

K200010 FilmArray BCID2 Control Panel M416Apr 2, 2020
91 days to decisionK200010 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k200010/>**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	Jan 2, 2020
Decision date	Apr 2, 2020
Days to decision	91 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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