

K242678 Definium Pace Select ETOct 1, 2024
25 days to decisionK242678 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k242678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Sep 6, 2024
Decision date	Oct 1, 2024
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Hualun Medical Systems Co. , Ltd.
Location	Beijing, CN
Contact	Kenny Ma
510(k) history	12 submissions · 12 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242678/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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