

**K211139 CUBE Air Purifier**Nov 26, 2021  
224 days to decisionK211139 · Product code: **FRA** · General Hospital  
Source: <https://www.510kdatabase.net/k211139/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	Apr 16, 2021
Decision date	Nov 26, 2021
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Samsung Electronics Co., Ltd.</b>
Location	Echo, OR, US
Contact	Hana Jung
Website	<a href="http://www.samsung.com">http://www.samsung.com</a>
510(k) history	40 submissions · 39 cleared · 2013-2024

Samsung Electronics Co., Ltd. is a South Korean multinational electronics corporation headquartered in Suwon. The company maintains a regulatory presence in the United States through its Echo, US location. Samsung has submitted total applications for FDA 510(k) clearance and received clearances. The company's regulatory focus centers on Radiology devices, which represent 83% of submissions. Samsung's FDA 510(k) clearance history spans from 2013 to 2024, with recent clearances demonstrating continued regulatory activity in medical imaging and cardiovascular monitoring tech...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdlab, Inc.</b>
Contact	Kyoungju Kim

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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k211139/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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