

K173612 Optima XR646 HDDec 11, 2017
19 days to decisionK173612 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k173612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 22, 2017
Decision date	Dec 11, 2017
Days to decision	19 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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