

K243463 BIOFIRE FILMARRAY Tropical Fever Panel

Dec 5, 2024
27 days to decision

K243463 · Product code: **QMV** · Microbiology
Source: <https://www.510kdatabase.net/k243463/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device To Detect And Identify Selected Microbial Agents That Cause Acute Febrile Illness (QMV)
Date received	Nov 8, 2024
Decision date	Dec 5, 2024
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biofire Diagnostics, LLC (Biomerieux)
Location	Salt Lake City, UT, US
Contact	Karli Plenert
510(k) history	2 submissions · 2 cleared · 2024-2024
