

**K211194 Molekule Air Pro**Aug 20, 2021  
121 days to decisionK211194 · Product code: **FRA** · General Hospital  
Source: <https://www.510kdatabase.net/k211194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	Apr 21, 2021
Decision date	Aug 20, 2021
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Molekule, Inc.</b>
Location	San Francisco, CA, US
Contact	Frank Bianco
510(k) history	3 submissions · 3 cleared · 2020-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hymann, Phelps, &amp; Mcnamara P.C.</b>
Contact	Adrienne R. Lenz

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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