

K241289 SPOTFIRE RSP Pos & Neg ControlsMay 30, 2024
23 days to decisionK241289 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k241289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	May 7, 2024
Decision date	May 30, 2024
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SPOTFIRE RSP Negative Control

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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