

K232933 AirKEE P900May 16, 2024
239 days to decisionK232933 · Product code: **FRA** · General Hospital
Source: <https://www.510kdatabase.net/k232933/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	Sep 20, 2023
Decision date	May 16, 2024
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Healkee Medical Pte, Ltd.
Location	Singapore, SG
Contact	William Tao
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Charles & International, LLC
Contact	Shanshan Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232933/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026