FDA 510(k) Premarket Notification

K250750 INNOVISION-P5

CLEARED

Jul 18, 2025
128 days to decision

K250750 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k250750/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Mar 12, 2025
Decision date	Jul 18, 2025
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dk Medical Systems Co., Ltd.**
Location	Pyeongtaek-Si, KR
Contact	Sung-moon Hong
510(k) history	3 submissions · 3 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	**KMC, Inc.**
Contact	DongHa Lee

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