

K202382 FilmArray Global Fever Panel External Control KitNov 20, 2020
92 days to decisionK202382 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k202382/>**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	Aug 20, 2020
Decision date	Nov 20, 2020
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

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...
