

K242119 INNOVISION-EXIIJan 3, 2025
168 days to decisionK242119 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k242119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Jul 19, 2024
Decision date	Jan 3, 2025
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dk Medical System
Location	Pyeongtaek-Si, KR
Contact	Sung-moon Hong
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Kim Dave

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242119/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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