FDA 510(k) Premarket Notification

K150663 Diagnostic X-ray System

CLEARED

May 7, 2015
52 days to decision

K150663 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k150663/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Mar 16, 2015
Decision date	May 7, 2015
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osko, Inc.**
Location	Miami, FL, US
Contact	WANG CHOI
510(k) history	6 submissions · 6 cleared · 2015-2020