

**K221253 SPOTFIRE RSP Positive Control, SPOTFIRE RSP
Negative Control**Feb 3, 2023
277 days to decisionK221253 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k221253/>**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 2, 2022
Decision date	Feb 3, 2023
Days to decision	277 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221253/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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