June 14, 2024

Suzhou Beiang Smart Technology Co., Ltd.
% Chung Lun Chen
Regulatory Consultant
Lexnovia Venture Studio Ltd.
1F, No. 10, Lane 10, Section 3, Zhongxiao E. Road
Da'an District
Taipei, 106083
Taiwan

Re: K240696
Trade/Device Name: Airdog X8 Air Purifier (KJ800F-X8)
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: FRF
Dated: May 16, 2024
Received: May 16, 2024

Dear Chung Lun Chen:

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240696

Device Name
Airdog X8 Air Purifier (KJ800F-X8)

Indications for Use *(Describe)*

The Airdog X8 Air Purifier 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 X8 has been demonstrated to effectively inactivate H3N2 and reduce Staphylococcus albus by 4 log with L5 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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K240696 510(k) Summary

Date	Mar 14, 2024
Manufacturer/ 510(k) Owner	Suzhou Beiang Smart Technology Co., Ltd. 175#, SONGBEI ROAD, SUZHOU INDUSTRIAL PARK, JIANGSU PROVINCE, 215000, CHINA
Contact Person	Yan Zhang Phone: +86-18626114866 E-mail: yan@beiantech.com
Device Trade Name	Airdog X8 Air Purifier (KJ800F-X8)
Common Name	Air Purifier/ 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 X8 Air Purifier (X8) is a mobile air cleaner. The air from the room enters the X8 and passes a pre-filter, ionization frame, ionization field, collecting plates and carbon filter that captures particular matter and biological agents from the air. The X8 contains multiple PCB modules, device status indicators, power switch and a display panel, it allows user to select between different operation parameters, including auto-mode, sleep mode and wind speed.

The Ionization wireframe and the collecting plate can be cleaned routinely and are reusable. X8 is powered from an AC wall outlet. It is intended to be used indoors only. The device is not intended to be connected to other instruments or medical devices.

Models

KJ800F-X8

Indications for Use

The Airdog X8 Air Purifier 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 X8 Air Purifier has been demonstrated to effectively inactivate H3N2 and reduce Staphylococcus albus by 4 log with L5 speed.

Predicate Device(s) K211507
Airdog X5 Recirculating Air Cleaner (model KJ300F-X5)/ BeiAng Air Tech Ltd.

Summary of Comparison and Technological Characteristics

	Proposed Device	Predicate Device	Comparison
Device Name	**Airdog X8 Air Purifier**	**Airdog X5 Recirculating Air Cleaner (model KJ300F-X5)**	-
510(k) #	K240696	K211507	-
Applicant	Suzhou Beiang Smart Technology Co., Ltd.	BeiAng Air Tech Ltd.	Same
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 X8 Air Purifier 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 X8 has been demonstrated to effectively inactivate H3N2 and reduce Staphylococcus albus by 4 log with L5 speed.	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.	Same. 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-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)	Same
Power Source	100-240V~50-60Hz	100-240V~50-60Hz	Same
Weight(kg)	19.7	10.7	Different
Dimension	29.92 inch (H) x 14.96 inch (W) x 14.96 inch (L)	25.59 inch (H) x 12.04 inch (W) x 12.44 inch (L)	Different
Reduction of biological agents	H3N2 Influenza virus reduced by 99.99% with operation with L5 speed	H3N2 Influenza virus reduced by 99.99% with operation with L4 speed	Similar
Filtration of particles	Produces a 4-log reduction in PM2.5 particles in 120 minutes in a $30m^3$ chamber	Produces a 4-log reduction in PM2.5 particles in 120 minutes in a $30m^3$ chamber	Same
Ozone emitted	Meet the requirements of UL867(<50ppb) for ozone and USA CRB	Meet the requirements of UL 867(<50ppb) for ozone and USA CRB	Same
Standards used	ANSI C.63.18: 2014 IEC 62304 ed.1.1 ISO 14971 UL 867:2011 Ed.5 CSA C22.2#187:2020 Ed.5 FCC Part 15 Subpart B ICES-003 Issue 7: 2020 IEC 60335-2-65	IEC 60601-1: 2005/A1:2012 ANSI C.63.18: 2014 IEC 62304 ed.1.1 ISO 14971	Different

Discussion on Performance Data Non-Clinical Tests	Bench tests show that the X8 produces 4-log reduction of particles, 4-log elimination ratio of total bacteria counts, a 4-log reduction in H3N2 Influenza virus and produce ozone emission which meets the requirements of UL867 for ozone and USA CRB. Software verification and validation testing were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Pre-market Submission 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 the legally marketed predicate device(s).