

K213753 PurgoJun 1, 2022
183 days to decisionK213753 · Product code: **FRA** · General Hospital
Source: <https://www.510kdatabase.net/k213753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	Nov 30, 2021
Decision date	Jun 1, 2022
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aeroclean Technologies, LLC
Location	Palm Beach Gardens, FL, US
Contact	Riachard Foster
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	MethodSense, Inc.
Contact	Rita King

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213753/> 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 27, 2026