

**K160068 FilmArray Respiratory Panel (RP) for use with
FilmArray Torch**Feb 8, 2016
26 days to decisionK160068 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k160068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jan 13, 2016
Decision date	Feb 8, 2016
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biofire Diagnostics, LLC
Location	Salt Lake City, UT, US
Contact	KRISTEN J. KANACK
Website	http://www.biofire.com/
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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