FDA 510(k) Premarket Notification

K201902 MammaPrint

CLEARED

Nov 5, 2020
120 days to decision

K201902 · Product code: **NYI** · Pathology
Source: https://www.510kdatabase.net/k201902/

SUBMISSION DETAILS

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

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