

K213057 ExamVue DuoFeb 18, 2022
149 days to decisionK213057 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k213057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Sep 22, 2021
Decision date	Feb 18, 2022
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jpi Healthcare Co, Ltd.
Location	Bayside, NY, US
Contact	Sam Kang
510(k) history	8 submissions · 8 cleared · 1995-2025

REGULATORY CONSULTANT

Consulting firm	Jpi Healthcare Solutions, Inc.
Contact	William Little

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

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