

K161573 FilmArray RP EZ Control Panel M265Sep 2, 2016
87 days to decisionK161573 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k161573/>**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	Jun 7, 2016
Decision date	Sep 2, 2016
Days to decision	87 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

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