September 14, 2022

Winix Inc.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K220990
Trade/Device Name: Qorda QD1
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: FRF
Dated: August 22, 2022
Received: August 23, 2022

Dear April Lee:

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)*
K220990

Device Name
Qorda QD1

Indications for Use *(Describe)*
The Qorda QD1 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 Qorda QD1 has been demonstrated to remove the following organisms under the following exposure conditions:

Organism	Fan Speed	Average Maximum log reduction	Exposure Time
MS2 bacteriophage	Turbo MODE	5.6 log reduction	20 minutes
	Sleep MODE	4.9 log reduction	45 minutes
Bacillus subtilis endospores	Turbo MODE	4.4 log reduction	20 minutes
	Sleep MODE	4.3 log reduction	60 minutes

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

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Device Information

- Trade Name: Qorda QD1
- Classification Name: Medical recirculating air cleaner
- Common Name: Air Filtration System, HEPA Air Filtration System
- Product Code: FRF
- Panel: General Hospital
- Regulation Number: 21 CFR 880.5045
- Device Class: Class II
- Date prepared: 08/22/2022

Primary Predicate Device

- K200321, Novaerus NV1050 manufactured by Novaerus US Inc.

Indications for use

The Qorda QD1 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.

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	Sleep MODE	4.3 log reduction	60 minutes

Device Description

Qorda QD1 is a freestanding medical recirculation air cleaner that facilitates movement with wheels. The device includes two pre-filters, two deodorizing filters, two HEPA filters (Total 6 filters – 3 filters in the front panel and 3 filters in the rear panel), and a manual for users.

The device can adjust the air volume in four stages through manual operation (Level 1, Level2, Level3, Turbo) and Sleep mode. When operating in sleep mode, the equipment LED and PlasmaWave are turned off and operated with low noise.

The device contains the following additional functions.
①Child lock: Button lock function that prevents children or pets from changing their current motion mode even if they accidentally operate device.
②Filter Replacement Guide: The remaining filter life is displayed on the front display of the device and tells you when to replace the filter.
③Adjustment of illuminance: You can adjust the illuminance in four stages (100%, 50%, 20%, OFF).
④You can turn on or off the PlasmaWave.
⑤The timer allows the equipment to turn off automatically after a certain period of time.

Qorda QD1 inhales air in both directions on the front and rear of the device and purifies it through the four cleaning steps below:

[Pre-Filter]
The air is drawn in through the cover front, passes through the Pre-Filter then moves to two filters stages(CD Carbon Filter, True HEPA Filter). The Pre-Filter protects CD Carbon Filter, True HEPA Filter inside the Pre-Filter.

[CD Carbon Filter]
Reduces any ozone generated as a byproduct of the plasma field. It also prolongs the True HEPA Filter lifespan.

[True HEPA Filter]
True HEPA Filter captures 99.99%* of airborne ultrafine particles as small as 0.003 microns.
*Based on independent laboratory test conducted on particles as small as 0.003 microns in size.

[PlasmaWave]
PlasmaWave Technology has been tested by an independent third-party laboratory to remove particles from the air for medical purposes.

Summary of Technological Characteristics

The subject and primary predicate device (K200321) are similar in indications, design, fundamental technology, functions, and principle of operation.

A table to compare the technical characteristics is below.

	Subject Device	Primary Predicate	Discussion
K number	K220990	K200321	
Product Name	Qorda QD1	Novaerus NV 1050	
Common Name	Air Filtration System, HEPA Air Filtration System	Air Filtration System, HEPA Air Filtration System	Identical
Product Code	FRF	FRF	Identical
Regulation Number	21 CFR 880.5045	21 CFR 880.5045	Identical
Class	Class II	Class II	Identical
Device Illustration			Identical
Intended Use/Indications for Use	The Qorda QD1 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 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.	Identical
Number of Filters	6	3	Difference
Air purifying Mechanism	4 steps (Pre-Filter, CD Carbon Filter, True HEPA Filter, Plasma technology)	4 steps (Pre-Filter, CD Carbon Filter, HEPA Filter, Plasma technology)	Identical
Use Location	Medical Facilities and Home	Medical Facilities	Difference
Technology	Air from the room is passed through a plasma field to inactivate airborne micro-organisms. A True HEPA Filter traps the resulting debris and a CD Carbon Filter absorbs any ozone generated as a byproduct of the plasma field.	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.	Identical
Device size (inches)	14.6 in(W) x 14.6 in(D) x 32.6 in(H)	19.0 (w) x 19.1 (D) x 36.5 (h)	Difference
Device weight	14.1 kg (30.9 lbs)	112lb (51 kg)	

Power source	120 VAC	110V AC	Similar
Air change rates	6,000 to 27,900 ft3/h (170 to 790 m3/h) in 5 steps	6,400 to 31,925 ft3/h (180 to 904 m3/h) in 5 steps	Difference
Reduction of biological agents	The QD1 unit, set to 'Turbo', was effective at reducing both organisms(the MS2 bacteriophage and *Bacillus subtilis* endospores) by the FDA required net log reduction of 4.0 or greater (equivalent to 99.99% or greater reduction) within 20 minutes when operating in a room of 579 ft^3 (16.4 m^3).	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 (16.4m3)	Difference
Filtration of particles	The QD1 produces a 3 log reduction in 0.5 to 4.0 µm sized particles in 10 minutes when operating at Turbo speed in a room of 579 ft^3 (16.4 m^3).	NV1050 produces a 4 log reduction in 0.5 to 2.0 µm sized particles in 10 minutes in a 580ft3 (16.4m3) sealed room	Difference
Ozone emitted	Ozone is being generated at a level of less than 2.07 ppb during the operation of the device.	Ozone emissions below 10 ppb (1/5th FDA limit for medical devices)	Similar
Operational range	Operating temperature: 5℃ ~ 40℃ Relative humidity: 15% ~ 90%	Temperature: 50°F to 95°F (10°C to 35 °C) Relative humidity: 10 to 75%RH	Similar
Storage range	Operating temperature: 5℃ ~ 40℃ Relative humidity: 10% ~ 80%	Temperature: 13°F to 160°F (-10°C to + 71°C) Relative humidity: 10 to 93%RH	Similar
Standards used	IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014 & IEC 60601-1-6:2013 IEC 60601-1-11:2015	IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014	Similar

Non-clinical Testing

1) Electrical Safety and Electromagnetic Compatibility
Electrical, mechanical, environmental safety and performance testing were conducted according to standard IEC 60601-1:2005/A1:2012, IEC 60601-1-11:2015 and EMC testing was conducted according to IEC 60601-1- 2:2014. All test results were satisfying with the standards.

2) Performance 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
Ozone emissions	Confirm ozone emissions are below the maximum permitted levels <0.050 ppm	Ozone emitted to be <0.050 ppm	Pass with the device operating in normal operating conditions under both TURBO and SLEEP Modes. The QD1 units averaged under 1.0 ppb of ozone emission throughout the 24-hour testing, with a maximum generation level less than 2.07 ppb. Testing was conducted in a chamber (internal dimensions are 9.1 ft x 9.1 ft x 7 ft, with a displacement volume of 579 ft^3, or 16.4 m^3.)
Filtration of particles	To demonstrate that the device can produce a 4 log reduction in particles	The device produces a 4 log reduction in the concentration of µm sized the two organism types(the MS2 bacteriophage and *Bacillus subtilis* endospores) and poly-styrene latex (PSL) microspheres	The QD1 produces a 3 log reduction in 0.5 to 4.0 µm sized particles in 10 minutes when operating at Turbo speed in a chamber (internal dimensions are 9.1 ft x 9.1 ft x 7 ft, with a displacement volume of 579 ft^3, or 16.4 m^3
Combined Operation	To demonstrate the performance of the Qorda QD1 at maximum speed to inactivate and filter out specified micro-organisms	To produce a 4 log reduction in the specified microorganisms	QD1 showed the following results in the the MS2 bacteriophage and *Bacillus subtilis* endospores removal performance test. • The QD1 unit, set to 'Turbo', was effective at reduction of both organisms by the required net log reduction of 4.0 or greater (equivalent to 99.99% or greater reduction) within 20 minutes when operating in a chamber (internal dimensions are 9.1 ft x 9.1 ft x 7 ft, with a displacement volume of 579 ft^3, or 16.4 m^3.)

Air Change Rate Test	To demonstrate the performance from 6,000 to 27,900 ft^3/h (170 to 790 m^3/h) in 5 steps. (Level 1, Level 2, Level 3, Turbo, Sleep)	The criteria of air change rate in each mode is higher than the following: Sleep mode is 6,000 ft3/h. Level 1 mode is 11,400 ft^3/h. Level 2 mode is 13,800 ft^3/h. Level 3 mode is 16,200 ft^3/h. Turbo mode is 27,900 ft^3/h.	Air change rate of the QD1 showed that all results were higher than the standard air change range required for each stage.
Software Validation Report	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(Class B)" level of concern.		

Clinical Data
Not applicable

Conclusion
The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K220990, Qorda QD1, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200321.