

K203680 BioFire JI Control Panel M420Jul 22, 2022
582 days to decisionK203680 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k203680/>**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	Dec 17, 2020
Decision date	Jul 22, 2022
Days to decision	582 days
Third-party review	No
Combination product	No
PCCP authorized	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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