

**K201902 MammaPrint**Nov 5, 2020  
120 days to decisionK201902 · Product code: **NYI** · Pathology  
Source: <https://www.510kdatabase.net/k201902/>**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	Jul 8, 2020
Decision date	Nov 5, 2020
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Agendia, Inc.</b>
Location	Irvine, CA, US
Contact	Marcelo Trevino
510(k) history	2 submissions · 2 cleared · 2020-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201902/> 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 26, 2026