

K213362 BioFire Global Fever Special Pathogens PanelMar 22, 2023
526 days to decisionK213362 · Product code: **QVR** · Microbiology
Source: <https://www.510kdatabase.net/k213362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiplex Nucleic Acid Detection System For Biothreat Agents (QVR)
Date received	Oct 12, 2021
Decision date	Mar 22, 2023
Days to decision	526 days
Third-party review	No
Summary / Statement	Summary
Other names	BIOFIRE SHIELD Control Kit for the BioFire Global Fever Special Pathogens Panel

APPLICANT

Company	Biofire Defense, LLC
Location	Salt Lake City, UT, US
Contact	Cynthia Phillips
Website	https://www.biofiredefense.com
510(k) history	9 submissions · 7 cleared · 2017-2025

Biofire Defense, LLC is a specialized molecular diagnostics and biothreat detection company with a manufacturing facility in Salt Lake City, US. Backed by bioMérieux, the company serves the U.S. Department of Defense, CDC, and public health agencies. BioFire Defense delivers fast, accurate PCR-based diagnostic solutions for infectious disease detection and biological threat identification. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2017. All submissions focus on Microbiology devices, reflecting the company's core exp...