

**K260577 FilmArray TF Control Panel M527**May 19, 2026  
88 days to decisionK260577 · Product code: **PMN** · Microbiology  
Source: <https://www.510kdatabase.net/k260577/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	Feb 20, 2026
Decision date	May 19, 2026
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maine Molecular Quality Controls, Inc.</b>
Location	Scarborough, ME, US
Contact	Joan Gordon
510(k) history	15 submissions · 14 cleared · 2006-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260577/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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