

K202304 NYU Langone Genome PACT (Genome Profiling of Actionable Cancer Targets)Jul 14, 2021
334 days to decisionK202304 · Product code: **PZM** · Pathology
Source: <https://www.510kdatabase.net/k202304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Next Generation Sequencing Based Tumor Profiling Test (PZM)
Date received	Aug 14, 2020
Decision date	Jul 14, 2021
Days to decision	334 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Nyu Langone Medical Center
Location	New York, NY, US
Contact	Matija Snuderl
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	New York State Department of Health
Contact	Derek Symula

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202304/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026