

**K170604 FilmArray Respiratory Panel 2 (RP2)**May 30, 2017  
90 days to decisionK170604 · Product code: **OCC** · Microbiology  
Source: <https://www.510kdatabase.net/k170604/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Mar 1, 2017
Decision date	May 30, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biofire Diagnostics, LLC</b>
Location	Salt Lake City, UT, US
Contact	Kristen J. Kanack
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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