

K160459 FilmArray Gastrointestinal Panel (GI) for use with FilmArray TorchApr 1, 2016
42 days to decisionK160459 · Product code: PCH · Microbiology
Source: <https://www.510kdatabase.net/k160459/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH) |
| Date received | Feb 19, 2016 |
| Decision date | Apr 1, 2016 |
| Days to decision | 42 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.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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