FDA 510(k) Premarket Notification

K250348 JLK-AILink

CLEARED

Feb 25, 2025
19 days to decision

K250348 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k250348/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 6, 2025
Decision date	Feb 25, 2025
Days to decision	19 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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