

K251595 COVID-19 Detect Rapid Self -TestOct 12, 2025
138 days to decisionK251595 · Product code: QYT · Microbiology
Source: <https://www.510kdatabase.net/k251595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	May 27, 2025
Decision date	Oct 12, 2025
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	InBios International, Inc.
Location	Seattle, WA, US
Contact	Annabel Tsai
510(k) history	7 submissions · 5 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251595/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026