

K220870 BioFire Global Fever Panel, BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel

Oct 20, 2022
209 days to decisionK220870 · Product code: **QMV** · Microbiology
Source: <https://www.510kdatabase.net/k220870/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device To Detect And Identify Selected Microbial Agents That Cause Acute Febrile Illness (QMV)
Date received	Mar 25, 2022
Decision date	Oct 20, 2022
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biofire Defense, LLC
Location	Salt Lake City, UT, US
Contact	Cynthia Pillips
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...