

K143005 FilmArray Gastrointestinal (GI) Panel for use with the FilmArray 2.0

Feb 19, 2015
122 days to decisionK143005 · Product code: PCH · Microbiology
Source: <https://www.510kdatabase.net/k143005/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Oct 20, 2014
Decision date	Feb 19, 2015
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biofire Diagnostics, LLC
Location	Salt Lake City, UT, US
Contact	Kristen 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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