FDA 510(k) Premarket Notification

K113248 AERODR SYSTEM WITH P-21

CLEARED

Jan 17, 2012
75 days to decision

K113248 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k113248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	Nov 3, 2011
Decision date	Jan 17, 2012
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Konica Minolta Medical & Graphic, Inc.**
Location	Hachioji-Shi Tokyo, JP
Contact	RUSSELL MUNVES
510(k) history	27 submissions · 27 cleared · 2002-2013