

**K252421 JLK-NCCT**Mar 24, 2026  
235 days to decisionK252421 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k252421/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Aug 1, 2025
Decision date	Mar 24, 2026
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>JLK, Inc.</b>
Location	Seoul, KR
Contact	Dongmin Kim
510(k) history	8 submissions · 8 cleared · 2024-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells</b>
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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