

**K101454 MAMMAPRINT**Jan 28, 2011  
248 days to decisionK101454 · Product code: **NYI** · Pathology  
Source: <https://www.510kdatabase.net/k101454/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Classifier, Prognostic, Recurrence Risk Assessment, Rna Gene Expression, Breast Cancer (NYI)
Date received	May 25, 2010
Decision date	Jan 28, 2011
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Agendia</b>
Location	Amsterdam, NL
Contact	Guido Brink
510(k) history	3 submissions · 3 cleared · 2009-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101454/> 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 14, 2026