FDA 510(k) Premarket Notification

CLEARED

K243256 WELLlife™ COVID-19 / Influenza A&B Home Test

Jan 16, 2025
93 days to decision

K243256 · Product code: **SCA** · Microbiology
Source: https://www.510kdatabase.net/k243256/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Respiratory Virus Antigen Detection Test (SCA)
Date received	Oct 15, 2024
Decision date	Jan 16, 2025
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	WELLlife™ COVID-19 / Influenza A&B AntigenTest

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k243256/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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