FDA 510(k) Premarket Notification

K242709 JLK-PWI

CLEARED

Nov 4, 2024
56 days to decision

K242709 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k242709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 9, 2024
Decision date	Nov 4, 2024
Days to decision	56 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