

**K111324 CR MAMMOGRAPHY SYSTEM WITH DX-M DIGITIZER**Dec 22, 2011  
225 days to decisionK111324 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k111324/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	May 11, 2011
Decision date	Dec 22, 2011
Days to decision	225 days
Third-party review	No
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/k111324/> 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