

K250650 SpotLight / SpotLight Duo with Low Dose Lung Cancer Screening OptionApr 15, 2025
42 days to decisionK250650 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k250650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Mar 4, 2025
Decision date	Apr 15, 2025
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arineta , Ltd.
Location	Caesarea, IL
Contact	Yaara Tirosh-Kamienchick
510(k) history	5 submissions · 5 cleared · 2016-2025

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