

K241652 DASH® SARS-CoV-2 & Flu A/B TestDec 20, 2024
196 days to decisionK241652 · Product code: **QOF** · Microbiology
Source: <https://www.510kdatabase.net/k241652/>**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	Jun 7, 2024
Decision date	Dec 20, 2024
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nuclein, LLC
Location	Austin, TX, US
Contact	Ben Treece
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241652/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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