FDA 510(k) Premarket Notification

CLEARED

K230404 BIOFIRE FILMARRAY Gastrointestinal (GI) Panel

Mar 16, 2023
29 days to decision

K230404 · Product code: **PCH** · Microbiology
Source: https://www.510kdatabase.net/k230404/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Feb 15, 2023
Decision date	Mar 16, 2023
Days to decision	29 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	Kevin Bourzac
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...