

**K152639 DR 600**Dec 11, 2015  
87 days to decisionK152639 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k152639/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Sep 15, 2015
Decision date	Dec 11, 2015
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Agfa Healthcare N.V.</b>
Location	Mortsel, BE
Contact	Koren Vervoort
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/k152639/> 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 16, 2026