

**K230719 BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini**Apr 13, 2023  
29 days to decisionK230719 · Product code: **QOF** · Microbiology  
Source: <https://www.510kdatabase.net/k230719/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Mar 15, 2023
Decision date	Apr 13, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biofire Diagnostics, LLC</b>
Location	Salt Lake City, UT, US
Contact	Kevin Bourzac
Website	<a href="http://www.biofiredx.com/">http://www.biofiredx.com/</a>
510(k) history	28 submissions · 24 cleared · 2015-2025

Biofire Diagnostics, LLC specializes in microbiology diagnostic systems for syndromic infectious disease testing. The company, with a manufacturing facility in Salt Lake City, develops rapid molecular diagnostic platforms that detect viruses, bacteria, parasites, yeast, and antimicrobial resistance genes. The BIOFIRE® FILMARRAY® System and BIOFIRE® SPOTFIRE® System deliver results in approximately one hour. Biofire Diagnostics has received FDA 510(k) clearances from total submissions since its first clearance in 2015. The company maintains 100% focus on microbiology devic...

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