

K251289 WELLlife COVID-19 Antigen Test Rx

Oct 22, 2025
180 days to decision

K251289 · Product code: **QVF** · Microbiology
Source: <https://www.510kdatabase.net/k251289/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
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 25, 2025
Decision date	Oct 22, 2025
Days to decision	180 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	Kaiyu Xiao
510(k) history	43 submissions · 43 cleared · 2005-2026
