

**K190222 FilmArray Pneumonia/Pneumoniaplus Control**May 3, 2019  
87 days to decisionK190222 · Product code: **PMN** · Microbiology  
Source: <https://www.510kdatabase.net/k190222/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	Feb 5, 2019
Decision date	May 3, 2019
Days to decision	87 days
Third-party review	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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