

K143178 FilmArray 2.0 SystemJan 30, 2015
87 days to decisionK143178 · Product code: **NSU** · Microbiology
Source: <https://www.510kdatabase.net/k143178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation For Clinical Multiplex Test Systems (NSU)
Date received	Nov 4, 2014
Decision date	Jan 30, 2015
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biofire Diagnostics, LLC
Location	Salt Lake City, UT, US
Contact	Kristen Kanack, PhD
Website	http://www.biofiredx.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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