# FDA Clearance

**The device is a mobile air cleaner intended to be used to remove particles from the air for medical purposes. The device has been demonstrated to effectively inactivate H3N2 and reduce Staphylococcus albus by 4 log with L4 speed.**

# Reports & Certificates

## Airdog X5

Silicon Valley Air Expert Inc.

November 22, 2022

Beiang Air Tech LTD.
℅ Tyra Chiu
Regulatory Specialist
Medical Wizdom, LLC
12F.-4, No. 81, Sec. 2, Chang'an E. Rd., Zhongshan Dist.
Taipei, 10491
Taiwan

Re: K211507
Trade/Device Name: Airdog X5 Recirculating Air Cleaner (model KJ300F-X5)
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical recirculating air cleaner
Regulatory Class: Class II
Product Code: FRF
Dated: October 21, 2022
Received: October 21, 2022

Dear Tyra Chiu:

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, 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)*
K211507

Device Name
Airdog X5 Recirculating Air Cleaner (model KJ300F-X5)

Indications for Use *(Describe)*
The Airdog is a mobile air cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for indoor use only.
The Airdog has been demonstrated to effectively inactivate H3N2 and reduce Staphylococcus albus by 4 log with L4 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

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|---|---|
| **Date** | November 22, 2022 |
| **Manufacturer/ 510(k) Owner** | BeiAng Air Tech Ltd.<br>175#, SONGBEI ROAD, SUZHOU INDUSTRIAL PARK, JIANGSU PROVINCE, 215000, CHINA |
| **Contact Person** | Yan Zhang<br>Phone: +86-19951234257<br>E-mail: yan@beiantech.com |
| **Device Trade Name** | Airdog X5 Recirculating Air Cleaner (model KJ300F-X5) |
| **Common Name** | Medical Recirculating Air Cleaner |
| **Classification Name** | Cleaner, Air, Medical Recirculating |
| **Device Class** | II |
| **Review Panel** | General Hospital |
| **Regelation Number** | 880.5045 |
| **Product Code** | FRF |

**Device Description and Technology Characteristics**

The Airdog X5 Recirculating Air Cleaner is a floor-standing air cleaner with an air quality sensor. The air from the room enters the X5 and passes a pre-filter, ionization frame, ionization field, collecting plates and carbon layer that captures particular matter and virus from the air. The X5 contains multiple PCB modules, air quality sensor, device status indicators, power switch and a display panel, it allows user to select between different operation parameter, including auto-mode, sleep mode and wind speed. The Ionization Wireframe and the Collecting Plate can be cleaned routinely and are reusable. X5 is powered from an AC wall outlet. It is intended to be used indoors only.

**Models** KJ300F-X5

**Indications for Use** The Airdog is a mobile air cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for indoor use only.
The Airdog has been demonstrated to effectively inactivate *H3N2* and reduce *Staphylococcus albus* by 4 log with L4 speed.

**Predicate Device(s)** K200321
Novaerus NV1050/ Novaerus US Inc

## Summary of Comparison and Technological Characteristics

| | Proposed Device | Predicate Device | Comparison |
|---|---|---|---|
| **Device Name** | Airdog X5 Recirculating Air Cleaner(model KJ300F-X5) | Novaerus NV1050 | - |
| 510(k) # | K211507 | K200321 | - |
| Applicant | BeiAng Air Tech Ltd. | Novaerus US Inc | - |
| Product code | FRF (21 CFR 880.5045) | FRF (21 CFR 880.5045) | Same |
| Classification | II | II | Same |
| OTC use | YES | YES | Same |
| Intended Use | The Airdog is a mobile air cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for indoor use only.<br>The Airdog has been demonstrated to effectively inactivate H3N2 and reduce Staphylococcus albus by 4 log with L4 speed. | The Novaerus NV 1050 is intended as a room recirculating air cleaner. The system is used for filtering out and inactivating airborne particles form the air for medical purpose | Same.<br>Both devices are room recirculating air cleaners for medical purpose. |
| Use Environment | Indoor | Indoor | Same |

| | | | |
|---|---|---|---|
| Technology | Air from the room is passed through a plasma ion field to neutralize airborne micro-organisms. A negative charged dust collecting electrode traps the resulting debris and a third carbon stage absorbs any ozone generated as a byproduct. (ETL test results also show that even if the carbon net is removed, the ozone is lower than the regulatory requirements) | 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 | Similar. Both have the plasma filed and carbon filter. The predicate device use HEPA filter to traps the resulting debris while the subject device uses a negative charged dust collecting electrode. |
| Power Source | 100-240V~50-60Hz | 110V AC | Different |
| Weight(kg) | 10.7 | 51 | Different |
| Dimension | 25.59 inch (H)* 12.04 inch (W) *12.44 inch (L) | 36.5 inch (H) x 19.0 inch (W) x 19.1inch (L) | Different |
| Reduction of biological agents | H3N2 Influenza virus inactivating by 99.99% with operation with L4 speed Staphylococcus albus reduced by 99.99% in 1 hour | 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 | Similar. Both are capable of reducing specified biological agents by 4 log. |
| Filtration of particles | produces a 4 log reduction in $PM_{2.5}$ particles in 120 minutes in a 30 $m^3$ chamber | 4 log reduction in 0.5 to 2.0 µm sized particles in 10 minutes in a 580ft3 (16.4m3) sealed room | Similar. Both are capable of reducing particles by 4 log |
| Ozone emitted | Meet the requirements of ul867 (<50ppb) for ozone and USA CRB | below 10 ppb | Similar. Both <50ppb |
| Standards used | IEC 60601-1: 2005/A1:2012<br>IEC 60601-1-2: 2014<br>IEC 62304 ed.1.1<br>ISO 14971 | IEC 60601-1: 2005/A1:2012 | Different. |

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| **Discussion on Performance Data Non-Clinical Tests** | Bench tests show that the X5 produces 4-log reduction of particles, 4-log elimination ratio of total bacteria counts, a 4-log inactivation in H3N2 Influenza virus and produce ozone emission which meets the requirements of ul867 for ozone and USA CRB.<br><br>Software verification and validation 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." |
| **Discussion on Clinical Test Performed** | Not applicable |
| **Conclusion** | 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. |