FDA 510(k) Premarket Notification

K242119 INNOVISION-EXII

CLEARED

Jan 3, 2025
168 days to decision

K242119 · 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