

**K252199 AGFA HealthCare Enterprise Imaging**Oct 15, 2025  
93 days to decisionK252199 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k252199/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 14, 2025
Decision date	Oct 15, 2025
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Agfa Healthcare N.V.</b>
Location	Mortsel, BE
Contact	Jodi Coleman
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/k252199/> 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 13, 2026