

K240280 Nano-Check™ RSV TestJul 30, 2024
180 days to decisionK240280 · Product code: **GQG** · Microbiology
Source: <https://www.510kdatabase.net/k240280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Antigen, Cf (including Cf Controls), Respiratory Syncytial Virus (GQG)
Date received	Feb 1, 2024
Decision date	Jul 30, 2024
Days to decision	180 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

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