

K140407 FILMARRAY GASTROINTESTINAL (GI) PANELMay 2, 2014
73 days to decisionK140407 · Product code: **PCH** · Microbiology
Source: <https://www.510kdatabase.net/k140407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Feb 18, 2014
Decision date	May 2, 2014
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biofire Diagnostics
Location	Salt Lake City, UT, US
Contact	BETH LINGENFELTER
Website	http://www.biofiredx.com/
510(k) history	2 submissions · 2 cleared · 2014-2023

Biofire Diagnostics specializes in syndromic infectious disease diagnostics with a manufacturing facility in Salt Lake City, US. The company develops rapid molecular testing systems designed to identify multiple pathogens and antimicrobial resistance markers in a single assay. Biofire Diagnostics has received FDA 510(k) clearances from total submissions, all in the Microbiology category. The company's regulatory history spans from 2014 to 2023. Note: The company is currently inactive with no clearances in more than five years and should be treated as a historical record. ...