

**K173171 FilmArray RP2/RP2plus Control Panel**

Nov 24, 2017  
56 days to decision

K173171 · Product code: **PMN** · Microbiology  
Source: <https://www.510kdatabase.net/k173171/>

**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	Sep 29, 2017
Decision date	Nov 24, 2017
Days to decision	56 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k173171/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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