FDA 510(k) Premarket Notification

K243363 JLK-ICH

CLEARED

Jan 3, 2025
66 days to decision

K243363 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k243363/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Oct 29, 2024
Decision date	Jan 3, 2025
Days to decision	66 days
Third-party review	No
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	**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