

K122119 DX-D FULL LEG FULL SPINESep 13, 2012
58 days to decisionK122119 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k122119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Jul 17, 2012
Decision date	Sep 13, 2012
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Afga Healthcare N.V.
Location	Brevard, NC, US
Contact	DAVID LEDWIG
510(k) history	1 submissions · 1 cleared · 2012-2012

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