

**K250750 INNOVISION-P5**Jul 18, 2025  
128 days to decisionK250750 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k250750/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>KMC, Inc.</b>
Contact	DongHa Lee

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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