operational range	Temperature: 50°F to 95°F (10°C to 35 °C) Relative humidity: 10 to 75 %RH	Temperature: 41°F to 95°F (5°C to 35°C) Relative humidity < 95 % non-condensing	Similar
Storage range	Temperature: 13°F to 160°F (-10°C to + 71°C) Relative humidity: 10 to 93 %RH	Temperature: 32°F to 113°F (0°C to 45°C) Relative humidity: 20 % to 90 %	Similar
Standards used	IEC 60601-1: 2005/A1:2012 IEC 60601-1-2:2014	IEC 60601-1; IEC 60601-1-2	Identical

7. SUMMARY OF NON-CLINICAL DATA

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria of the standards listed below:

Test name/ Methodology/ Standard name	Purpose	Acceptance Criteria	Result
IEC60601-1:2005/A1;2012	Device electrical safety	Pass the requirements of the consensus standard	Pass
IEC60601-1-2:2014	Device Electromagnetic Compatibility	Pass the requirements of the consensus standard	Pass
Ozone emissions	Confirm ozone emissions are below the maximum permitted levels <0.050 ppm	Ozone emitted to be <0.050 ppm	Pass in normal operating conditions and single fault conditions including operating with blocked and past end of life filters
Inactivation of Micro-organisms	To demonstrate that the plasma technology alone can produce a 4 log reduction in viable micro-organisms	The plasma generator alone produces a 4 log reduction in a specified micro-organism	A single plasma generator of the type embodied in the NV1050 produced a 4 log reduction in MS2 Bacteriophage in 5 hours when operating in a sealed 580ft3 (16.4m3) room
Filtration of particles	To demonstrate that the filter banks alone can produce a 4 log reduction in particles	The device produces a 4 log reduction in the concentration of µm sized polystyrene microspheres	The device produced a 4 log reduction in the concentration of 0.5 to 2.0 µm sized polystyrene microspheres in a sealed 580ft3 (16.4m3) room in 10 minutes
Combined Operation	To demonstrate the performance of the NV1050 at maximum speed to inactivate and filter out specified micro-organisms	To produce a 4 log reduction in the specified micro-organisms	NV1050 running at maximum speed in a 580ft3 (16.4m3)sealed room: • *Bacillus Globigii Endospores*: A 4 log reduction produced in 15 minutes. Prolonged operation over 24 hours to confirm that the reduction in the micro-organisms was maintained and no viable micro-organisms were

			recycled back into the ambient air. • *MS2 Bacteriophage* : A 4 log reduction produced in 15 minutes.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

8. CONCLUSIONS

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.