

K233611 SPOTFIRE RSP Pos & Neg Controls (M425), SPOTFIRE RSP Positive Control (M42638), SPOTFIRE RSP Negative Control (M42738)Mar 26, 2024
134 days to decisionK233611 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k233611/>**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	Nov 13, 2023
Decision date	Mar 26, 2024
Days to decision	134 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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