

K250788 Definium Tempo SelectAug 28, 2025
167 days to decisionK250788 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k250788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Mar 14, 2025
Decision date	Aug 28, 2025
Days to decision	167 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	Ma Kenny
510(k) history	12 submissions · 12 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250788/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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