

K210973 MammaPrint FFPE NGS KitSep 8, 2022
526 days to decisionK210973 · Product code: **NYI** · Pathology
Source: <https://www.510kdatabase.net/k210973/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Classifier, Prognostic, Recurrence Risk Assessment, Rna Gene Expression, Breast Cancer (NYI)
Date received	Mar 31, 2021
Decision date	Sep 8, 2022
Days to decision	526 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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