

## K243822 BioFire Warrior Panel

Mar 12, 2025  
90 days to decision

K243822 · Product code: **PRD** · Microbiology  
Source: <https://www.510kdatabase.net/k243822/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Dec 12, 2024
Decision date	Mar 12, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BioFire Warrior Panel Control Kit

### APPLICANT

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Company	<b>Biofire Defense, LLC</b>
Location	Salt Lake City, UT, US
Contact	David Rabiger
Website	<a href="https://www.biofiredefense.com">https://www.biofiredefense.com</a>
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...