May 23, 2024

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

Re: K232642
Trade/Device Name: AirKEE T900
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: April 17, 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: 2024.05.23 20:55:02 -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

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)*
K232642

Device Name
AirKEE T900

Indications for Use *(Describe)*
AirKEE T900 is a medical ultraviolet air purifier intended for medical purposes to capture and destroy bacterial, mold, and viruses in the air through the multi-stage air filtration system and exposure to ultraviolet radiation.

AirKEE T900 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) Room Temperature Test |
|---|---|---|
| Bacteria | Staphylococcus albus | Log 4 (99.99%)/60 minutes @ high fan speed<br>Log 4 (99.99%)/120 minutes @ low fan speed |
| Bacteria | Escherichia coli | Log 4 (99.99%)/60 minutes @ high fan speed<br>Log 4 (99.99%)/120 minutes @ low fan speed |
| Mold | Penicillium rocqueforti | Log 4 (99.99%)/60 minutes @ high fan speed |
| Mold | Aspergillus Niger | 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, H3N2 | 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K232642 - 510(k) Summary

## HealKEE Medical Pte Ltd

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


**Submitter:** HealKEE Medical Pte Ltd
11 North Buona Vista Drive, Level 08-09
The Metropolis Tower 2, Singapore 138589

**Primary Contact:** Shanshan Liu, Consultant
Charles & International LLC
Email: sliu@charlieintl.com
Phone: 617-893-3456

**Company Contact:** William Tao
Title: Founder & CEO
Email: william.tao@healkee.com
Phone: +65 6808 7770


**Date Prepared:** May 21st, 2024

**Trade Name:** AirKEE T900

**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 T900 is a mobile 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 T900 is controlled via a touchscreen control panel on the machine.

AirKEE T900's main components consist of:
Multi-stage air treatment

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

System control

- an electronic control system to power and control the device
- a touch panel interface to indicate the working status of the device and consumables

AirKEE T900's multi-stage air treatment: Air enters through the bottommost chamber and passes through primary G4 filter, where large particulate matter will be removed. G4 filtered air then passes through modified activated carbon and patented nano-material filter for further removal. Microorganisms will be inactivated by UV, and photocatalysts. Lastly, HEPA H14 filter eliminates 99.99% of the remaining particles (0.1 microns in diameter). The treated air then exits through the top of the machine.

The touch 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 T900 is a medical ultraviolet air purifier intended for medical purposes to capture and destroy bacterial, mold, and viruses in the air through the multi-stage air filtration system and exposure to ultraviolet radiation.

AirKEE T900 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) Room Temperature Test** |
|---|---|---|
| Bacteria | Staphylococcus albus | Log 4 ( 99.99%)/60 minutes @ high fan speed<br>Log 4 ( 99.99%)/120 minutes @ low fan speed |
| Bacteria | Escherichia coli | Log 4 ( 99.99%)/60 minutes @ high fan speed<br>Log 4 ( 99.99%)/120 minutes @ low fan speed |
| Mold | Penicillium rocqueforti | Log 4 ( 99.99%)/60 minutes @ high fan speed |
| Mold | Aspergillus Niger | 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, H3N2 | Log 4 ( 99.99%)/120 minutes @ low fan speed |

**Comparison of Technological Characteristics with Predicate Device:**

| Item | **AirKEE T900**<br>(K232642)<br>*Subject Device* | **Aura Storm**<br>(K212644)<br>*Predicate* | **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 T900 is a medical ultraviolet air purifier intended for medical purposes to capture and destroy bacterial, mold, and viruses in the air through the multi-stage air filtration system and exposure to ultraviolet radiation.<br><br>AirKEE T900 has been demonstrated to eliminate the following test microorganisms entrained on the filter of the subject device under the following exposure conditions:<br><br>Staphylococcus albus<br>Log 4 (99.99%)/ 60 minutes at high fan speed/ 120 minutes at low fan speed;<br>Escherichia coli<br>Log 4 (99.99%)/ 60 minutes at high fan speed/ 120 minutes at low fan speed;<br>Penicillium rocqueforti<br>Log 4 (99.99%)/ 60 minutes at fan high speed; | 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.<br><br>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**<br>The Indications for use of the devices are identical. The devices have different performance metrics for the chosen microorganisms. |

| | | | |
|---|---|---|---|
| | Aspergillus Niger<br>Log 4 (99.99%)/ 120 minutes at low fan speed;<br>Influenza A virus, H1N1<br>Log 4 (99.99%)/ 60 minutes at high fan speed<br>Influenza A virus, H3N2<br>Log 4 (99.99%)/ 120 minutes at low fan speed | reduction / entrainment time (minutes) at Fan Speed 1. Room Temperature test:<br>Log 4<br>(99.99%) / 120 minutes. | |
| **User** | Healthcare Professional<br>Lay User | Healthcare Professional<br>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 T900 can be placed anywhere in a room for general air treatment.<br><br>AirKEE T900 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 TiO2 lined photocatalyst that destroys microorganisms entrained on the | UV light of sufficient energy (UV-C) activates a TiO2 lined photocatalyst that destroys microorganisms entrained on the | **Identical** |

| | | | |
|---|---|---|---|
| | filter through a photochemical reaction, plus the addition of a pre-filter, activated carbon and patented nano-material filter, and HEPA filter. | filter through a photochemical reaction, plus the addition of a pre-filter and HEPA filter. | |
| **-Installation** | Free standing | Free standing | **Identical** |
| **Filter** | <u>Primary Filter</u><br>• G4 filter to trap larger particles<br><u>HEPA Filter</u><br>• Double cylindrical design HEPA (H14) filter eliminates 99.99% of particles 0.1 microns in diameter<br><u>Activated Carbon and Patented Nanomaterial Filter</u> | <u>Pre-Filter</u><br>• Synthetic screen mesh type added prior to HEPA<br>• Designed to trap larger particles and keep them out of the HEPA<br>• Dimensions: 14 in x 15 in x 0.125 in<br><u>HEPA Filter</u><br>• MERV 13<br>• Dimensions: 14 in x 15 in x 0.6875 in<br><u>Catalytic Filter</u><br>• Patent Pending Hybrid Oxydizer with proprietary Dualaction Catalyst<br><u>Carbon/Cold Catalyst Oxidier Filter</u><br>• Dimensions: 14' x 15" x 0.625" | **Similar** |
| **Photocatalyst** | Titanium Dioxide | Proprietary Catalyst | **Similar** |
| **Light Source** | • UV Type: UV-C<br>• UV Light Source: LED<br>• Wavelength: 254.7nm<br>• Total of 36 6W ultraviolet tubes with single light intensity of 92μW/cm$^2$<br>• Total light intensity: 552μW/cm$^2$ | • UV-C Light Source: LED<br>• Wavelength: 253.7nm<br>• Total of 2 UV- C tube lamps (1 per side)<br>• Total UV Power: 8.0 W | **Identical** |
| **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 ft3 room | 5.5 ACH on high fan speed (speed 4), in a 4000 ft3 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 ±10% | 120 V | **Identical** |
| **Current** | 3.6 Amps | 0.55 Amps | **Similar** |
| **Power Consumption** | 783W ±5W | Up to 65 W | **Similar** |
| **Dimensions** | Unit dimension:<br>16.8”W x 26.4”L x 80.7”H<br>HEPA Filter (cylindrincal):<br>9.8” diameter x 10.0”H<br>Primary Filter:<br>23.0”x 6.6” x 1.2” | Outer frame dimensions:<br>23in(H) x 18.2in(W) x 10.6in(L)<br>Filter dimensions:<br>Pre-Filter:<br>14 in x 15 in x 0.125 in<br>HEPA Filter: | **Similar** |

| | | | |
|---|---|---|---|
| | Activated Carbon / Nanomaterial Filter:<br>23.4" x 10.7" x 1.1" | 14 in x 15 in x 0.6875 in<br>Catalytic Filter:<br>14 in x 15 in x 0.1875 in<br>Carbon/Cold Catalyst<br>Oxidizer Filter:<br>14 in x 15in x 0.625 in | |
| **Conformance with Standards** | UL 507 Standard for Electrical Fans<br><br>IEC 60601-1 Basic Safety and Essential Performance<br><br>IEC 60601-1-2 EMC. EMC for Medical Devices<br><br>IEST-RP-CC001.6 HEPA and ULPA Filters | UL 507 Standard for Electrical Fans<br><br>IEC 60601-1-2 EMC EMC for Medical Devices | **Similar** |
| **Device Performance microorganism** | AirKEE T900 has been demonstrated to eliminate the following test microorganisms entrained on the filter of the subject device under the following exposure conditions:<br><br>Staphylococcus albus<br>Log 4 (99.99%)/ 60 minutes at high fan speed/ 120 minutes at low fan speed;<br>Escherichia coli<br>Log 4 (99.99%)/ 60 minutes at high fan speed/ 120 minutes at low fan speed;<br>Penicillium rocqueforti<br>Log 4 (99.99%)/ 60 minutes at fan high 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 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** |

| | | | |
|---|---|---|---|
| | Aspergillus Niger<br>Log 4 (99.99%)/ 120 minutes at low fan speed;<br>Influenza A virus, H1N1<br>Log 4 (99.99%)/ 60 minutes at high fan speed<br>Influenza A virus, H3N2<br>Log 4 (99.99%)/ 120 minutes at low fan speed | reduction / entrainment time (minutes) at Fan Speed 1. Room Temperature test:<br>Log 4<br>(99.99%) / 120 minutes. | |
| **Device Performance Electrical and EMC** | UL 507 Standard for Electrical Fans<br><br>IEC 60601-1-2 EMC. EMC for Medical Devices<br><br>IEST-RP-CC001.6 HEPA and ULPA Filters | UL 507 Standard for Electrical Fans<br><br>IEC 60601-1-2 EMC.<br>EMC for Medical Devices.<br><br>ISO 29463 H13 ISO 35H Filtration testing | **Similar** |
| **Device Performance Ozone release level** | UL 867 - Electrostatic Air Cleaners | Unknown, not mentioned | **Different**<br>AirKEE T900 has done additional ozone testing to demonstrate the AirKEE T900 unit is able to operate at less than 0.05 ppm at its highest fan speed. |

**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 albus, Escherichia coli, Penicillium rocqueforti, 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<br>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 chamber at the highest fan speed. | Per Standard | Testing demonstrates the AirKEE T900 unit is able to operate at less than 0.05 ppm at its highest fan speed. |

**Conclusion**

The conclusions drawn from the non-clinical testing demonstrate that the subject device, AirKEE T900 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.