

**K202196 BioFire RP2.1/RP2.1plus Control Panel M441**Jun 24, 2021  
323 days to decisionK202196 · Product code: **PMN** · Microbiology  
Source: <https://www.510kdatabase.net/k202196/>**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	Aug 5, 2020
Decision date	Jun 24, 2021
Days to decision	323 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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