FDA 510(k) Premarket Notification

K221460 BioFire COVID-19 Test 2

CLEARED

Jul 25, 2022
67 days to decision

K221460 · Product code: **QQX** · Microbiology
Source: https://www.510kdatabase.net/k221460/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Specimen Nucleic Acid Sars-cov-2 Test (QQX)
Date received	May 19, 2022
Decision date	Jul 25, 2022
Days to decision	67 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 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...

REGULATORY CONSULTANT

Consulting firm	**Biofire Defence, LLC**
Contact	Cynthia Phillips

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov