

K211079 BioFire COVID-19 Test 2Nov 1, 2021
203 days to decisionK211079 · Product code: **QQX** · Microbiology
Source: <https://www.510kdatabase.net/k211079/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Specimen Nucleic Acid Sars-cov-2 Test (QQX)
Date received	Apr 12, 2021
Decision date	Nov 1, 2021
Days to decision	203 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...