

**K103050 DX-D 300**Oct 29, 2010  
14 days to decisionK103050 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k103050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Oct 15, 2010
Decision date	Oct 29, 2010
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Agfa Healthcare N.V.</b>
Location	Mortsel, BE
Contact	PHIL CUSCUNA
510(k) history	27 submissions · 27 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103050/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 17, 2026