

K230370 SpotLight/SpotLight Duo (with DLIR option)Oct 13, 2023
245 days to decisionK230370 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k230370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Feb 10, 2023
Decision date	Oct 13, 2023
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John Smith

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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