

**K211181 Idylla MSI Test**Feb 27, 2023  
678 days to decisionK211181 · Product code: **PZJ** · Pathology  
Source: <https://www.510kdatabase.net/k211181/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lynch Syndrome Test System (PZJ)
Date received	Apr 20, 2021
Decision date	Feb 27, 2023
Days to decision	678 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocartis NV</b>
Location	Mechelen, BE
Contact	Elnaz Jokar
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211181/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026