

**K103597 DX-D 100**Jan 3, 2011  
26 days to decisionK103597 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k103597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Dec 8, 2010
Decision date	Jan 3, 2011
Days to decision	26 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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