

K231187 Nano-Check™ COVID-19 Antigen TestJan 23, 2024
272 days to decisionK231187 · Product code: **QVF** · Microbiology
Source: <https://www.510kdatabase.net/k231187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Simple Point-of-care Device To Directly Detect Sars-cov-2 Viral Targets From Clinical Specimens In Near-patient Settings (QVF)
Date received	Apr 26, 2023
Decision date	Jan 23, 2024
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nano-Ditech Corporation
Location	Cranbury, NJ, US
Contact	James B Chang
510(k) history	6 submissions · 6 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231187/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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