

K160457 FilmArray Blood Culture Identification (BCID) panel for use with FilmArray Torch

Mar 15, 2016
25 days to decision

K160457 · Product code: **PEN** · Microbiology
Source: <https://www.510kdatabase.net/k160457/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gram-negative Bacteria And Associated Resistance Markers (PEN)
Date received	Feb 19, 2016
Decision date	Mar 15, 2016
Days to decision	25 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.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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Device record: <https://www.510kdatabase.net/k160457/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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