FDA 510(k) Premarket Notification

CLEARED

K213954 BIOFIRE SPOTFIRE Respiratory (R) Panel

Feb 3, 2023
413 days to decision

K213954 · Product code: **QOF** · Microbiology
Source: https://www.510kdatabase.net/k213954/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Dec 17, 2021
Decision date	Feb 3, 2023
Days to decision	413 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biofire Diagnostics**
Location	Salt Lake City, UT, US
Contact	Kevin Bourzac
Website	http://www.biofiredx.com/
510(k) history	2 submissions · 2 cleared · 2014-2023

Biofire Diagnostics specializes in syndromic infectious disease diagnostics with a manufacturing facility in Salt Lake City, US. The company develops rapid molecular testing systems designed to identify multiple pathogens and antimicrobial resistance markers in a single assay. Biofire Diagnostics has received FDA 510(k) clearances from total submissions, all in the Microbiology category. The company's regulatory history spans from 2014 to 2023. Note: The company is currently inactive with no clearances in more than five years and should be treated as a historical record. ...