FDA 510(k) Premarket Notification

K250790 INNOVISION-DXII

CLEARED

Aug 1, 2025
140 days to decision

K250790 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k250790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Mar 14, 2025
Decision date	Aug 1, 2025
Days to decision	140 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