

K241317 Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)Sep 30, 2024
143 days to decisionK241317 · Product code: QYT · Microbiology
Source: <https://www.510kdatabase.net/k241317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	May 10, 2024
Decision date	Sep 30, 2024
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Wondfo Biotech Co., Ltd.
Location	Yardley, PA, US
Contact	Xiao Kaiyu
510(k) history	43 submissions · 43 cleared · 2005-2026

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