

**K230868 SPOTFIRE® RSP Pos & Neg Controls, SPOTFIRE®  
RSP Positive Control, SPOTFIRE® RSP Negative Control**Apr 13, 2023  
15 days to decisionK230868 · Product code: **PMN** · Microbiology  
Source: <https://www.510kdatabase.net/k230868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	Mar 29, 2023
Decision date	Apr 13, 2023
Days to decision	15 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	14 submissions · 13 cleared · 2006-2025

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