

K180966 FilmArray Pneumonia PanelNov 9, 2018
210 days to decisionK180966 · Product code: **QDP** · Microbiology
Source: <https://www.510kdatabase.net/k180966/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Panel (QDP)
Date received	Apr 13, 2018
Decision date	Nov 9, 2018
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	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...