

K192063 PGDx elio tissue completeApr 24, 2020
267 days to decisionK192063 · Product code: **PZM** · Pathology
Source: <https://www.510kdatabase.net/k192063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Next Generation Sequencing Based Tumor Profiling Test (PZM)
Date received	Aug 1, 2019
Decision date	Apr 24, 2020
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Personal Genome Diagnostics
Location	Baltimore, MD, US
Contact	Jennifer Dickey
510(k) history	1 submissions · 1 cleared · 2020-2020

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