

K203189 AEROCURE-MDJan 21, 2021
86 days to decisionK203189 · Product code: **FRA** · General Hospital
Source: <https://www.510kdatabase.net/k203189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	Oct 27, 2020
Decision date	Jan 21, 2021
Days to decision	86 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aerobiotix, Inc.
Location	Miamisburg, OH, US
Contact	David Kirschman
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Accelerated Device Approval Services
Contact	Rafael Aguila

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

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