

K143270 Optima XR646Feb 18, 2015
97 days to decisionK143270 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k143270/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 13, 2014
Decision date	Feb 18, 2015
Days to decision	97 days
Third-party review	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

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