



May 16, 2024

HealKEE Medical Pte Ltd
% Shanshan Liu
Charles & International LLC
45 Ashford St
Allston, Massachusetts 02134

Re: K232933
Trade/Device Name: AirKEE P900
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: April 20, 2024
Received: April 22, 2024

Dear Shanshan Liu:

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.

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,

Stephen A. Anisko -S Digitally signed by
Stephen A. Anisko -S
Date: 2024.05.16
15:31:19 -04'00'

for: Christopher Dugard
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use510(k) Number (if known)
K232933Device Name
AirKEE P900**Indications for Use (Describe)**

AirKEE P900 is a medical ultraviolet air purifier intended for medical purposes to capture and destroy bacteria, mold, and viruses in the air through the multi-stage air filtration system and exposure to ultraviolet radiation.

AirKEE P900 has been demonstrated to eliminate the following test microorganisms entrained on the filter of the subject device under the following exposure conditions:

Test Item		Avg. max Log Reduction/Entrainment Time (min) (in a 20m ³ chamber)
Bacteria	Staphylococcus aureus	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Bacteria	Escherichia coli	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Bacteria	Klebsiella pneumoniae	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Bacteria	Pseudomonas aeruginosa	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Bacteria	Serratia marcescens	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Mold	Aspergillus Niger	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Virus	Influenza A virus, H1N1	Log 4 (99.99%)/60 minutes @ high fan speed
Virus	Influenza A virus, H3N3	Log 4 (99.99%)/120 minutes @ low fan speed

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

K232933 - HealKee Medical Pte Ltd

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: HealKee Medical Pte Ltd
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Date Prepared: May 1st, 2024

Trade Name: AirKEE P900

Regulation Number: 21 CFR 880.6500

Regulation Name: Medical Ultraviolet Air Purifier

Regulatory Class: Class II

Common Name: Air Purifier

Classification Name: Purifier, Air, Ultraviolet, Medical

Review Panel: General Hospital

Product Code: FRA

Predicate Device(s):

	Predicate
Trade Name	Aura Storm
510(k) Submitter / Holder	Invictus Lighting
510(k) Number	K212644
Regulation Number	21 CFR 880.6500
Classification	Class II
Classification Panel	General Hospital
Product Code	FRA

Device Description:

AirKEE P900 is a mobile multi-function medical ultraviolet air purifier. It is used to destroy bacteria in the air by exposure to ultraviolet radiation. It may be used for medical purposes which can include hospitals, medical facilities, medical clinics, nursing facilities, and dental facilities. AirKEE P900 is controlled via a touchscreen control panel on the machine.

AirKEE P900's main components consist of:

Multi-stage air treatment

- a filtration system with primary filter, HEPA filter, activated carbon filter, and nano-material filter
- UV lamps that generate UV-C irradiation to inactivate and eliminate microorganisms
- a motor/impeller to move air through the filtration system

System control

- a touch panel interface to indicate the working status of the device and consumables

AirKEE P900's multi-stage air treatment: Air enters through the bottommost chamber and fans direct the air in an upwards manner. Firstly, air passes through primary G4 filter, where large particulate matter will be removed. G4 filtered air then passes through patented nano-material filter for further removal. Microorganisms will be inactivated by UV, and photocatalysts. Air then passes through activated carbon filter. Lastly, HEPA H13 filter eliminates 99.99% of the remaining particles (0.1 microns in diameter). The treated air then exits through the top in an upwards manner.

The control panel allows reading, troubleshooting functions, and settings of various function. Its enhanced user interface with touchscreen function allows easier navigation of the system.

Indications for Use:

AirKEE P900 is a medical ultraviolet air purifier intended for medical purposes to capture and destroy bacteria, mold, and viruses in the air through the multi-stage air filtration system and exposure to ultraviolet radiation.

AirKEE P900 has been demonstrated to eliminate the following test microorganisms entrained on the filter of the subject device under the following exposure conditions:

Test Item		Avg. max Log Reduction/Entrainment Time (min) (in a 20m ³ chamber)
Bacteria	Staphylococcus aureus	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Bacteria	Escherichia coli	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Bacteria	Klebsiella pneumoniae	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Bacteria	Pseudomonas aeruginosa	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Bacteria	Serratia marcescens	Log 4 (99.99%)/60 minutes @ high fan speed Log 4 (99.99%)/120 minutes @ low fan speed
Mold	Aspergillus Niger	Log 4 (99.99%)/60 minutes @ high fan speed

		Log 4 (99.99%)/120 minutes @ low fan speed
Virus	Influenza A virus, H1N1	Log 4 (99.99%)/60 minutes @ high fan speed
Virus	Influenza A virus, H3N3	Log 4 (99.99%)/120 minutes @ low fan speed

Comparison of Technological Characteristics with Predicate Device:

Item	AirKEE P900 <i>Subject Device</i>	Aura Storm (K212644) <i>Predicate</i>	Comparison
Device Type	Medical Ultraviolet Air Purifier	Medical Ultraviolet Air Purifier	Identical
Product Code	FRA	FRA	Identical
Classification Regulation	21 CFR 880.6500	21 CFR 880.6500	Identical
Class	II	II	Identical
Rx/OTC	OTC	OTC	Identical
Indications for Use	AirKEE P900 is a medical ultraviolet air purifier intended for medical purposes to capture and destroy bacteria, mold, and viruses in the air through the multi-stage air filtration system and exposure to ultraviolet radiation. AirKEE P900 has been demonstrated to eliminate the following test microorganisms entrained on the filter of the subject device under the following exposure conditions: Staphylococcus aureus Log 4 (99.99%)/ 60 minutes at high fan speed / 120 minutes at low fan speed; Escherichia coli Log 4 (99.99%)/60 minutes at high fan speed / 120 minutes at low fan speed; Klebsiella pneumoniae Log 4 (99.99%)/ 60 minutes at high fan speed / 120 minutes at low fan speed; Pseudomonas aeruginosa	The Aura Storm air purifier is a device intended for medical purposes that is used to capture and destroy bacteria and viruses in the air through the multi-stage filtration system and exposure to ultraviolet radiation. The Aura Storm air purifier has been demonstrated to destroy the following bacteria: Staphylococcus albicans, Staphylococcus aureus, and Escherichia Coli; and virus: A/PR8/34 H1N1 virus entrained on the filter of the subject device under the following exposure conditions: Average Maximum log reduction / entrainment time (minutes) at Fan Speed 4. Room Temperature test: Log 4 (99.99%) / 60 minutes. Average Maximum log	Similar The Indications for use of the devices are identical. The devices have different performance metrics for the chosen microorganisms.

	Log 4 (99.99%)/ 60 minutes at high fan speed / 120 minutes at low fan speed; Serratia marcescens Log 4 (99.99%)/60 minutes at high fan speed / 120 minutes at low fan speed; Aspergillus Niger Log 4 (99.99%)/ 60 minutes at high fan speed / 120 minutes at low fan speed; Influenza A virus, H1N1 Log 4 (99.99%)/ 60 minutes at high fan speed Influenza A virus, H3N3 Log 4 (99.99%)/ 120 minutes at low fan speed	reduction / entrainment time (minutes) at Fan Speed 1. Room Temperature test: Log 4 (99.99%) / 120 minutes.	
User	Healthcare Professional Lay User	Healthcare Professional Lay User	Identical
Environment for Use	Hospitals, medical facilities, medical clinics, nursing facilities, and dental facilities.	Hospitals, medical facilities, medical clinics, nursing facilities, and dental facilities.	Identical
Placement	AirKEE P900 can be placed anywhere in a room for general air treatment. AirKEE P900 is designed for rooms up to 3000 ft³.	Aura Storm is designed for rooms up to 2773 square feet.	Similar
User Control	Touch panel with selection of operating mode (Manual, Silent), 3 fan speeds, UV lamp on/off, medical lighting on/off.	Touch panel with 4 manual fan settings, automode, UV Lamp on/off, Anion on/off, lock and timer.	Similar

Software	Basic Firmware; used to turn the unit on, off, change fan speed, and other administrative functions (timer, UV)	Basic Firmware, used to turn the unit on, off, and change fan speed.	Similar
Mechanism of Action	UV light of sufficient energy (UV-C) activates a TiO ₂ lined photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction, plus the addition of a pre-filter, activated carbon and patented nano-material filter, and HEPA filter.	UV light of sufficient energy (UV-C) activates a TiO ₂ lined photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction, plus the addition of a pre-filter and HEPA filter.	Identical
-Installation	Free standing	Free standing	Identical
Filter	<u>Primary Filter</u> - G4 filter to trap larger particles <u>HEPA Filter</u> - HEPA (H13) filter eliminates 99.99% of particles 0.1 microns in diameter <u>Activated Carbon and Patented Nanomaterial Filter</u>	<u>Pre-Filter</u> - Synthetic screen mesh type added prior to HEPA - Designed to trap larger particles and keep them out of the HEPA - Dimensions: 14 in x 15 in x 0.125 in <u>HEPA Filter</u> - MERV 13 - Dimensions: 14 in x 15 in x 0.6875 in <u>Catalytic Filter</u> - Patent Pending Hybrid Oxydizer with proprietary Dualaction Catalyst <u>Carbon/Cold Catalyst Oxidier Filter</u> - Dimensions: 14' x 15" x 0.625"	Similar
Photocatalyst	Titanium Dioxide	Proprietary Catalyst	Similar
Light Source	- UV Type: UV-C - UV Light Source: LED	- UV-C Light Source: LED - Wavelength: 253.7nm	Identical

	- Wavelength: 254.7nm - Total of 36 6W ultraviolet tubes with single light intensity of $92\mu\text{W}/\text{cm}^2$ - Total light intensity: $552\mu\text{W}/\text{cm}^2$	- Total of 2 UV- C tube lamps (1 per side) - Total UV Power: 8.0 W	
Air Source	Centrifugal Fan	Centrifugal Fan	Identical
Flow Control	Three speeds (low, medium, high)	4 speeds (low, medium, high, boost) and auto mode provide up to 370 CFM	Similar
Device Air Changes Per Hour (ACH)	13 ACH on high fan speed in a 3000 ft ³ room	5.5 ACH on high fan speed (speed 4), in a 4000 ft ³ room	Similar
Fan Exposure Safety Features	Non-removable grill at air output to prevent the user from accessing spinning fan without tools. Safety feature confirmed by UL 507.	Non-removable grill at air output and the switch safety feature at the inlet prevent the user from accessing spinning fan without tools. Safety feature confirmed by ETL tested to UL 507.	Similar
UV Light Exposure Safety Features	Touchscreen monitor allows user to switch off the UV lights prior to opening filter doors. Besides, UV lights are also located at the inner side of the machine which prevents direct UV exposure.	There are two sets of Safety switches on the Aura Storm. The first is on both outer doors where the magnetic switch will disengage and the unit will not turn on. A secondary switch in the Aura Storm filter and if the filter is either improperly installed or the filter is missing, the unit will not operate. The unit will not operate with a generic filter and an Invictus filter must be used for the system to work. These switches have been designed to protect the user from any possibility of exposure to direct contact with UV light. Safety feature confirmed by ETL to UL 507 safety standard.	Similar
Input Voltage	110V $\pm$ 10%	120 V	Identical
Current	3.6 Amps	0.55 Amps	Similar

Power Consumption	783W ±5W	Up to 65 W	Similar
Dimensions	<u>Unit dimension:</u> 16.8”W x 26.4”L x 80.7”H <u>HEPA Filter (cylindrical):</u> 9.8” diameter x 10.0”H <u>Primary Filter:</u> 23.0”x 6.6” x 1.2” <u>Activated Carbon / Nanomaterial Filter:</u> 23.4” x 10.7” x 1.1”	<u>Outer frame dimensions:</u> 23in(H) x 18.2in(W) x 10.6in(L) <u>Filter dimensions:</u> <u>Pre-Filter:</u> 14 in x 15 in x 0.125 in <u>HEPA Filter:</u> 14 in x 15 in x 0.6875 in <u>Catalytic Filter:</u> 14 in x 15 in x 0.1875 in <u>Carbon/Cold Catalyst</u> <u>Oxidizer Filter:</u> 14 in x 15in x 0.625 in	Similar
Conformance with Standards	UL 507 Standard for Electrical Fans IEC 60601-1 Basic Safety and Essential Performance IEC 60601-1-2 EMC. EMC for Medical Devices IEST-RP-CC001.6 HEPA and ULPA Filters	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC EMC for Medical Devices	Similar
Device Performance microorganism	AirKEE P900 has been demonstrated to eliminate the following test microorganisms entrained on the filter of the subject device under the following exposure conditions: Staphylococcus aureus Log 4 (99.99%)/ 60 minutes at high fan speed / 120 minutes at low fan speed;	The Aura Storm air purifier has been demonstrated to destroy the following bacteria: Staphylococcus albicans, Staphylococcus aureus, and Escherichia Coli; and virus: A/PR8/34 H1N1 virus entrained on the filter of the	Similar

	Escherichia coli Log 4 (99.99%)/60 minutes at high fan speed / 120 minutes at low fan speed; Klebsiella pneumoniae Log 4 (99.99%)/ 60 minutes at high fan speed / 120 minutes at low fan speed; Pseudomonas aeruginosa Log 4 (99.99%)/ 60 minutes at high fan speed / 120 minutes at low fan speed; Serratia marcescens Log 4 (99.99%)/60 minutes at high fan speed / 120 minutes at low fan speed; Aspergillus Niger Log 4 (99.99%)/ 60 minutes at high fan speed / 120 minutes at low fan speed; Influenza A virus, H1N1 Log 4 (99.99%)/ 60 minutes at high fan speed Influenza A virus, H3N3 Log 4 (99.99%)/ 120 minutes at low fan speed	subject device under the following exposure conditions: Average Maximum log reduction / entrainment time (minutes) at Fan Speed 4. Room Temperature test: Log 4 (99.99%) / 60 minutes. Average Maximum log reduction / entrainment time (minutes) at Fan Speed 1. Room Temperature test: Log 4 (99.99%) / 120 minutes.	
Device Performance Electrical and EMC	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices IEST-RP-CC001.6 HEPA and ULPA Filters	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices. ISO 29463 H13 ISO 35H Filtration testing	Similar
Device Performance Ozone release level	UL 867 - Electrostatic Air Cleaners	Unknown, not mentioned	Different AirKEE P900 has done additional

			ozone testing to demonstrate the AirKEE P900 unit is able to operate at less than 0.05 ppm at its highest fan speed.
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Summary of Non-Clinical Tests

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Microorganism Performance	Internal Standards	To understand the log reduction rate for Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Serratia marcescens, Aspergillus Niger, and Influenza A virus.	4 Log reduction (99.99%)	4 Log reduction in 60 minutes at high fan speed; and 4 Log reduction in 120 minutes at low fan speed.
Fractional Efficiency	IEST-RP-CC001.6-HEPA and ULPA Filters	Fractional efficiency testing was performed on the AirKEE filter per IEST-RP-CC001.6 Type H test to determine the fractional efficiency percentage of varying size ranges.	Per Standard particles	Filter fractional efficiency percentage of 99.99% at 0.1-0.2µm.
Electrical safety and electromagnetic compatibility testing	UL 507 Standard for Electrical Fans IEC 60601-1-2 EMC. EMC for Medical Devices	General requirements for basic safety and essential performance including UV light leakage and intensity	Per Standard	Pass
Ozone	UL 867 - Electrostatic Air Cleaners	Ozone testing was performed per UL 867 by monitoring the ozone concentration in a test	Per Standard	Testing demonstrates the AirKEE P900 unit is able to

		chamber at the highest fan speed.		operate at less than 0.05 ppm at its highest fan speed.
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Conclusion

The conclusions drawn from the non-clinical testing demonstrate that the subject device, AirKEE P900 is as safe, as effective, and performs as well as or better than the legally marketed predicate, K212644 Class II (21 CFR 880.6500), product code FRA.