FDA 510(k) Premarket Notification

K202339 Molekule Air Mini, Molekule Air Mini +

CLEARED

Feb 23, 2021
190 days to decision

K202339 · Product code: **FRA** · General Hospital
Source: https://www.510kdatabase.net/k202339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	Aug 17, 2020
Decision date	Feb 23, 2021
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hyman, Phelps & McNamara, P.C.**
Contact	Adrienne R. Lenz

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