

K251526 FilmArray GI Control Panel M238Aug 14, 2025
87 days to decisionK251526 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k251526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	May 19, 2025
Decision date	Aug 14, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Maine Molecular Quality Controls, Inc.
Location	Scarborough, ME, US
Contact	Joan Gordon
510(k) history	14 submissions · 13 cleared · 2006-2025

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