

K252932 Fast PCR Mini Respiratory Panel

Jun 12, 2026
270 days to decision

K252932 · Product code: **QOF** · Microbiology
Source: <https://www.510kdatabase.net/k252932/>

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	Sep 15, 2025
Decision date	Jun 12, 2026
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Autonomous Medical Devices Incorporated
Location	Santa Ana, CA, US
Contact	Aiyng Sun
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k252932/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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