

**K170883 FilmArray NGDS Warrior Panel**Jun 22, 2017  
90 days to decisionK170883 · Product code: **PRD** · Microbiology  
Source: <https://www.510kdatabase.net/k170883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Mar 24, 2017
Decision date	Jun 22, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biofire Defense, LLC</b>
Location	Salt Lake City, UT, US
Contact	Cynthia Phillips
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...

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