

K251563 WELLlife Flu A&B Home TestAug 20, 2025
90 days to decisionK251563 · Product code: **SCA** · Microbiology
Source: <https://www.510kdatabase.net/k251563/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Respiratory Virus Antigen Detection Test (SCA)
Date received	May 22, 2025
Decision date	Aug 20, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	WELLlife Influenza A&B Test

APPLICANT

Company	Wondfo USA Co., Ltd.
Location	San Diego, CA, US
Contact	Kaiyu Xiao
510(k) history	2 submissions · 2 cleared · 2025-2025

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