

**K260235 CellDx-Tissue**May 12, 2026  
106 days to decisionK260235 · Product code: **PZM** · Pathology  
Source: <https://www.510kdatabase.net/k260235/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Next Generation Sequencing Based Tumor Profiling Test (PZM)
Date received	Jan 26, 2026
Decision date	May 12, 2026
Days to decision	106 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Datar Cancer Genetics Private Limited</b>
Location	Nasik, IN
Contact	Dadasaheb Akolkar
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Global Quality and Regulatory Services</b>
Contact	Abdel B Halim

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260235/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 27, 2026