

**K250003 GENESEQPRIME NGS Tumor Profiling Assay (FFPE)
(GS6005)**Aug 29, 2025
239 days to decisionK250003 · Product code: **PZM** · Pathology
Source: <https://www.510kdatabase.net/k250003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Next Generation Sequencing Based Tumor Profiling Test (PZM)
Date received	Jan 2, 2025
Decision date	Aug 29, 2025
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Geneseq Technology, Inc.
Location	Toronto, CA
Contact	Xue Wu
510(k) history	1 submissions · 1 cleared · 2025-2025

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