June 14, 2023

Synexis, LLC
Laura LeBoeuf
VP Quality, Regulatory, Clinical Affairs
11711 W. 79th Street
Lenexa, Kansas 66214

Re: K221540
Trade/Device Name: Synexis Sphere Rx
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical ultraviolet air purifier
Regulatory Class: Class II
Product Code: FRA
Dated: June 8, 2023
Received: June 12, 2023

Dear Laura LeBoeuf:

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 -S

Clarence W. Murray III, Ph.D.
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
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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)*
K221540

Device Name
Synexis Sphere Rx

Indications for Use *(Describe)*

The Synexis Sphere Rx is a stand-alone air purifier device intended for medical purposes and is used for the reduction of bacteria and viruses in the air. The device is intended for use in professional healthcare environments. The Sphere Rx is not intended for use near HF surgical equipment or MRI settings.

The Synexis Sphere Rx air purifier demonstrated a ≥ 4 log reduction of bacteria and viruses under the following exposure/ working conditions:

Organism Type	Organism Name	Test Temp/RH	Avg Net Log Reduction/Time@ High Fan Speed
Gram- bacteria	K. aerogenes	25±3 deg C, 60 ±5% RH	4.25 / 240m
Gram+ bacteria	S. epidermidis	25±3 deg C, 60 ±5% RH	4.19 / 360m
Virus	MS2	25±3 deg C, 60 ±5% RH	4.55 / 300m

Organism Type	Organism Name	Test Temp/RH	Avg Net Log Reduction/Time@ Low Fan Speed
Gram- bacteria	K. aerogenes	25±3 deg C, 60 ±5% RH	4.25 / 240m
Gram+ bacteria	S. epidermidis	25±3 deg C, 60 ±5% RH	4.13 / 480m
Virus	MS2	25±3 deg C, 60 ±5% RH	4.11 / 480m

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

Synexis Sphere Rx Air Purifier System K221540

Owner's Name & Address:	Synexis LLC 11711 W 79th Street Lenexa, KS 66214
Contact Person:	Laura LeBoeuf VP Quality, Regulatory, Clinical Affairs 512-517-5680 lleboeuf@synexis.com
Submission Compiled By:	Lisa Peterson Kaedon Consulting, LLC lpeterson@kaedonconsulting.com
Date:	June 8, 2023
Trade Name:	Synexis Sphere Rx
Common Name:	Air Purifier
Product Code:	FRA
Classification:	Class II (21 CFR 880.6500)
Classification Name	Medical UV Air Purifier
Predicate Devices:	Primary K211194 – Molekule Air Pro Additional K201220 – Aerus Medical Guardian
Device Description	The Synexis Sphere Rx is a photocatalytic air purifier that utilizes a photocatalytic oxidation purification process involving a light-activated catalyst which reacts with organic pollutants to oxidize them. The Sphere Rx draws ambient air through multiple filters including a carbon filter, a MERV filter and a photocatalytic filter that Synexis refers to as a 'Sail'. When the ambient air containing oxygen and water molecules contacts the photocatalytic filter exposed to UV light, a chemical reaction is initiated inside the device that generates hydroxyl radicals, super oxides and hydrogen peroxides. Synexis refers to the hydrogen peroxide molecules as dry hydrogen peroxide or DHP to distinguish these molecules from the aqueous form of hydrogen peroxide.

The mechanism of action for the Sphere Rx photocatalytic air purifier to reduce microorganisms, including bacteria and viruses, in the air for small room environments relies on combination of capture and destruction. Ambient air is continuously circulated through MERV and carbon filters and a photocatalytic medium under UV light exposure inside the device to achieve a 4 log reduction.

Indications for Use:

The Synexis Sphere Rx is a stand-alone air purifier device intended for medical purposes and is used for the reduction of bacteria and viruses in the air. The device is intended for use in professional healthcare environments. The Sphere Rx is not intended for use near HF surgical equipment or MRI settings.

The Synexis Sphere Rx air purifier demonstrated a ≥ 4 log reduction of bacteria and viruses under the following exposure/working conditions:

Organism Type	Organism Name	Test Condition Temp/RH	Average Net Log Reduction/Time @ High Fan Speed	Average Net Log Reduction/Time @ Low Fan Speed
Gram Negative Bacteria	***K. aerogenes***	**25±3ºC, 60 ±5% RH**	**4.25 / 240m**	**4.25 / 240m**
Gram Positive Bacteria	***S. epidermidis***	**25±3ºC, 60 ±5% RH**	**4.19 / 360m**	**4.13 / 480m**
Virus	**MS2 bacteriophage**	**25±3ºC, 60 ±5% RH**	**4.55 / 300m**	**4.11 / 480m**

Technological Characteristics:

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

Table 1. Technological Characteristics Comparison

	Synexis Sphere Rx	Molekule Air Pro (K211194)	Aerus Medical Guardian (K201220)	Discussion of Differences
510 (k) Holder	Synexis, LLC	Molekule	Aerus Medical, LLC	N/A
Device Type	Medical Ultraviolet Air purifier	Medical Ultraviolet Air purifier	Medical Ultraviolet Air purifier	None
Product Code	FRA	FRA	FRA	None
Classification Regulation	21 C.F.R. § 880.6500	21 C.F.R. § 880.6500	21 C.F.R. § 880.6500	None
Class	II	II	II	None
Patient Population	Not specified	Not specified	Not specified	None
Rx/OTC	OTC	OTC	OTC	None
User	Healthcare Professional	Healthcare Professional Lay User	Healthcare Professional	Sphere Rx and Guardian for professional use only.

	Synexis Sphere Rx	Molekule Air Pro	Aerus Medical Guardian	Discussion of Differences
Indications for Use	The Synexis Sphere Rx is a stand-alone air purifier device intended for medical purposes and is used for the reduction of bacteria and viruses in the air. The device is intended for use in professional healthcare environments. The Sphere Rx is not intended for use near HF surgical equipment or in MRI settings. The Synexis Sphere Rx demonstrated the reduction of K. aerogenes and S. epidermis bacteria, and MS2 virus, under the following exposure/working conditions: Average Net Log Reduction / Time @ High Fan Speed. Room Temperature Test Klebsiella aerogenes 4.25 / 240 mins Staphylococcus epidermidis 4.19 / 360 mins MS2 bacteriophage 4.55 / 300 mins Average Net Log Reduction / Time @ Low Fan Speed. Room Temperature Test Klebsiella aerogenes 4.25 / 240 mins Staphylococcus epidermidis 4.13 / 480 mins MS2 bacteriophage 4.11 / 480 mins	The Molekule Air Pro air purifier is a device intended for medical purposes that is used to capture 95% of particulate matter and destroy bacteria, mold, and viruses by exposure to ultraviolet radiation when operated in Auto Mode Standard or manual mode at fan speed 2 or higher. The Molekule Air Pro air purifier has been demonstrated to entrain and destroy the following bioaerosols under the following exposure/working conditions: Average Net Log Reduction / Time @ Fan Speed 6. Room Temperature Test Escherichia Coli 4.20 +/- 0.11 / 90 mins Bacillus Subtilis 4.02 +/- 0.23 / 30 mins Aspergillus Brasiliensis 4.15 ± 0.06 / 60 mins MS2 Bacteriophage 4.38 ± 0.15 / 30 mins Single Pass Mechanical Filtration Efficiency Particulate Matter 0.3 to 1.0 micron size particles 95% or greater according to ASHRAE 52.2	The Aerus Medical Guardian, model F170A is a device intended for medical purposes that is used for the reduction of staphylococcus epidermidis and erwinia herbicola bacteria, MS2 and Phi-X174 viruses and aspergillum niger fungal spores and bacillus globigii bacterial spores from the air in a temperature-controlled professional healthcare environment of 70 – 71˚F, 40 – 45% RH. The Aerus Guardian demonstrated the reduction of staphylococcus epidermidis and erwinia herbicola bacteria, MS2 and Phi-X174 viruses and aspergillum niger fungal spores and bacillus globigii bacterial spores under the following conditions: Staphylococcus epidermidis 5.95 / 60 Erwinia herbicola 5.12 / 60 MS2 5.58 / 60 Phi-X174 4.19 / 60 Aspergillus niger 4.12 / 60 Bacillus globigii 4.22 / 60	The subject and predicate devices are intended to reduce microbes in the air by exposure to ultraviolet radiation. The devices demonstrate a 4-log reduction of bacteria and viruses in the air and any minor differences in the wording of the indications for use statement do not impact the intended use of the subject device as compared to the predicate.

	Synexis Sphere Rx	Molekule Air Pro	Aerus Medical Guardian	Discussion of Differences
Environment of Use	Hospital and other healthcare setting.	Hospital and other healthcare setting. Home healthcare.	Hospital and other healthcare setting.	Sphere Rx and Guardian intended for professional use only.

	Synexis Sphere Rx	Molekule Air Pro	Aerus Medical Guardian	Discussion of Differences
Placement	The Sphere Rx can be mounted on the wall or placed on a table using the stand. The Sphere Rx is not intended for use in surgical suites or rooms with air separation devices. It is designed for rooms under 1000ft^2	Air Pro will work in any room, but giving it space in a central location, is recommended. Placement near the patient is key. It should not be used in surgical suites or in rooms with air separation devices. It is designed for rooms under 1000 ft^2.	Place the Aerus Medical Guardian in a location that allows air to move freely into, around and out of the unit. Allow minimum of 12" of clearance around intake grill (airflow input). Use in temperature-controlled professional healthcare environment of 70 – 71˚F, 40 - 45% RH. It is designed for use in 3,000 ft^3 / 8-10 ft ceilings	The Sphere Rx can be mounted on the wall or placed on a table using the stand.
User Control	Standard switch to control fan speed (low, medium, high) and basic on/off switch.	LCD screen with capacitive touchscreen interface. User Interface includes several dedicated screens for fan speed control, PM sensor readings in addition to other administrative functions. Application controls mimic device touch panel.	Device touch panel to control fan speed, on/off setting and reset control.	Sphere Rx uses standard switch for fan speed control and on/off switch with no capacitive touchscreen interface. The user controls are similar to most other devices that healthcare professionals and lay persons are accustomed to using.

	Synexis Sphere Rx	Molekule Air Pro	Aerus Medical Guardian	Discussion of Differences
Software	Basic firmware (circuit board) to turn unit on/off and change fan speed.	Basic Firmware and App used to turn the unit on, off, and change fan speed.	Basic firmware (circuit board) to turn unit on/off and change fan speed.	Sphere Rx and Guardian utilize basic firmware (circuit board) to turn the unit on/off and change fan speed.
Mechanism of Action	UV light of sufficient energy (UV-A) activates photocatalyst that reduces microorganisms in the air through a photochemical reaction.	UV light of sufficient energy (UV-A) activates photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction.	ActivePure® Cell which contains two UVGI (Ultra Violet Germicidal Irradiation) bulbs plus a TiO2 based photocatalyst reduces microorganisms in the air through a photochemical reaction.	None. The subject and predicate devices reduce microorganisms in the air through a photochemical reaction using UV light.
Installation	Wall mount or free standing	Free standing	Free standing	Sphere Rx equipped with wall mount option
Filter(s)	'Sail' Filter coated with proprietary photocatalyst. Total surface area: 22 in^2 Carbon Filter MERV11 Filter	Total Filter surface area: 1779 in^2 Filter coated with proprietary photocatalyst and a metal wire mesh MERV16	HEPA filter Multipoint ionizer Two pieces of polycarbonate honeycomb material with a combined surface area of 708 square inches, coated with a TiO2 based catalyst called ActivePure®	Subject and predicate utilize similar filters to entrain microorganisms as well as filters coated with a photocatalyst to reduce microorganisms in the air using a photochemical reaction.
Photocatalyst	Proprietary catalyst	Proprietary catalyst	Proprietary catalyst	None. Subject and predicates use titanium dioxide (TiO2) catalyst

	Synexis Sphere Rx	Molekule Air Pro	Aerus Guardian	Discussion of Differences
Light Source	UV Light Source: Custom UV-A Bulb Wavelength: 320-400 nm Total UV Power: 21 W	UV Light Source: LED Wavelength: 320-400 nm Total of 20 UV LEDs split amongst 5 PCBs (4 LEDs per PCB) Total UV Power: 16 W Filter Irradiance (Minimum): 20 W/m^2	Two 10-watt UVGI bulbs operating at a wavelength of 254nm	Sphere Rx and Air Pro use UV-A wavelength and Guardian uses UVGI.
Air Source	Centrifugal Fan	Centrifugal Fan	Centrifugal Fan	None
Flow Control	3 speeds (low, medium, high) Provide 10-30 CFM airflow rate	6 speeds (low-high) Provide 25-260 CFM airflow rate	4 speeds (low-high) Provide 90 - 300 CFM airflow rate	Air Pro and Guardian offer higher fan speeds
Device Air Changes Per Hour (ACH)	Roughly 30 CFM in a 1000 ft^2 room on high setting	Roughly 260 CFM in a 1000 ft^2 room on setting 6	Roughly 300 CFM in a 3000 ft^3 room on high setting	Air Pro and Guardian offer higher fan speeds

	Synexis Sphere Rx	Molekule Air Pro	Aerus Guardian	Discussion of Differences
UV Light Exposure Safety Features	Unit automatically turns off when door to access UV-A bulb is opened.	If a validated, serialized, Molekule filter is missing, the unit will not operate. The unit authenticates the filter via NFC, before and during operation. The purpose of this system is to protect the user from any possibility of exposure to direct contact with UV-A light that would occur without a genuine Molekule Filter being present.	Unit automatically turns off when door to access UVGI bulbs is opened.	Sphere Rx and Guardian automatically turn off when door to access bulb is opened.
Fan Exposure Safety Features	Inlet and outlet grate blocks user from accessing spinning fan. Safety feature confirmed by UL 507.	Vanes at outlet and Honeycomb inlet of fan with small enough grating to block user from accessing spinning fan without tools. Safety feature confirmed by UL 507.	Inlet and outlet grate blocks user from accessing spinning fan. Safety feature confirmed by UL 507.	None
Input Voltage	120 Volt	120 Volt	120 Volt	None

	Synexis Sphere Rx	Molekule Air Pro air purifier	Aerus Guardian	Discussion of Differences

Current	Up to 0.75 Amps	Up to 1.27 Amps	Up to 1.0 Amps	Air Pro and Guardian offer higher fan speeds
Power Consumption	Up to 90 Watts	Up to 152.8 Watts	Up to 117 Watts	Air Pro and Guardian offer higher fan speeds
Electronic Data Interface	N/A	NFC WLAN (2.4 GHZ)	N/A	Sphere Rx does not utilize electronic data interface
Dimensions	Width: 18.7 in (47.5 cm) Height: 18.7 in (47.5 cm) Depth: 7.7 in (17.8 cm)	Height: 23.11 in (587 mm) Diameter: 10.83 in (275 mm)	26.5"H x 11.5"W x 21.0"D 673mm H x 292mm W x 533mm D	The Sphere Rx is a smaller stand-alone unit that can be wall mounted or placed on a table top.
Standards	FCC Part 15 B Radio Frequency Devices UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC for Medical Devices	FCC Part 15 C Radio Frequency Devices UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC for Medical Devices	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC for Medical Devices	Sphere Rx and Air Pro comply with additional FCC standards for home health use. Although compliant with FCC standards for home health, Synexis is not seeking the home health indication in this submission.

Non-Clinical Performance Data: Non-clinical device performance testing was conducted on the subject Synexis Sphere Rx device to assess the performance and safety of the device. Performance testing was conducted in accordance with approved Synexis protocols and included the following:

- Kill kinetics testing to verify subject device achieves 4 log reduction of defined organisms
- Composition of air testing to verify subject device emissions do not exceed permissible exposure limits for seven (7) gaseous species
- Electrical safety and EMC compatibility in accordance UL 507:2017 Electric Fans and IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests, respectively.

Table 2 summarizes the performance and safety test results for the Sphere Rx device.

Table 2. Non-Clinical Results Summary

Electrical Safety and EMC	**Standard**	**Result**
Electrical Safety	UL 507:2017 Electric Fans	PASS
EMC compatibility	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests	PASS
Compound	**Exposure Limit**	**Result**
H_2O_2 gas	≤ 5.8 ppb (Tox Risk Assessment)	PASS
O_3	≤.05ppm (UL 867)	PASS
SO_2	≤ 2ppm (NIOSH)	PASS
CO	≤ 35ppm (NIOSH)	PASS
NO_2	≤ 1ppm (NIOSH)	PASS
CH_2O	≤ .016 ppm (NIOSH)	PASS
Total VOCs	≤ 1.4 ppm (EC Joint Research Report 19)	PASS
Organism Type/Name	**Average Net Log Reduction/Time @ High Fan Speed**	**Result**
Gram Negative Bacteria *K. aerogenes*	4.25 / 240m	PASS
Gram Positive Bacteria *S. epidermidis*	4.19 / 360m	PASS
Virus MS2 bacteriophage	4.55 / 300m	PASS

Organism Type/Name	Average Net Log Reduction/Time @ Low Fan Speed	Result
Gram Negative Bacteria *K. aerogenes*	4.25 / 240m	PASS
Gram Positive Bacteria *S. epidermidis*	4.13 / 480m	PASS
Virus MS2 bacteriophage	4.11 / 480m	PASS

Clinical Performance Data: Not Applicable.

Conclusion: Synexis concludes that the nonclinical tests demonstrate that the Sphere Rx air purifier is as safe, as effective, and performs as well as the legally marketed predicate device.