

**K081092 MODIFICATION TO MAMMAPRINT**

Dec 11, 2009  
603 days to decision

K081092 · Product code: **NYI** · Pathology  
Source: <https://www.510kdatabase.net/k081092/>

**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	Apr 17, 2008
Decision date	Dec 11, 2009
Days to decision	603 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/k081092/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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