

K261475 BIOFIRE® FILMARRAY® Tropical Fever Panel Control Kit

Jul 17, 2026
73 days to decision

K261475 · Product code: PMN · Microbiology
Source: <https://www.510kdatabase.net/k261475/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	May 5, 2026
Decision date	Jul 17, 2026
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biofire Defense, LLC
Location	Salt Lake City, UT, US
Contact	David Rabiger
Website	https://www.biofiredefense.com
510(k) history	10 submissions · 8 cleared · 2017-2026

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...