

K080252 MODIFICATION TO MAMMAPRINTJul 21, 2008
172 days to decisionK080252 · Product code: **NYI** · Pathology
Source: <https://www.510kdatabase.net/k080252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Classifier, Prognostic, Recurrence Risk Assessment, Rna Gene Expression, Breast Cancer (NYI)
Date received	Jan 31, 2008
Decision date	Jul 21, 2008
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Agendia BV
Location	Amsterdam, NL
Contact	Guido Brink
510(k) history	3 submissions · 2 cleared · 2007-2008

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